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Pay-for-Performance: Is Medicare a Good Candidate?

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INTRODUCTION

According to one prominent study, adults in the United States receive the generally accepted standard of preventive, acute, and chronic care only about 55% of the time.[1] The likelihood that patients will receive recommended care "varie[s] substantially according to the particular medical condition, ranging from 78.7 percent of recommended care . . . for senile cataract to 10.5 percent of recommended care . . . for alcohol dependence."[2] Evidence of low-quality care appears in Medicare, the federal health program for the elderly and disabled.[3] Quality of care does not appear to be higher in areas where Medicare spending is higher.[4] In fact, some studies point to the somewhat paradoxical conclusion that

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1. Elizabeth A. McGlynn et al., *The Quality of Health Care Delivered to Adults in the United States*, 348 NEW ENG. J. MED. 2635 (2003). *See also* Steven M. Asch et al., *Who Is at Greatest Risk for Receiving Poor-Quality Health Care?*, 354 NEW ENG. J. MED. 1147, 1147 (2006) ("Overall, participants received 54.9 percent of recommended care. . . . [T]here was only moderate variation in quality-of-care scores among sociodemographic subgroups.").

2. McGlynn et al., *supra* note 1, at 2635.

3. *See* Elliott S. Fisher et al., *The Implications of Regional Variations in Medicare Spending. Part 1: The Content, Quality, and Accessibility of Care*, 138 ANNALS INTERNAL MED. 273, 283 (2003) (reporting that the percentage of patients from select cohorts who received recommended care ranged from 19.7% to 87.7%) [hereinafter Fisher et al., *Part 1*]. *See also* Asch et al., *supra* note 1, at 1150; Priscilla Hollander et al., *Quality of Care of Medicare Patients with Diabetes in a Metropolitan Fee-for-Service Primary Care Integrated Delivery System*, 20 AM. J. MED. QUALITY 344 (2005).

4. Fisher et al., *Part 1*, *supra* note 3, at 273. Patients in high-spending regions received sixty percent more care, but those higher Medicare expenditures did not translate into higher-quality care. "The increased utilization was explained by more frequent physician visits, especially in the inpatient setting[,]. . . more frequent tests and minor (but not major) procedures, and increased use

Medicare patients are often less likely to receive recommended care in regions where Medicare expenditures are highest.[5]

Third-party payment is a potential contributor to the under-provision of quality health care. Most health care payments in the United States are made by third parties, usually employers, insurers, or government.[6] Those purchasers typically reimburse health care providers on the basis of the volume and intensity of the services provided, rather than the quality or cost-effectiveness of those services.[7] The result is a financing system akin to paying academics on the basis of the volume and intensity of footnotes.[8]

Medicare is the most obvious example of a quality-blind third-party purchaser. Former Medicare administrator Tom Scully notes that, within a hospital referral region, Medicare pays "the exact same amount for hip replacement and the same amount for a heart bypass, if you're the best hospital or the worst hospital."[9] The Medicare Payment Advisory Commission has written:

> In the Medicare program, the payment system is largely neutral or negative towards quality. All providers meeting basic requirements are paid the same regardless of the quality of service provided. At times providers are paid even more when quality is worse, such as when complications occur as the result of error.[10]

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of specialists and hospitals." *Id.* Nor did higher spending translate into decreased mortality, better functional status, or higher patient satisfaction. Elliott S. Fisher et al., *The Implications of Regional Variations in Medicare Spending. Part 2: Health Outcomes and Satisfaction with Care*, 138 ANNALS INTERNAL MED. 288, 288 (2003).

5. Katherine Baicker & Amitabh Chandra, Medicare Spending, *The Physician Workforce, And Beneficiaries' Quality of Care*, W4 Health Aff. - Web Exclusive, April 7, 2004, at W4-184, W4-192, http://content.healthaffairs.org/cgi/reprint/hlthaff.w4.184v1.pdf ("States that spend more per Medicare beneficiary are not states that provide higher quality care. In fact, additional spending is positively correlated with end-of-life care but negatively correlated with the use of effective care."). *See also* Fisher et al., *Part 1*, *supra* note 3, at 273 ("Quality of care in higher-spending regions was no better on most measures and was worse for several preventive care measures."); *id.* at 283 (reporting that for seven out of ten types of recommended care, Medicare spending within a hospital referral region was inversely related to the quality of care).

6. *See, e.g.*, Ctrs. for Medicare & Medicaid Servs., Office of the Actuary, Nat'l Health Statistics Group, National Health Expenditures Web Tables 8, http://www.cms.hhs.gov/National HealthExpendData/downloads/tables.pdf (last visited Dec. 10, 2006).

7. *See, e.g.*, U.S. Fed. Trade Comm'n & U.S. Dep't of Justice, Improving Health Care: A Dose of Competition 5, 13 (Executive Summary) (2004), *available at* http://www.ftc.gov/reports/ healthcare/040723healthcarerpt.pdf; DAVID M. CUTLER, YOUR MONEY OR YOUR LIFE 101 (2004).

8. Such a payment system may or may not improve the overall quality of analysis, but assuredly it would result in overuse of low-quality footnotes.

9. U.S. Fed. Trade Comm'n & U.S. Dep't of Justice, *supra* note 7, ch. 2, at 30.

10. MEDICARE PAYMENT ADVISORY COMM'N, REPORT TO THE CONGRESS: VARIATION AND INNOVATION IN MEDICARE 108 (2003), *available at* http://www.medpac.gov/publications/

Medicare's massive influence on the health care system has made it a major focus of efforts to solve the problems caused by quality-blind third-party purchasing.

Reform efforts have led third-party payors to experiment with financial incentives that encourage physicians and hospitals to provide recommended care. Such initiatives are termed "quality-based purchasing" (QBP) or "pay-for-performance" (P4P). P4P is an outgrowth of the "evidence-based medicine" (EBM) movement, which argues that providers too often rely on their own judgment, because scientific evidence on the effectiveness of medical interventions is either unavailable or ignored.[11] P4P attempts to use financial incentives to encourage providers to adhere more closely to evidence-based standards of care. As described by one academic proponent: "The key to the quality-based payment system is that it differentiates between the intensity of medical care and the value of it. . . . Health-based payments . . . reward high-value services regardless of their intensity. Thus, there are no incentives to overprovide or underprovide services."[12] By tying financial incentives to superior modes of care, advocates of third-party P4P hope to harness providers' self-interest in the service of higher-quality care.

A number of P4P initiatives are already under way in both the public and private sectors. Commercial insurers such as Aetna, PacifiCare, and WellPoint have been leaders in the field; Highmark Blue Cross Blue Shield has experimented with P4P since 1994. Those private-sector programs reward physicians and facilities for meeting performance goals, including patient satisfaction, preventive care, chronic care, acute care, and smoking cessation.[13]

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congressional_reports/June03_Entire_Report.pdf. *See also* Reed Abelson, *Medicare Says Bonuses Can Improve Hospital Care*, N.Y. TIMES, Nov. 15, 2005, at C3 ("When Intermountain Health Care, a Salt Lake City hospital system, improved care for its pneumonia patients by making sure they received the right drugs, it lost money because Medicare continues to pay less when patients have fewer complications and require less extensive care."); John E. Wennberg, Variation in Use of Medicare Services Among Regions and Selected Academic Medical Centers: Is More Better?, Duncan W. Clark Lecture at New York Academy of Medicine 2 (Jan. 24, 2005), *available at* http://www.dartmouthatlas.org/atlases/NYAM_Lecture.pdf (discussing under-use of high-quality care and overuse of low-quality care in Medicare).

11. *See* Evidence-Based Med. Working Group, *Evidence-Based Medicine: A New Approach to Teaching the Practice of Medicine*, 268 JAMA 2420 (1992); R. Brian Haynes, *What Kind of Evidence Is It That Evidence-Based Medicine Advocates Want Health Care Providers and Consumers to Pay Attention to?*, 2 BMC HEALTH SERVICES RES. 1 (2002), *available at* http://www.biomedcentral.com/content/pdf/1472-6963-2-3.pdf; Jack Hitt, *Evidence-Based Medicine*, N.Y. TIMES MAG., Dec. 9, 2001, at 68.

12. CUTLER, *supra* note 7, at 101.

13. *Medicare Value-Based Purchasing for Physicians' Services Act of 2005: Hearing on H.R. 3617 Before the Subcomm. on Health of the H. Comm. on Ways and Means*, 109th Cong. (2005) (statement of Karen Ignagni, President and Chief Executive Officer, America's Health Insurance Plans), *available at* http://waysandmeans.house.gov/hearings.asp?formmode=view&id=3820 [hereinafter *Medicare Hearing*].

Medicare currently has ten demonstration programs underway that tie higher reimbursements to data reporting and a variety of quality indices (including structural, process, and outcome measures) across various types of care (though typically for chronic illnesses) and care settings.[14]

Provider-focused financial incentives for high-quality care have the potential to improve quality in many instances. However, caution is in order. Creating a P4P program – where third-party purchasers create financial incentives for providers to deliver quality care – is an immensely difficult task. Quality has multiple dimensions and is often highly subjective, making "quality care" impossible to define uniformly for diverse populations. Even when it is possible to settle on a reasonable definition of quality, measures can be difficult to translate into financial incentives.

These difficulties suggest two approaches that would maximize the potential of P4P while minimizing any harm. First, private experiments with provider-focused P4P incentives are preferable to public experiments. The current system of private P4P programs allows insurers and employers to conduct experiments and learn from each other's successes. Competition to improve the quality of care in a cost-effective manner encourages private purchasers to experiment with P4P, and private control gives purchasers flexibility in designing and altering those experiments. As important, private P4P experiments confine any harmful failures to smaller populations. As discussed below, the politics of Medicare all but guarantees that any potential harm resulting from a P4P scheme would, in the context of Medicare, be more likely to occur, harm more patients, and take longer to correct. Therefore, Congress should confine provider-focused P4P incentives to the Medicare Advantage program, under which beneficiaries can choose a private plan that provides Medicare-covered services. Congress should resist the temptation to expand P4P into traditional Medicare.

Second, employers and insurers should experiment not only with provider-focused financial incentives but with patient-focused financial incentives as well. For example, private insurers "are offering consumers reduced co-payments, deductibles, and/or premiums in exchange for using providers deemed to be of higher quality, based on specific performance measures."[15] A weakness of provider-focused financial incentives is that they can affect the quality of care, or even a patient's access to care, without the patient's knowledge. In contrast, patient-focused financial incentives would engage patients in the pursuit of quality, while allowing patients and their doctors to deviate from "best practices" if doing so fits the patient's needs.

This Article proceeds as follows. Part I discusses the practical difficulties

14. Press Release, Ctrs. for Medicare & Medicaid Servs., Medicare "Pay for Performance (P4P)" Initiatives (Jan. 31, 2005), *available at* http://www.cms.hhs.gov/apps/media/press/release.asp?Counter=1343.

15. *Medicare Hearing*, *supra* note 13.

involved in designing a system that enables third-party purchasers to reward providers for high-quality medical care, particularly given the absence of research on the cost-effectiveness of such efforts. Part II considers how health care providers might respond to a P4P scheme, and how those responses might affect the cost and quality of medical care and insurance. Part III examines what the evidence says about whether P4P improves quality. Part IV begins with a brief sketch of Medicare's experiments with P4P and efforts to expand P4P within that program. Part IV then argues that the pitfalls of P4P are more likely to occur in traditional Medicare, and offers proposals on how to bring the benefits of P4P to seniors while minimizing their exposure to harm.

I. PITFALLS OF THIRD-PARTY P4P

Identifying and rewarding quality are difficult tasks for any third-party purchaser. As one study of P4P measures notes, "[e]xperience in other industries has shown that developing performance measures for complex phenomena is difficult and that inappropriate measures can have significant negative consequences."[16] Defining quality health care is not as straightforward as it might appear. Quality is a complex and often subjective concept. Even relatively objective measures of quality can be difficult to translate into financial incentives that succeed in improving the quality of care. This Part outlines the challenges faced by third-party purchasers, whether public or private, when attempting to improve quality through provider-focused financial incentives.

A. Defining Quality

The first challenge is to identify the dimensions of quality to be promoted. P4P programs typically rely on some mix of four types of quality measures: patient outcomes, processes, structural factors, and patient satisfaction.[17] Each dimension presents strengths and weaknesses as a measure of health care quality. Combining multiple dimensions can capture the strengths of each, but at the cost of added complexity.

Patient outcomes are the most obvious measure of health care quality. For example, outcome measures for heart attack patients could include patients' post-

16. R. ADAMS DUDLEY ET AL., U.S. DEP'T OF HEALTH & HUMAN SERVS., STRATEGIES TO SUPPORT QUALITY-BASED PURCHASING 68 (2004), *available at* http://www.ahrq.gov/downloads/pub/evidence/pdf/qbpurch/qbpurch.pdf (citing C. D. Ittner & D. F. Larcker, *Coming Up Short on Nonfinancial Performance Measurement*, 81 HARV. BUS. REV. 88, 88-95, 139 (2003)).

17. For example, a PacifiCare "quality incentive program" rewards physicians based on measures of patient satisfaction, as well as process measures such as "rates of cervical cancer screening, mammography, and hemoglobin . . . testing for diabetic patients." Meredith B. Rosenthal et al., *Early Experience with Pay-for-Performance: From Concept to Practice*, 294 JAMA 1788, 1789 (2005).

intervention cholesterol levels, readmission rates, or mortality rates. However, outcome measures have limitations. First, patients may differ in their desired outcomes.[18] Second, patient outcomes can be influenced by factors other than the medical intervention. For example, readmission and mortality rates for heart attack patients may be influenced by the severity of illness. Patients' cholesterol levels may be influenced by their adherence to a prescribed drug regimen (e.g., statins). Such factors contribute to patient outcomes but say little about the providers' performance. As a result, providers are understandably reluctant to be rewarded or penalized on the basis of factors they cannot control. A third and related limitation of outcome measures is that "although outcomes might indicate good or bad care in the aggregate, they do not give an insight into the nature and location of the deficiencies or strengths to which the outcome might be attributed."[19] Finally, measuring outcomes such as mortality can involve a considerable lag. Along with other factors, the desire to have a more immediate influence on quality has led many purchasers to focus on "aspects of care with proven relationships to desirable patient outcomes,"[20] which are more readily measured than patient outcomes.

One attempt to capture those aspects is process measures, which track a provider's adherence to accepted treatment guidelines that are based on scientific evidence. Rather than reward a provider on the basis of cholesterol levels or mortality rates of heart attack patients, a process measure would reward providers based on how often they check cholesterol levels or prescribe beta-blockers for those patients. Process measures are the most often discussed type of P4P quality measure;[21] thus their potential shortcomings will be discussed in more detail throughout Sections I.B and I.C below.

Structural quality measures attempt to evaluate the setting in which a provider delivers medical care. Such measures can include "the adequacy of facilities and equipment; the qualifications of medical staff and their organization; the administrative structure and operations of programs and institutions providing care; fiscal organization and the like."[22] Examples include

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18. *See generally* Avedis Donabedian, *Evaluating the Quality of Medical Care*, 83 MILBANK Q. 691, 694 (2005), *reprinted from* 44 MILBANK MEMORIAL FUND Q. 166 (1966), *available at* http://www.milbank.org/quarterly/830416donabedian.pdf (indicating that, for instance, "although fixing a congenitally dislocated hip joint in a given position is considered good medicine for the white man, it can prove crippling for the Navajo Indian who spends much time seated on the floor or in the saddle.").

19. *Id.*

20. U.S. Agency for Health Care Research & Quality, AHRQ Patient Safety Network Glossary: Structure-Process-Outcome Triad, http://psnet.ahrq.gov/glossary.aspx (last visited Dec. 10, 2006).

21. *See generally* DUDLEY ET AL., *supra* note 16, at 9, 69-70 (providing a survey of the literature on P4P experiments that finds more efforts based on process measures than on structural or outcomes measures).

22. Donabedian, *supra* note 18, at 695.

whether a hospital uses health information technologies such as electronic prescribing, electronic medical records, or patient registries. Structural quality measures have obvious appeal, but they also present limitations. The mere availability of sophisticated human and physical capital offers no direct evidence of whether those resources are being used optimally. Meeting structural quality measures can also require large investments, which raise costs and may undercut cost-effectiveness.

Table 1: Tradeoffs Presented by Measuring and Rewarding Different Dimensions of Quality

Quality Measure	*Upside*	*Downside*
Patient outcomes	Captures patient health	Desired outcomes vary across patients Factors beyond control of providers affect outcomes Does not reveal how positive outcomes were achieved Providers can game outcome measures by selecting healthier patients Requires case-mix adjustment to demonstrate improved health Measurement lags
Processes	Captures provider actions that promote health	Can encourage inappropriate care for outliers Providers can game process measures through patient selection, data manipulation, etc.
Structural	Captures whether providers use human/ physical capital known to improve health/ convenience	Does not measure whether capital is used optimally Can require large investments by providers
Patient satisfaction	Measures whether providers meet patient expectations Captures intangible/ subjective aspects of quality	Poor performers may score well if patients are ignorant of higher-quality options
Incorporating multiple types of quality measures	Captures benefits of each measure used	Adds complexity and cost Can discourage physician compliance

Finally, patient satisfaction measures typically depend on surveys that ask patients about their experiences with a provider. Those measures presumably can capture aspects of quality that structural, process, and outcome measures cannot (e.g., convenience, waiting time, comfort, bedside manner, and level of trust between patient and physician). However, patient satisfaction measures present shortcomings because patients are not necessarily in the best position to evaluate the quality of care. For example, providers who deliver low-quality care may score well on patient satisfaction measures if patients are unaware that higher-quality care is available.

B. Collecting Reliable Data

A third-party payor's ability to create financial incentives that guide providers toward recommended care depends on the availability of data that demonstrate a relationship between inputs and outcomes. Purchasers face significant challenges in accumulating and applying accurate data. These include finding quality data that relate various inputs to outcomes, translating data into performance measures, making allowances for atypical patients, and targeting, calibrating, and continually adjusting performance measures and financial incentives in the face of uncertainty about the reliability of new findings.

1. Availability of Data

The success of pay-for-performance (also referred to as "quality-based purchasing," or QBP) depends on third-party purchasers having access to data that relate inputs to clinical outcomes. Such data exist for many but not all areas of care. According to one survey:

> A prominent barrier to QBP is that the science of performance measurement is still underdeveloped. Purchasers interested in QBP have limited choices for performance measures and these disproportionately target preventive care and structure or processes rather than outcomes. That is, the available set of metrics is not broadly representative of all care, while purchasers must pay for care across the entire clinical spectrum.[23]

At present, it is difficult or impossible to know for what share of health care expenditures useful data exist.[24] Where data are not available, third-party

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23. DUDLEY ET AL., *supra* note 16, at 7.

24. The Centers for Medicare & Medicaid services provide this slippery description of the availability of such data:

> A preliminary assessment indicates that *the specialties* for which *some* measures have been developed *account for about half* of Medicare physician spending. Specialties *accounting for* another 40 percent of *physician* spending have measures under

purchasers have little ability to use financial incentives to drive quality improvements.

2. Quality of Data

Where data are available, purchasers must consider whether the data employed show a true relationship between a metric and a desired outcome. Even accurate data can be misinterpreted or rendered out of date by subsequent research.

Ensuring that clinical data show a true relationship between a metric and a desired outcome is no small challenge. According to R. Brian Haynes, a prominent advocate of using more scientific data in clinical practice, "the advance of knowledge is incremental, with many false steps, and with breakthroughs few and far between, so that only a very tiny fraction of the reports in the medical literature signal new knowledge that is both adequately tested and important enough for practitioners to depend upon and apply."[25] Inaccurate findings are apparently not difficult to come by in the medical literature. Recent analyses suggest that one-third of frequently cited clinical studies are either incorrect or overstate the effect of clinical interventions[26] and that "most current published research findings are false."[27]

Concerns even exist about the quality of data used in the clinical practice guidelines (CPGs) that often serve as the basis for performance measures and financial incentives. For example, some researchers question whether clinical trials are too often "stopped early for benefit" – that is, when preliminary results appear positive and convincing. One study notes that "[p]rofessional organizations continue to issue recommendations on the basis of trials stopped early for benefit, including those . . . that seem most likely to overestimate effects."[28] One expert notes that CPGs "have been reported to be variably flawed

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> development. . . . In addition, virtually all specialties have noted that evidence-based guidelines for best practices have been developed for *many* important aspects of the care they provide. Such guidelines *do not apply to all patients* receiving care from a particular specialty, but they do generally reflect the state of medical evidence about what works best in the specialty for *many* of the common problems they treat.

Value-Based Purchasing for Physicians Under Medicare: Hearing Before the Subcomm. on Health of the H. Comm. on Ways and Means, 109th Cong. (2005) (statement of Mark B. McClellan, Dep't of Health & Human Servs.) (emphasis added), *available at* http://waysandmeans.house.gov/hearings.asp?formmode=view&id=4678.

25. Haynes, *supra* note 11, at 1.

26. *See, e.g.*, John P. A. Ioannidis, *Contradicted and Initially Stronger Effects in Highly Cited Clinical Research*, 294 JAMA 218 (2005).

27. John P. A. Ioannidis, *Why Most Published Research Findings Are False*, 2 PUB. LIBR. SCI. MED. 696, 696 (2005).

28. Victor M. Montori et al., *Randomized Trials Stopped Early for Benefit: A Systematic Review*, 294 JAMA 2203, 2208 (2005) ("Such recommendations include the use of perioperative β-

in terms of conflict of interest, specialty turf battles, endorsement of new or relatively unproven pharmaceutical agents, and focus on a single condition compared with a broader clinical focus."[29]

And even accurate data grow old. Part of the challenge of P4P is to update performance targets and provider financial incentives on the basis of the most recent reliable data. That challenge is also not straightforward; experts often disagree about the significance or reliability of new clinical findings. According to one review of experts' use of new clinical information:

> Discrepancies were detected between the meta-analytic patterns of effectiveness in the randomized trials and the recommendations of reviewers. Review articles often failed to mention important advances or exhibited delays in recommending effective preventive measures. In some cases, treatments that have no effect on mortality or are potentially harmful continued to be recommended by several clinical experts.[30]

Whether a particular CPG's recommendations are overly cautious, hasty, or lack rigor is often a matter of opinion, and third-party purchasers have no clear guide for when they should incorporate new data. However, failure to assimilate accurate new data puts purchasers back where they do not want to be – paying for inferior quality.

Although assimilating new clinical data is essential, it also presents a tradeoff for purchasers. Collecting new data is costly. New data are often persuasive but not definitive. How often a purchaser chooses to integrate new data into the performance incentives it offers providers, and providers' perceptions of the reliability of the data, will influence how providers respond to the financial incentives and thus the effectiveness of those incentives.

3. Outliers

Even when high-quality, timely data are available, translating those findings into performance measures is complicated by outliers – patients who deviate from the mean either in their preferences or their response to treatment. "Quality" will have a different meaning for outliers than it does for most patients. P4P schemes that encourage providers to treat outliers like the average patient can therefore create perverse incentives that encourage low-quality care. Because

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blockers in patients undergoing vascular surgery" made by the American College of Cardiologists and the American Heart Association.).

29. Patrick J. O'Connor, *Adding Value to Evidence-Based Clinical Guidelines*, 294 JAMA 741, 741 (2005).

30. Elliott M. Antman et al., *A Comparison of Results of Meta-Analyses of Randomized Control Trials and Recommendations of Clinical Experts: Treatments for Myocardial Infarction*, 268 JAMA 240, 240 (1992).

patients are often unaware of the financial arrangements between their insurer and provider, those perverse incentives can affect the quality of care without the patients' knowledge.

Some patients are clinical outliers. Even when randomized clinical trials accurately demonstrate the health benefits of an intervention, those benefits are not uniform across the thousands of patients within the trial, much less across the millions of patients in the general population.[31] A treatment's overall beneficial effects may hide different effects on subgroups, including no effect or even harmful effects. For example, patients may respond differently to a given intervention as a result of multiple illnesses or interactions with treatment regimens for such co-morbidities.[32] Financial incentives that encourage providers to treat such outliers according to what benefits the majority of patients may inadvertently encourage low-quality or even harmful care.

For example, the administration of beta-blockers to patients with cardiovascular disease is a common quality measure.[33] However, a recent study found that among acute coronary syndrome patients prescribed beta-blockers, certain genotype groups had lower rates of survival. The authors caution, "[f]urther studies of the efficacy of ß-blocker treatment . . . is [sic] warranted to be sure that we are not institutionalizing therapy through the adoption of health care quality performance measures that may offer little benefit, or even potential harm, to these patient subgroups."[34] One could infer from this study that compliance with a widely used quality measure could actually increase mortality

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31. As O'Connor has stated:

> [A]ll evidence-based recommendations are not of equal clinical benefit to a patient. Benefits documented in clinical trials are 'average' benefits and even within the trials the degree of benefit received from an intervention depends on many patient-specific factors. Practicing physicians care for patients with even greater patient-specific variation (because of restrictive eligibility criteria in most clinical trials), so it is not surprising to find wide variation in the benefits obtained. When treating elderly patients with multiple comorbid conditions, the complexity of care is compounded by the need to simultaneously address multiple clinical domains.

O'Connor, *supra* note 29, at 742.

32. A co-morbidity is a coexistent but unrelated disease or disorder.

33. *See, e.g.*, CTRS. FOR MEDICARE & MEDICAID SERVS., HOSPITAL QUALITY INITIATIVE OVERVIEW 2 (2005), *available at* http://www.cms.hhs.gov/HospitalQualityInits/downloads/HospitalOverview200512.pdf (noting that two of the ten quality measures in the Hospital Quality Initiative demonstration program are administration of beta-blockers at (1) arrival and (2) discharge for acute myocardial infarction (AMI)); PREMIER, INC., CENTERS FOR MEDICARE AND MEDICAID SERVICES (CMS)/PREMIER HOSPITAL QUALITY INCENTIVE DEMONSTRATION PROJECT: PROJECT OVERVIEW AND FINDINGS FROM YEAR ONE 6 (2006), *available at* http://www.premierinc.com/quality-safety/tools-services/p4p/hqi/hqi-whitepaper041306.pdf (same).

34. David E. Lanfear et al., *β_2-Adrenergic Receptor Genotype and Survival Among Patients Receiving β-Blocker Therapy After an Acute Coronary Syndrome*, 294 JAMA 1526, 1532 (2005).

among some patients.[35]

Another outlier challenge involves patients with co-morbidities. Many patients, particularly the elderly, suffer from multiple chronic diseases. Having multiple health conditions exposes patients to multiple treatment regimens and a correspondingly heightened risk of adverse drug events.[36] However, many CPGs lack guidance specific to the elderly and patients with co-morbidities. One study examining leading CPGs for nine chronic illnesses found that only four of the nine "addressed older individuals with multiple comorbidities."[37]

Pay-for-performance measures that lack data specific to patients with co-morbidities can create significant perverse incentives for providers and quality problems for patients.[38] Following CPGs for each disease often results in multiple drug regimens. Yet little is known about how multiple medications, prescribed according to disease-specific guidelines, affect patients with numerous chronic conditions. It is thus possible that a provider who complies with P4P guidelines for treating each of a patient's chronic illnesses would deliver lower-quality care relative to a provider who makes more individualized prescribing decisions.[39] The prospect of suffering financial penalties for providing individualized care to such patients could discourage providers from caring for patients with co-morbidities altogether.[40]

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35. Not all acute coronary syndromes are AMIs. The example is offered not as proof that beta-blockers harm certain patient subgroups, but to demonstrate the plausibility that aggregate benefits may conceal harm among subgroups.

36. *See* Cynthia M. Boyd et al., *Clinical Practice Guidelines and Quality of Care for Older Patients with Multiple Comorbid Diseases: Implications for Pay for Performance*, 294 JAMA 716, 716 (2005).

37. *Id.* at 718.

38. *See id.* at 716.

39. Mary E. Tinetti et al., *Potential Pitfalls of Disease-Specific Guidelines for Patients with Multiple Conditions*, 315 NEW ENG. J. MED. 2870, 2872 (2004) ("Individual medications that impart disease-specific benefits may be less beneficial, or even harmful, when taken along with other medications by patients with multiple coexisting conditions and variable health outcomes."). *See also* Boyd et al., *supra* note 36, at 716 ("Basing standards for quality of care and pay for performance on existing CPGs could lead to inappropriate judgment of the care provided to older individuals with complex comorbidities and could create perverse incentives that . . . diminish the quality of their care.").

40. Boyd et al., *supra* note 36, at 722. The author is aware of no definitive evidence that providers have gamed P4P schemes by avoiding particular patients. However, research suggests that providers do frequently game payment systems. *See, e.g.*, Leemore S. Dafny, *How Do Hospitals Respond to Price Changes?*, 95 AM. ECON. REV. 1525, 1545 (2005) (noting that hospitals are "quite sophisticated" in their ability to increase reimbursements by gaming changes in Medicare payments); Matthew K. Wynia et al., *Physician Manipulation of Reimbursement Rules for Patients: Between a Rock and a Hard Place*, 283 JAMA 1858 (2000) (discussing physicians manipulating reimbursement rules). Results of a P4P program in Britain's National Health Service raised concerns about gaming. Tim Doran et al., *Pay-for-Performance Programs in Family Practices in the United Kingdom*, 355 NEW ENG. J. MED. 375, 383 (2006) (suggesting providers may have improved their scores on performance measures by arbitrarily excluding from those measurements

Other patients deviate from the mean in their preferences for particular health outcomes.[41] Older patients and those with numerous health problems often have treatment goals that conflict with P4P measures:

> Is a statin or beta-blocker, for example, as part of an 11-drug regimen, likely to provide greater benefit or greater harm to a 73-year-old whose priority is maximal energy, strength, and alertness today and who is willing to take on an increased risk of myocardial infarction or stroke over the next 5 or 10 years?[42]

For reasons of practicality, a P4P scheme might take account of easily measurable outcomes such as readmission or mortality rates, or processes such as statin or beta-blocker prescriptions, but not outcomes such as energy, strength, or alertness. Under such a payment system, a provider would be penalized for treating patients according to their preferences.

For all of these reasons, outliers raise issues of equity between physicians compensated according to a P4P framework. Although P4P schemes are meant to correct some of the inequities of existing quality-blind payment systems,[43] they can create similar inequities by penalizing physicians who provide quality care by correctly treating a patient as an outlier.

The existence of outliers points to the limited usefulness of aggregate data in promoting quality.[44] Much medical practice relies on the use of "unorganized knowledge"[45] about the circumstances of each patient and her preferences. As

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patients who would have lowered the providers' scores); Laura A. Peterson et al., *Does Pay-for-Performance Improve the Quality of Health Care?*, 145 ANNALS INTERNAL MED. 265, 268 (2006) (citing four studies that found evidence of "gaming behavior").

41. *See* Tinetti et al., *supra* note 39, at 2870.

42. *Id.* at 2872. *See generally* U.S. Food & Drug Admin., U.S. Dep't of Health & Human Servs., *Updates: New Drug to Lower Cholesterol*, 37 FDA CONSUMER MAG. 6 (2003), *available at* http://www.fda.gov/fdac/departs/2003/603_upd.html ("In rare instances, severe muscle pain and muscle weakness resulting in kidney damage have been associated with statin drugs."); U.S. Food & Drug Admin., U.S. Dep't of Health & Human Servs., *High Blood Pressure Medicines to Help You*, http://www.fda.gov/womens/MedicineCharts/highbloodpressure.pdf (indicating that "[c]ommon [s]ide [e]ffects" of beta-blockers include "[f]eeling tired . . . [d]izziness . . . [f]eeling lightheaded.")

43. *See Pay for Performance in Medicare: Hearing Before the S. Comm. on Finance*, 109th Cong. 9 (2005) (statement of Mark E. Miller, Executive Director, Medicare Payment Advisory Commission), *available at* http://www.medpac.gov/publications/congressional_testimony/Testimony_P4P.pdf ("Pay for performance will also address an inequity in the current payment system: paying the provider who gives his patients better care the same as the provider who does not.").

44. Though theoretically possible to gather quality data specific to outliers, accounting for all the possible combinations of physiological differences, comorbidities, and varied preferences of patients quickly yields a staggering number of outlier categories. Beyond a certain point, collecting quality data for outliers becomes cost-ineffective, and ultimately statistically prohibitive (as it becomes difficult to find enough subjects to conduct clinical trials).

45. F. A. Hayek, *The Use of Knowledge in Society*, 35 AM. ECON. REV. 519 (1945). In a

one advocate of EBM acknowledges, "evidence from research can be no more than one component of any clinical decision. Other key components are the circumstances of the patient (as assessed through the expertise of the clinician), and the preferences of the patient."[46] Aggregate data will be applicable to large numbers of patients. However, it is difficult for a distant decisionmaker to identify those instances in which the data do not apply.

C. Tradeoffs

Beyond the challenges involved in defining quality and collecting useful data, third-party purchasers face a third set of challenges: those associated with translating the data into performance measures and financial incentives. Here, too, the exercise is far from straightforward. Creating and administering P4P measures and financial incentives require making tradeoffs amid uncertainty about the optimal target of incentives, the most effective types of performance targets, and the size of financial incentives. Poorly calibrated incentives can result in no effect, higher expenditures, inequities, reduced access to care, or even low-quality and inappropriate care.

1. Identifying the Optimal Target of Incentives

The first challenge is to determine which provider should be the target of the incentive. Poorly targeted financial incentives may create perverse incentives for providers to over-prescribe, under-prescribe, or unnecessarily compartmentalize care. For most performance measures, the question is resolved if the patient receives care from an integrated health care system responsible for all aspects of treatment. In those cases, the incentive would be targeted at the institution, such as Kaiser Permanente or the Veterans Health Administration.[47]

However, patients typically receive care in non-integrated settings. According to Stanford University's Alan Garber:

> [T]he conceptual basis for assigning responsibility is unclear when a patient is treated by multiple physicians, some of whom the patient selects without the concurrence or even knowledge of the others. An adult with diabetes mellitus could receive care regularly from an internist, cardiologist, ophthalmologist, and podiatrist, each of whom could adjust medications and share in the

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medical context, "unorganized knowledge" would include the particular financial and physical circumstances of individual patients and each patient's preferences for specific health outcomes, such as longevity, alertness, strength, etc. Physicians, who interact with individual patients, are in a better position to collect and use this knowledge than third-party purchasers who are farther removed from the patient.

46. Haynes, *supra* note 11, at 4.

47. *See* Alan M. Garber, *Evidence-Based Guidelines as a Foundation for Performance Incentives*, 24 HEALTH AFF. 174, 175 (2005).

monitoring of disease complications and the side effects of treatment.[48]

Which provider or providers should be penalized if the patient is not prescribed a recommended drug therapy, such as an angiotensin-converting enzyme (ACE) inhibitor? If the internist prescribes an ACE inhibitor and the cardiologist does not, should the cardiologist be penalized? What if the situation is reversed? Holding both responsible could lead to over-prescribing and even less coordination of care. Holding only one responsible (say, the cardiologist) could also lead to over-prescribing but also could lead to unnecessary compartmentalization of certain aspects of care (e.g., only cardiologists prescribing ACE inhibitors).

Table 2: Tradeoffs Presented by Different Targets of Financial Incentives

Target of Financial Incentives	*Upside*	*Downside*
Individual physicians/ provider groups	Affects behavior of individual physicians/ groups Allows purchasers to evaluate individual physicians/groups	Difficult to assign responsibility for outcomes or compliance with process measures Can encourage duplicative efforts, poor coordination of care
Integrated health care system	Avoids problems of duplication, poor coordination of care	Many patients do not receive care in integrated settings

Whether a provider is responsible for a given outcome – and should therefore be the target of outcome-based financial incentives – can be even less clear. Continuing with the example: "If the patient requires a toe amputation that should have been preventable, which of several physicians and nurses caring for the patient should be considered responsible? To what degree does the patient bear responsibility?"[49]

2. Selecting Performance Targets

Purchasers must also select the performance targets against which providers will be judged. Options include holding providers to an absolute standard (achievement), judging them against their peers (relative performance), judging them against prior performance (improvement), or some combination thereof.

48. *Id.* at 176.
49. *Id.*

Each option presents tradeoffs that will affect providers' responses to the financial incentives and the quality of care provided. Combining different types of performance targets can capture the benefits of each, but at the cost of added complexity.

An example of a performance measure based on absolute achievement would be one that rewards all providers if they prescribe beta-blockers to ninety percent of patients who suffer acute myocardial infarction (AMI). Such a measure gives each provider a clear picture of what is required to obtain the reward. An absolute goal helps providers plan their responses and can reduce uncertainty about whether an investment in improvement will pay off. At the same time, absolute performance targets mostly reward providers who are already performing at the desired level. In one P4P initiative in which rewards were based on a fixed performance target, seventy-five percent of bonuses went to providers who were already exceeding the performance target.[50] Such results may correct inequities that third-party payment systems create among providers. However, some observers note that absolute targets "may produce little gain in quality for the money spent."[51] Furthermore, fixed performance targets provide no incentive for providers to improve beyond the uppermost target.

In contrast, a performance target set relative to a provider's peers might reward the ten percent of providers who have the highest rates of prescribing beta-blockers to AMI patients in a given year. For instance, a Medicare P4P demonstration program (discussed in Part IV) awards bonuses to hospitals in the top two deciles in each of a number of metrics.[52] A relative performance target is a moving target that depends on the behavior of other providers. Because the threshold for compliance cannot be known in advance, providers possess less certainty that a given compliance strategy will lead to a reward. As a result, performance targets that judge providers relative to their peers may result in increased compliance efforts among top performers but little effort at improvement among those who begin the competition farthest from the target. What research has been done on relative performance measures suggests that they may discourage compliance.[53]

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50. Rosenthal et al., *supra* note 17, at 1792.

51. *Id.* at 1788.

52. Press Release, Ctrs. for Medicare & Medicaid Servs., Medicare Demonstration Shows Hospital Quality of Care Improves with Payments Tied to Quality (Nov. 14, 2005), *available at* http://www.cms.hhs.gov/apps/media/press/release.asp?Counter=1729 [hereinafter Medicare Demonstration].

53. *See, e.g.*, DUDLEY ET AL., *supra* note 16, at 28. This survey of P4P experiments (discussed further in Part III) found only two randomized, controlled studies that examined relative performance measures. "The two studies in which the provider faced significant uncertainty about whether they could achieve success – in each case because the incentive was tied to performance *relative* to other groups, and this benchmark was unknown during the time when performance was measured – were negative." *Id.*

Fixed and relative performance targets, which tend to set high standards for all providers, may fail to elicit responses from providers who begin the game far from the target. In contrast, financial incentives based on improvement over past performance may motivate even poorly performing providers to improve. Such incentives, for example, could reward providers for every ten percentage point improvement on a given metric. But such a performance target would do little to encourage improvement among providers in the top decile. Whether increments of improvement are judged along an absolute scale or a relative scale, providers already above the ninetieth percentile would have little incentive to improve. Moreover, using improvement as the sole criterion for financial rewards would create equity problems: Poor performers could receive higher bonuses than providers with consistently high performance.

Table 3: Tradeoffs Presented by Different Types of Performance Targets

Type of Performance Target	*Upside*	*Downside*
Absolute achievement	Clear expectations reduce uncertainty Allow providers to plan	Cost-ineffective; most bonuses go to already-high performers No incentive to improve beyond the upper-most target Can discourage improvement among poor performers
Relative performance	Can increase competition among high performers	Less certainty that compliance efforts will be rewarded Can discourage compliance among poor performers
Improvement	Encourage low-performers to improve Targeting absolute improvement reduces uncertainty	Already-high performers have less room for improvement Poor performers could receive larger bonuses than high performers
Combining two or more types of performance targets	Encourages compliance among all providers	Adds complexity and cost Poor performers could receive larger bonuses than high performers

For a P4P arrangement to encourage improvement among all providers, it must employ some combination of financial incentives tied to absolute or relative performance targets, and separate rewards for improvement. However, including multiple performance targets and rewards adds complexity and gives all providers an opportunity to increase their incomes, creating affordability problems. One solution to the affordability problem is to offset the cost of rewards through the use of penalties – that is, by reducing payments to poor performers. However, the prospect of reduced incomes makes it more likely that providers would resist a P4P scheme.

3. Sizing and Timing Financial Incentives

The size of financial incentives offered to providers is a key consideration. Incentives that are too small will fail to induce behavioral change.[54] On the other hand, incentives that are too large can encourage cost-ineffective or even inappropriate care, as well as make a P4P program unaffordable. The task is further complicated by the fact that different providers will respond to the same incentive in different ways.

Some observers suggest that financial incentives must account for at least ten percent of a physician's income.[55] However, a provider's response to a financial incentive depends primarily, not on the *absolute* size of the incentive, but on the *net* size of the incentive. Suppose a provider could obtain a $90,000 bonus by implementing a $100,000 electronic patient registry. If that bonus plus other benefits of implementing the registry do not at least match the cost of implementing the registry, the incentive would have no effect on the provider's behavior. To cause this provider to change his behavior, the bonus (plus other benefits) must exceed $100,000. That is, to change a provider's behavior, net revenue (R_N) must be positive, meaning the actual financial incentive (R_A) must exceed the cost to providers of compliance (C_C):

$$R_N = R_A - C_C$$

This insight is important because providers will have different compliance costs. Yet a survey of randomized controlled trials of P4P schemes found that none reported data on the cost of complying with the performance measures.[56]

54. *See*, Rosenthal et al., *supra* note 17, at 1792-93.

55. Gary J. Young et al., *Conceptual Issues in the Design and Implementation of Pay-for-Quality Programs*, 20 AM. J. MED. QUALITY 144, 146 (2005).

56. DUDLEY ET AL., *supra* note 16, at 23.

Table 4: Tradeoffs – Size of Financial Incentives

Size of Financial Incentives	*Upside*	*Downside*
Modest	Makes P4P scheme affordable Encourages compliance among providers who can do so at lowest cost	May fail to induce compliance Rewards may go to already-high performers
Large	More likely to induce broad compliance	Makes P4P scheme less affordable May be cost-ineffective

Another factor complicating the calibration of financial incentives is providers' income goals. As R. Adams Dudley, a professor of medicine at the University of California San Francisco and a leading researcher of P4P efforts, notes, "[a] provider whose income is at or near a preferred income target may be less likely to respond to an incentive of a given amount than a provider who is not yet achieving his or her target income."[57]

How a P4P scheme treats compliant versus noncompliant providers will affect both quality and costs. One way to encourage greater compliance is to ensure that the disincentives for noncompliance are large enough to encourage providers to invest in meeting the performance targets. Such disincentives could be merely relative – that is, noncompliant providers could be held harmless but paid less than compliant providers. A more controversial option is to reduce payments to noncompliant providers. Financial penalties can improve overall affordability, but at the cost of provider resistance (as discussed in Section II.B). Nonetheless, without financial penalties, P4P can only increase health expenditures.

Table 5: Tradeoffs – Rewards and Penalties

Type of Financial Incentives	*Upside*	*Downside*
Rewards-only	Less provider resistance Rewards high performers Encourages poor performers to invest in improvement	Increases costs Holds poor performers harmless Creates incentives to game system

57. *Id.* at 11 (citing Allan Krasnik et al., *Changing Remuneration Systems: Effects on Activity in General Practice*, 300 BRIT. MED. J. 1698 (1990)).

Rewards and penalties	Penalizes poor performers Rewards high performers Encourages poor performers to invest in improvement	Increases likelihood of provider resistance Creates incentives to game system

Other important factors are the timeliness of rewards and the frequency with which they are altered or updated. Collecting compliance data takes time, but long delays between desired behavior and rewards reduce the value of those rewards. Some P4P programs can involve reward lags of six months.[58] Likewise, third-party payors may want to update the size or other aspects of financial rewards on the basis of new information. However, frequent changes to performance targets or financial incentives reduce the certainty, and thus the net value, of those rewards.

Table 6: Tradeoffs – Updating P4P Features

Frequency of Updates	*Upside*	*Downside*
Frequent	Makes use of latest scientific evidence Allows cost-effective calibration of incentives	Increases compliance costs for providers Encourages provider resistance
Infrequent	Predictability allows providers to plan	Rewards suboptimal care Reduces cost-effectiveness

D. Cost-Effectiveness

Even if P4P delivered demonstrable improvements in health care quality, that would not demonstrate that P4P is worthwhile. Designing a P4P program that is cost-effective is also a significant challenge. Despite significant health gains, many or all P4P designs could impose costs that outweigh those gains. Collecting evidence-based quality data, translating those data into performance measures, collecting data on provider compliance, distributing rewards, defending penalties, and continually updating a P4P scheme all involve significant financial commitments.[59]

Another important cost dimension is the hidden costs that P4P might impose

58. *See* Rosenthal et al., *supra* note 17, at 1789.

59. *E.g.*, *id.* at 1788 (noting that a "prototypical physician pay-for-performance program" made bonus payments of $3.4 million over a one-year period); Doran et al., *supra* note 40 at 376, 383 ("In 2004, the National Health Service committed £1.8 billion ($3.2 billion) in additional funding over a period of three years for a new pay-for-performance program for family practitioners.").

by encouraging inappropriate care or reducing access. For example, the cost of implementing a P4P scheme could lead private insurers to increase premiums. That in turn could reduce access to health coverage and lead to offsetting health losses. The problem exists in public programs as well. The cost of implementing P4P in Medicare could require spending reductions that reduce the quality of care elsewhere in the program, or higher taxes that make it more difficult for the non-elderly to afford coverage. The health gains that a P4P scheme "purchases" could also be outweighed by the health losses that result from encouraging inappropriate outlier care. The costs of P4P have yet to be quantified, much less compared to the potential benefits.[60]

II. HOW WILL PROVIDERS RESPOND?

Quality-based purchasing is designed to affect the behavior of providers for the benefit of patients. The problems posed by P4P in a health care setting are similar to those of other principal-agent settings, where the principal (here, purchasers) face difficulties creating financial incentives that encourage their agents (providers) to behave in the desired manner.[61]

Health care providers are highly suspicious of P4P efforts,[62] which have the potential to reduce provider incomes. The impact of a P4P scheme will be shaped in part by whether providers respond to financial incentives in the desired manner. Providers may respond in ways that defeat the exercise, increase costs, and even leave some patients worse off. This Part discusses the factors that will affect providers' receptivity to P4P schemes, what can happen if providers choose to undermine P4P efforts, and how P4P could affect individual providers' contributions to medical knowledge.

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60. E-mail from R. Adams Dudley, Associate Professor of Medicine & Health Policy, University of California, San Francisco to author (Aug. 3, 2006, 12:51:00 PST) (on file with author) [hereinafter Dudley E-mail] (indicating that "[t]here is no one who has published about cost or cost-effectiveness" of P4P efforts). *See generally* R. Adams Dudley, *Pay-for-Performance Research: How To Learn what Clinicians and Policy Makers Need To Know*, 294 JAMA 1821, 1822 (2005) (commenting on Rosenthal et al., *supra* note 17 and noting that "no prior pay-for-performance research has reported the cost of improving quality or how that compares with the incentives offered in the pay-for-performance program."). *But see* Peterson et al., *supra* note 40, at 267 (citing a study of one P4P experiment where "the author asserted that the incentive and administrative costs were small compared with potential gains in improved health and lower overall health care expenditures.").

61. For discussions of how monetary incentives fail to solve principal-agent problems in other areas, see, for example, Bruno S. Frey & Margit Osterloh, *Yes, Managers Should Be Paid Like Bureaucrats*, 14 J. MGMT. INQUIRY 96 (2005), and Michael C. Jensen & Kevin J. Murphy, *Performance Pay and Top-Management Incentives*, 98 J. POL. ECON. 225 (1990).

62. *E.g.*, Jim Molpus, *Pay for Performance: Is the Payoff Worth the Effort?*, HEALTHLEADERS ROUNDTABLE, Aug. 2005, at RT9 (2005), *available at* http://www.healthleadersmedia.com/pdf/roundpdf/roundtable-Aug-2005.pdf (noting that "[p]hysicians are still very, very suspicious of the motivation of these programs.").

A. Will Providers Buy In?

For financial incentives to encourage providers to change their behavior, providers first must believe the performance targets are attainable. Yet many factors that influence a provider's ability to meet performance targets are beyond a provider's control. For example, outcome measures are affected by a patient's underlying health status. Providers with sicker-than-average patients could be penalized for below-average outcomes, even if the care provided is of the highest quality. Most efforts to judge providers on patient outcomes are risk-adjusted, that is, they attempt to hold constant the severity of illness so that providers will not be penalized for treating sicker patients. Risk adjustment is meant to address the concern that "a provider could be rewarded and penalized based on the patients it attracts, rather than the quality of care it delivers."[63] Nonetheless, some hospital executives believe that "not in the near future, nor possibly ever, will we develop a reliable severity adjustment system."[64] Outcome measures and risk adjustment are likely to be perennial battlegrounds on which providers are pitted against those seeking to measure quality.

Other patient demographics may also influence a provider's ability to meet performance measures. A low-income patient is less likely to be able to afford all the prescriptions recommended for her multiple conditions. In such cases, providers may rationally choose to focus on a smaller number of affordable medications that offer the greatest benefit. If a P4P program financially penalizes such providers, it would punish them for the type of patients they treat, rather than their performance.

Some performance measures depend on patient cooperation, another factor often beyond the provider's control. One such measure is patient participation in smoking cessation programs.[65] Providers may have limited ability to persuade smokers to enroll in such programs.

Other factors will affect providers' receptivity to P4P schemes. If there are too many schemes, "[a] physician paid for diabetes control one way by the government and another way by the private sector might simply throw up his hands and ignore them both."[66] Providers' willingness to comply with P4P standards is also likely to decline if the number and complexity of schemes increase,[67] providers perceive the standards to be based on unreliable data, or

63. Garber, *supra* note 47, at 179.

64. Ateev Mehrotra et al., *Employers' Efforts to Measure and Improve Hospital Quality: Determinants of Success*, 22 HEALTH AFF. 60, 65 (2003) (noting that in interviews, some hospital executives expressed agreement with the statement).

65. *See* DUDLEY ET AL., *supra* note 16, at 29.

66. CUTLER, *supra* note 7, at 102.

67. *See* Molpus, *supra* note 62, at RT4 (noting that, according to one private P4P administrator, "[w]e are hearing complaints from clients about the demands of complying with different programs that are not using the same measures. Or even if they are using the same

payors are not transparent about the quality criteria.[68] Providers' reactions to any of those factors will be aggravated by the size of the financial disincentives involved, especially if those disincentives include potential losses in income.

Physicians have expressed opposition to many potential P4P designs. The American Medical Association has issued an official policy on the development of P4P programs, stating that "[t]he primary goal of any [P4P] program must be to promote quality patient care that is safe and effective across the health care delivery system, rather than to achieve monetary savings."[69] According to the AMA, all P4P programs must be completely voluntary; reimburse physicians the cost of their participation; finance rewards with supplemental funds; use "the best-available risk adjustment"; keep program features stable for at least two years;[70] and allow for deviation from guidelines when clinically appropriate with "minimal, but appropriate, documentation."[71] In addition, P4P programs must not employ financial penalties, judge individual physicians relative to one another, "threaten the economic viability of physician practices" that do not participate, judge physicians on the basis of factors beyond their control, or limit patient access to care.[72] Opposition from the AMA is one reason a P4P proposal was dropped from the fiscal year 2006 budget resolution.[73]

B. Will Providers Revolt?

If providers believe performance standards are too complicated or lack merit, or that they are being penalized for factors unrelated to their performance, they may act to undermine P4P efforts – not necessarily without reason, but often in ways that could harm patients. For example, providers could exert no effort to reach a P4P scheme's performance targets. In that case, patients often would receive care no better than they would have received in the absence of P4P.

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measures, the methodology and the application of the measurement sets differ.").

68. *See, e.g.*, Philip Betbeze, *Pay for Performance Tipping Point*, HEALTH LEADERS NEWS, Sept. 15, 2005, http://www.healthleadersmedia.com/viewcontent/72244.html (noting that the Medical Group Management Association, which represents physician group practices, has criticized a P4P scheme implemented by United Health: "'They allege that they are using established scientific measures of quality, but they've not been willing to say what they are or where they came from other than that they're in a piece of software that is proprietary,' says William F. Jessee, M.D., MGMA's president and CEO. 'That makes people suspicious.'").

69. Am. Med. Ass'n, H-450.947 Pay-for-Performance Principles and Guidelines, Health and Ethics Policies of the AMA House of Delegates, *available at* http://www.ama-assn.org/apps/pf_new/pf_online?f_n=browse&doc=policyfiles/HnE/H-450.947.HTM (last visited Dec. 10, 2006).

70. With the exception of changes based on clinical evidence.

71. Am. Med. Ass'n, *supra* note 69. The conditions listed in the text are not exhaustive. *Id.*

72. *Id.*

73. *See Congress Locks AMA into Pay-for-Performance Program in 2007*, INSIDE CMS, Jan. 12, 2006; Michael Romano, *AMA Deal Rankles Specialty Docs: Quality Pact with Feds Could Widen Professional Rift*, MOD. HEALTHCARE, Feb. 27, 2006, at 7.

Alternatively, providers could refuse to do business with third-party payors who tie payment to "unreasonable" performance measures. That response would disrupt many patients' access to care. Finally, providers could comply with a P4P scheme, but do so in ways that undermine the effectiveness of the financial incentives. Principally, those responses involve various ways that providers can "game the system" – preserving or increasing their incomes through technical compliance with performance measures but without improving (and often reducing) the quality of care for targeted patients.

Providers who believe they are being penalized for variables beyond their control can be expected to influence the variables they can control in order to protect their incomes. One method – patient selection – could jeopardize many patients' access to care. "If hospitals are paid for good surgical outcomes, they will want to operate on only the healthiest people."[74] If third-party payors reward providers on the basis of their patients' cholesterol levels, some providers may select patients who are most likely to stick to a cholesterol-lowering treatment regimen. And they may avoid those, such as low-income patients or those with multiple chronic illnesses, who will have the most difficulty complying with doctor's orders. Those patients could become "medical hot potatoes" who would find it increasingly difficult to obtain care and could be relegated to low-quality providers.[75]

Another method is data manipulation.[76] As many as fifty percent of physicians admit they have manipulated third-party reimbursement rules to secure coverage of a particular treatment for a patient (and payment for themselves).[77] As many as seventy percent of physicians state they would be willing to do so under certain circumstances.[78] Physicians report a number of tactics for manipulating data in order to obtain reimbursement that could also be used to game and defeat P4P measures.[79]

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74. CUTLER, *supra* note 7, at 109.

75. Boyd et al., *supra* note 36, at 722.

76. *See, e.g.*, CUTLER, *supra* note 7, at 108-09 ("If insurers are paid for controlling blood pressure in hypertensives, for example, they cannot be allowed to call everyone a hypertensive, knowing that most will be 'controlled' when blood pressure is actually tested.").

77. Sidney T. Bogardus, Jr. et al., *Physicians' Interactions with Third-Party Payers: Is Deception Necessary?*, 164 ARCHIVES INTERNAL MED. 1841, 1842 (2004). *See also* Wynia et al., *supra* note 40, at 1858. ("A sizable minority of physicians report manipulating reimbursement rules so patients can receive care that physicians perceive is necessary. Unless novel strategies are developed to address this, greater utilization restrictions in the health care system are likely to increase physicians' use of such manipulative 'covert advocacy' tactics.")

78. Bogardus, Jr. et al., *supra* note 77, at 1842.

79. Bogardus et al. stated:

> Tactics reported by physicians have included exaggerating the severity of the patient's condition, changing the patient's diagnosis for billing, or reporting signs or symptoms that the patient did not have. Deceptions may involve brief changes in wording, as when physicians use *rule out cancer* as the indication for a test rather

An experiment in the United Kingdom's National Health Service (NHS) provides an example of how physicians could game P4P performance measures. In 2004, the NHS rewarded family practitioners based on the proportion of the practitioner's patients who received recommended care.[80] To avoid encouraging inappropriate care for outliers, the NHS permitted physicians to exempt patients from the denominator when calculating that proportion. Researchers found the use of such exemptions to be the strongest predictor of whether a physician reached the performance targets and concluded, "[m]ore research is needed to determine whether these practices are excluding patients for sound clinical reasons or in order to increase income."[81]

Finally, providers may be able to defeat P4P incentives by manipulating the intensity of care. Research has documented wide regional variations in health care spending on similar patients.[82] Much of this spending is the result of greater intensity of care, such as more frequent hospital admissions and specialist consultations.[83] The history of managed care illustrates how difficult it is for third-party purchasers to reduce overuse. Where third-party purchasers are blind to or unable to control overuse, providers who are unwilling or unable to meet P4P performance targets may be able to preserve their incomes by increasing the intensity of the care they provide. Such strategies would increase expenditures while potentially reducing quality.[84]

C. How Will P4P Affect Experimentation and Learning?

Another important consideration is the effect that financial incentives will have on experimentation and learning. It is generally accepted that the use of clinical evidence in treatment decisions has been suboptimal and that providers have traditionally relied too heavily on the "art of medicine" or "clinical judgment."[85] However, as discussed earlier, clinical trials report average effects

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> than *screening*. Also, physicians may be willing to alter billing codes or to change elements of patient history (e.g., increasing the severity of a symptom or even creating nonexistent symptoms, such as claiming suicidal ideation to obtain a psychiatric referral) or results of physical examination (e.g., inventing findings such as breast lumps to obtain a referral for screening mammography).

Id. at 1842 (citations omitted). Strategies such as altering the severity of a condition or changing diagnoses could be employed to game performance measures just as they are used to game reimbursement rules.

80. Doran et al., *supra* note 40, at 375.

81. *Id.* at 375. "The generally low levels of exception reporting suggest that large-scale gaming was uncommon." *Id.* at 383.

82. Wennberg, *supra* note 10, at 2.

83. Fisher et al., *Part 1*, *supra* note 3, at 273.

84. *See generally id.* at 273.

85. David M. Eddy, *Evidence-Based Medicine: A Unified Approach*, 24 HEALTH AFF. 9, 10 (2005). *See also* Evidence-Based Medicine Working Group, *Evidence-Based Medicine: A New*

of interventions on patients who are selected for their lack of co-morbidities. Thus, while clinical evidence is essential, each provider can expect to treat some patients for whom "quality" will not be defined by the results of clinical trials.

In those cases, incentives to treat outliers like average patients could discourage providers from using their clinical judgment where it is appropriate. In any P4P scheme, providers arguably should be free to deviate from an "average patient" standard when dealing with patient subgroups for whom no evidence-based CPGs exist. Allowing that flexibility would enable providers to discover and disseminate new modes of treatment that later may be scrutinized in clinical trials.

Whether and how a P4P scheme creates such flexibility will affect both provider participation and the quality of care for outliers. Many performance targets include some flexibility. A target that rewards physicians when ninety percent of AMI patients are prescribed beta-blockers allows physicians to deviate from the standard in ten percent of cases. But payors and providers will differ over whether ten percent is sufficient flexibility or too little.

III. EVIDENCE OF THE EFFECTIVENESS OF P4P

Preserving providers' ability to exercise clinical judgment is particularly important when one considers the lack of evidence showing that evidence-based guidelines actually lead to better patient outcomes. According to one pioneer of evidence-based medicine:

> A fundamental assumption of EBM is that practitioners whose practice is based on an understanding of evidence from applied health care research will provide superior patient care compared with practitioners who rely on understanding of basic mechanisms and their own clinical experience. So far, no convincing direct evidence exists that shows that this assumption is correct.[86]

Much the same can be said of the performance of P4P. Although the aim of P4P is to use evidence to drive higher-quality care, very little evidence has been collected that shows that P4P actually delivers on its promise.

A 2004 survey of the literature found data on the effectiveness of P4P to be "sparse."[87] Researchers could locate only eight randomized, controlled studies that measured the ability of performance-based financial incentives to change provider behavior or to improve patient outcomes.

The results were mixed. The studies obtained both positive and negative

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Approach to Teaching the Practice of Medicine, 268 JAMA 2420 (1992); Simon R. J. Maxwell, *Evidence Based Prescribing*, 331 BRIT. MED. J. 247 (2005) (editorial); David L. Sackett et al., *Evidence-Based Medicine: What It Is and What It Isn't*, 312 BRIT. MED. J. 71 (1996) (editorial).

86. Haynes, *supra* note 11, at 2.

87. DUDLEY ET AL., *supra* note 16, at 63.

results when financial incentives were targeted to individual physicians, individual providers, and provider groups. According to the authors, "[t]here was no consistent relationship between the magnitude of the incentive and response, and in fact the largest single incentive (the bonus of up to $10,000) was ineffective."[88] As noted earlier, the studies examining relative performance targets, where providers lacked certainty about what would be required to obtain the reward, obtained negative results.[89] Two types of financial incentives, fee-for-service payment enhancements and bonuses, showed mixed results.[90] Results were also mixed for studies that measured whether financial incentives encouraged the use of preventive care.[91] Insofar as the studies provided any consistent evidence, it was that "in a general sense . . . incentives to achieve performance were more effective when the indicator to be followed required less patient cooperation (e.g., receiving vaccinations or answering questions about smoking) than when significant patient cooperation was needed (e.g., to quit smoking)."[92] While P4P may be a useful tool for improving health care quality, its effectiveness at changing provider behavior or improving outcomes has not been established.

Nor has the cost-effectiveness of P4P been established. Purchasers incur the expense of P4P with the expectation that it will be outweighed by improved health and cost savings. Yet little attention has been paid to whether those hoped-for results are worth the cost, both because the costs of P4P schemes have yet to be systematically measured[93] and also because effectiveness must be established before cost-effectiveness can be established.

The P4P movement proceeds from two premises: first, that clinicians tend to under-use evidence from randomized clinical trials and, second, that financial incentives can increase such use and improve the quality of care. Yet, whatever enthusiasm exists for P4P is not derived from the type of evidence of effectiveness that P4P enthusiasts believe should guide clinical practice. Third-party financial incentives remain an unproven tool for improving health care quality, let alone doing so in a cost-effective manner.

IV. P4P IN MEDICARE

Prominent health policy scholars,[94] most recently the Institute of Medicine,[95]

88. *Id.* at 28.
89. *Id.*
90. *Id.* at 28-29.
91. *Id.* at 29.
92. *Id.*
93. Dudley E-mail, *supra* note 60.
94. *E.g.*, Donald M. Berwick et al., *Open Letter: Paying For Performance: Medicare Should Lead*, 22 HEALTH AFF. 8 (2003).
95. INST. OF MED., NAT'L ACADEMIES, REWARDING PROVIDER PERFORMANCE: ALIGNING

have argued that Medicare should take the lead in paying for performance. Medicare has launched limited demonstration programs to test the concept. In 2005, Medicare released the first quality-based bonus payments in the program's history, following promising results from one P4P demonstration, the Premier Hospital Quality Incentive program.[96] That program, launched in 2003, collects data on about thirty quality indicators for joint replacements, coronary artery bypass grafts, heart attacks, heart failure, and pneumonia.[97] For each clinical area, hospitals that score in the first and second deciles receive bonus payments from Medicare of two percent and one percent of Medicare payments for those services, respectively.[98] After the first year, the demonstration used the bottom two deciles in each area of care to set baselines for poor performers.[99] In the third and subsequent years, Medicare will reduce payments by up to two percentage points to hospitals that score below those baselines in the clinical areas involved.[100] Medicare predicts that most hospitals will improve and that "few, if any, hospitals would get a payment reduction."[101] Medicare officials estimate that the demonstration program, by encouraging the use of more effective care, has thus far saved the lives of 235 heart attack patients.[102]

Congress is considering proposals to expand on those initiatives within Medicare. In the 109th Congress, the former chairman of the Health Subcommittee of the House Committee on Ways and Means, Representative Nancy Johnson (R-CT), introduced legislation that would give larger payment increases to physicians who meet administratively specified performance targets or who make significant progress toward meeting them.[103] Senator Chuck Grassley (R-IA) introduced even more expansive legislation, which would create P4P incentives for hospitals, physicians, Medicare Advantage plans, home health agencies, and other providers.[104] Language that would have broadened the use of P4P in Medicare was removed from the fiscal year 2006 budget reconciliation package just before final passage.[105] In late 2006, Congress passed legislation tying higher physician payments to quality reporting requirements, a move intended to facilitate broader P4P initiatives.[106]

INCENTIVES IN MEDICARE (2006).

96. Medicare Demonstration, *supra* note 52.

97. *Id.*

98. *Id.*

99. PREMIER, INC., *supra* note 33.

100. Medicare Demonstration, *supra* note 52.

101. *Id.*

102. Abelson, *supra* note 10, at C3.

103. Medicare Value-Based Purchasing for Physicians' Services Act of 2005, H.R. 3617, 109th Cong. (2005).

104. Medicare Value Purchasing Act of 2005, S.1356, 109th Cong. (2005).

105. *Budget Reconciliation Remains a Loose End for Congress; Senate-Approved Package Must Return to the House*, WASH. OUTLOOK, Dec. 23, 2005 (on file with author).

106. Robert Pear, *Medicare Links Doctors' Pay to Practices*, N.Y. TIMES, Dec. 12, 2006, at 1.

A. Special Challenges Posed by Medicare

Introducing P4P into the traditional Medicare program presents a number of unique problems. First, Medicare's elderly patient population is more likely to suffer from co-morbidities, which makes it more likely that a P4P scheme would encourage inappropriate care for some patients. Second, the political forces that govern Medicare make it less likely that those perverse incentives would be corrected, and more likely that a P4P scheme would increase costs for taxpayers who finance the program. Finally, because Medicare greatly influences the behavior of private purchasers, any harm caused by a Medicare P4P scheme likely would spill over into the private sector as well.

1. Greater Potential for Error

Any harm that a P4P system could conceivably cause is more likely to appear in Medicare, for two reasons. First, Medicare's patient base is more susceptible than those of private insurers to the unintended harms that can result from P4P programs. This is due to the fact that Medicare enrollees are older, less healthy, and more likely to have low incomes[107] and to consume more medical care[108] than non-elderly Americans with private health insurance. Close to one-third of Medicare beneficiaries have four or more chronic conditions, and those patients account for nearly eighty percent of Medicare spending.[109] The large number of beneficiaries with chronic conditions increases the likelihood that a

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107. *See, e.g.*, Karen Davis et al., *Medicare Versus Private Insurance: Rhetoric And Reality*, W2 HEALTH AFF. - WEB EXCLUSIVE, Oct. 9, 2002, at W311, http://content.healthaffairs.org/cgi/reprint/hlthaff.w2.311v1.pdf. As Davis et al. write:

> Medicare beneficiaries are more likely than the privately insured are to be in poor health and have low incomes. In the survey, two-thirds of persons under age sixty-five with private health insurance rated their health status as excellent or very good, compared with two-fifths of elderly Medicare beneficiaries. The proportion of elderly Medicare beneficiaries rating their health as fair or poor was three times higher than that of privately insured adults. Four of five Medicare beneficiaries had a chronic condition, compared with just over one-third of the privately insured. Medicare beneficiaries were four times as likely as the privately insured were to report having two or more chronic conditions.

Id. at W313.

108. *See generally* Ctrs. for Medicare & Medicaid Servs., National Health Expenditure Data: Age Tables 1-6, http://www.cms.hhs.gov/NationalHealthExpendData/downloads/agetables.pdf (last visited Dec. 10, 2006) (showing that per capita personal health care expenditures for Americans age sixty-five and older are roughly four times those for Americans under age sixty-five in the table entitled, "Personal Health Care Spending by Type of Service, Age Group, and Source of Payment Distribution, Calendar Year 1996").

109. Robert A. Berenson & Jane Horvath, *Confronting the Barriers to Chronic Care Management in Medicare*, W3 HEALTH AFF. - WEB EXCLUSIVE, Jan. 22, 2003, at W3-37, W3-38, http://content.healthaffairs.org/cgi/reprint/hlthaff.w3.37v1.pdf.

P4P scheme would create incentives to mistreat such patients and turn them into "medical hot potatoes"[110] that providers would try to avoid. Those patients are at the highest risk for the type of adverse drug interactions that can come from strict adherence to multiple CPGs and P4P measures.[111] Moreover, Medicare patients are more likely to have treatment goals that differ from those assumed by CPGs and P4P measures.[112] As a result, a Medicare P4P effort is more likely to create harmful financial incentives than efforts focused on non-elderly patients.

Compounding this challenge is the fact that Medicare is a creature of the political process. The political forces that govern Medicare would shape each phase of a P4P initiative. Insulating that process from politics would be impossible. The choices involved would directly affect the incomes of up to "700,000 physicians, 6,000 hospitals and thousands of other providers and suppliers"[113] who depend on Medicare for their livelihood. The tradeoffs made in structuring a Medicare P4P program would also affect the quality and accessibility of care for some 42 million seniors,[114] the tax burden of hundreds of millions of Americans, and the availability of federal revenues for other priorities.

Parties with a stake in the tradeoffs involved would seek to influence Congress, the Centers for Medicare and Medicaid Services (CMS), and whatever other bodies make or influence Medicare policy. For nearly a decade, the health care industry has led other sectors of the economy in terms of dollars spent lobbying Congress,[115] and employing P4P financial incentives in Medicare would only increase such lobbying. The unavoidable political pressure would reduce Medicare's flexibility to make timely, focused, and evidence-based adjustments

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110. Boyd et al., *supra* note 36, at 722 ("Current pay-for-performance initiatives can create financial incentives for physicians to focus on certain diseases and younger or healthier Medicare patients.").

111. *Id.* at 720.

112. *See* Tinetti et al., *supra* note 39 at 2870. ("[E]vidence is emerging that patients, particularly elderly patients and those with multiple conditions, vary in regard to the amount of importance they place on health outcomes such as longer survival, the prevention of specific disease events, and physical and cognitive functioning, as well as in the amount of inconvenience and risk of adverse effects they are willing to tolerate.")

113. Press Release, Ctrs. for Medicare & Medicaid Servs., Fact Sheet: HCFA Management Reforms (May 1, 2000), *available at* http://www.cms.hhs.gov/apps/media/press/release.asp?Counter=379.

114. EARL DIRK HOFFMAN, JR. ET AL., BRIEF SUMMARIES OF MEDICARE & MEDICAID: TITLE XVIII AND TITLE XIX OF THE SOCIAL SECURITY ACT AS OF NOVEMBER 1, 2005 6 (2006), *available at* http://www.cms.hhs.gov/MedicareProgramRatesStats/downloads/MedicareMedicaidSummaries2005.pdf.

115. *See* PoliticalMoneyLine, Leading Sector Spending for Federal Lobbying 7/1/05-12/31/05, Money in Politics Databases, http://www.tray.com/cgi-win/lp_sector.exe?DoFn=my&Year=05 (last visited Dec. 10, 2006). For more information, see previous reports dating back to Leading Sector Spending for Federal Lobbying 1/1/99–6/30/99, Money in Politics Databases, http://www.tray.com/cgi-win/lp_sector.exe?DoFn=my&Year=99 (last visited Dec. 10, 2006).

to its payment structure and would put upward pressure on Medicare outlays. The politicization of quality-based financial incentives could also be expected to politicize the search for data to guide those incentives, as interested parties seek federally financed research on modes of care that they believe should be rewarded for being of higher quality.

Indeed, rent-seeking behavior would attend every aspect of a Medicare P4P system. As do Medicare's payment systems broadly, a P4P system would spur congressional and administrative lobbying by providers who seek to protect or increase their incomes, who fear being penalized for factors beyond their control, who do not want to change the way they practice, who want additional research devoted to their modes of care, who seek to gain advantages over their competitors, who wish to ensure that performance measures can be gamed, who do not want the P4P system updated too frequently, and who want only one set of performance targets set by Medicare and adopted by private insurers. Political pressures would also come from those who see P4P as a way to reduce Medicare outlays. Given the future financial pressures facing Medicare[116] and the growing scarcity of federal resources for other congressional priorities, politicians and interest groups could be expected to exploit opportunities to squeeze provider payments. In contrast to past reductions in Medicare provider payments, P4P would allow future cuts to be packaged as quality-enhancing.

However, it is reasonable to predict that provider groups and Medicare beneficiaries would have the greatest influence over a Medicare P4P scheme and that such a scheme would increase Medicare outlays significantly. Providers and seniors have a more direct stake in how such a scheme is structured than do others. The benefits of their preferred policies are large and concentrated on groups that are relatively easy to organize for political action.[117] By comparison, the per capita benefits of using P4P to constrain Medicare spending are spread out among a larger group of individuals (i.e., taxpayers) that is more difficult to organize. The likely result is that Medicare would be able to create P4P financial incentives only by increasing outlays.

The political forces governing Medicare would also make a Medicare P4P system more rigid and slower to adapt than private P4P schemes. Given the influence that Medicare's P4P decisions would have on providers' incomes and the overall tax burden, those interest groups can be expected to use political

116. *See generally* GOV'T PRINTING OFFICE (GPO), THE 2006 ANNUAL REPORT OF THE BOARD OF TRUSTEES OF THE FEDERAL HOSPITAL INSURANCE AND FEDERAL SUPPLEMENTARY MEDICAL INSURANCE TRUST FUNDS (2006), *available at* http://www.cms.hhs.gov/ReportsTrustFunds/downloads/tr2006.pdf.

117. *See, e.g.*, Alan Garber, *Cost-Effectiveness and Evidence Evaluation as Criteria for Coverage Policy*, W4 HEALTH AFF. - WEB EXCLUSIVE, May 19, 2004, at W4-284, W4-293 (2004), http://content.healthaffairs.org/cgi/reprint/hlthaff.w4.284v1.pdf ("Because they are a large and politically powerful constituency, Medicare beneficiaries have a powerful voice in deliberations over any major change.").

pressure to block changes that they expect would adversely affect their interests. In contrast, private purchasers have greater flexibility when designing and adjusting their P4P schemes.[118] As a result, Medicare would take longer to correct errors than private third-party purchasers do.

Medicare would have to overlay a P4P scheme on its already complex administrative pricing responsibilities. Medicare currently operates sixteen different payment systems for various types of providers and health plans. The physician payment system alone must set prices for more than 7000 distinct services[119] in each of eighty-nine payment localities.[120] P4P would pile even more complexity on top of that system. Where CMS need now divine only one (quality-blind) payment for a service, P4P would require the agency to devise two payment levels: one for high-quality providers and one for low-quality providers.

Medicare's administered pricing systems have been criticized for spurring over-investment in some areas of care and under-investment in other areas[121] and for being slow to fix such errors.[122] For example, technological advances and productivity gains in ambulatory surgical centers (ASCs) have reduced the cost of care in those facilities. Yet Medicare payments to ASCs have not been adjusted to account for any such changes since 1988. This has led to a situation in which ASCs are often paid far more than hospital outpatient centers for the same procedures. Moreover, ASC payments will not be adjusted for these factors until 2008.[123]

The same rigidity would afflict Medicare's administration of performance-

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118. Providers have less power to block P4P experiments by private purchasers. Though providers can refuse to participate in a private P4P program, the insurer can still survive if its customers value the improvements in technical quality more than any reduced access that comes from providers being excluded from a plan's network or refusing to accept reimbursements offered to non-compliant providers as payment in full. If the insurer loses customers, on the other hand, that would signal to the insurer that its customers perceive that the costs of its P4P program outweigh the benefits.

119. MEDICARE PAYMENT ADVISORY COMM'N, PAYMENT BASICS: PHYSICIAN SERVICES PAYMENT SYSTEM 1 (2006), *available at* http://medpac.gov/publications/other_reports/Sept06_MedPAC_Payment_Basics_Physician.pdf.

120. MEDICARE PAYMENT ADVISORY COMM'N, REPORT TO THE CONGRESS: MEDICARE PAYMENT POLICY 11 (1999), *available at* http://www.medpac.gov/publications/congressional_reports/Mar99%20Ch1.pdf.

121. *See, e.g.*, U.S. FED. TRADE COMM'N & U.S. DEP'T OF JUSTICE, *supra* note 7, at 9 (executive summary).

122. *See, e.g., Medicare: Private Payer Strategies Suggest Options To Reduce Rapid Spending Growth: Hearing Before H. Subcomm. on Health, Comm. on Ways and Means,* 109th Cong. 7 (2006) (statement of Janet L. Shikles, U.S. General Accounting Office), *available at* http://www.gao.gov/archive/1996/he96138t.pdf ("Because of strict statutory constraints and its own burdensome regulatory and administrative procedures, [CMS] is slow to address overpricing and overutilization problems.").

123. U.S. Fed. Trade Comm'n & U.S. Dep't of Justice, *supra* note 7, ch. 3, at 25.

based payments. Inaccurate data, mis-targeted or mis-calibrated financial incentives, or perverse incentives that result in low-quality care could live on within Medicare well after a private purchaser might correct the error. This is particularly true where interest groups would have an incentive to preserve Medicare's error (e.g., where providers are receiving unwarranted financial bonuses).

2. A Large Wake

Not only would errors be more likely in a Medicare-administered P4P program, but the resulting harms would be far more widespread than those of similar errors by private payors. In addition to having a higher *proportion* of patients who are in poor health[124] and likely to be harmed by the unintended consequences of a P4P program, Medicare covers a much larger *number* of individuals than any private insurer. Medicare is the single largest purchaser of medical care in the United States, with thirty-seven million elderly and disabled enrollees in traditional Medicare and another five million enrolled in private plans.[125] Medicare beneficiaries also consume more medical care than the non-elderly. Finally, for reasons discussed below, they also would be less able than non-Medicare patients (or those patients' employers) to switch insurers if a P4P program causes unintended harm.

Any harms resulting from a Medicare P4P system would likely spill over into private insurance. Private insurers' payments are often heavily influenced by Medicare's payment rates.[126] If the federal government creates one P4P system for the traditional Medicare program, other third-party purchasers would face strong incentives to adopt that system as well. Many purchasers (e.g., state governments and private insurers, including Medicare Advantage plans) likely would rather have the federal government incur the costs of creating and updating their P4P scheme than incur those costs themselves. As a result, a Medicare P4P scheme likely would crowd out more flexible private efforts, and any harm it creates could spread beyond the Medicare population.

B. How To Address the Unique Pitfalls of Medicare P4P

P4P gives third-party payors considerable power to influence – for good or

124. *See* Davis et al., *supra* note 107, at 313.

125. Milt Freudenheim, *UnitedHealth to Buy PacifiCare in Push into Medicare*, N.Y. TIMES, July 7, 2005, at C1 (explaining that the nation's largest private insurer in 2004 was WellPoint, with 27.7 million enrollees).

126. Uwe E. Reinhardt, *The Medicare World from Both Sides: A Conversation with Tom Scully*, 22 HEALTH AFF. 167, 168 (2003). Tom Scully, former administrator of CMS, stated that "Medicare and Medicaid are such dominant players that the private sector has been forced to follow along – shadow pricing [those programs] in recent years." *Id.*

ill – the quality of care that patients receive. The potential for harmful errors generally, and in Medicare in particular, suggests that, at a minimum, individual patients should have the ability to move between health plans that employ P4P. The potential for harm can also be mitigated by cost-sharing features that assign patients greater financial responsibility for care rendered by providers who deviate from CPGs.

1. Confine P4P to Private Medicare Plans

One option that would enable Medicare beneficiaries to reap the benefits of P4P while minimizing any harm would be to restrict the use of provider-focused P4P incentives to private Medicare Advantage plans. Seniors could then select a health plan on the basis of a number of features, including its P4P scheme. Plans that pay for performance would be able to market themselves on the basis of quality and cost-effectiveness. An enrollee could switch plans during the annual open enrollment period (or perhaps more frequently) if she and her doctor determined that her health plan's P4P incentives were interfering with the quality of her care.

Confining P4P to private Medicare plans would also continue the learning process that allows for testing and refining P4P strategies. Instead of creating a single set of P4P measures and incentives, private Medicare plans would be able to experiment with different, competing P4P efforts. Best practices could be retained and emulated by other plans. As important, the harms resulting from ill-conceived financial incentives would be confined to smaller populations, and those incentives could be discarded sooner. Over time, Medicare Advantage plans would gravitate toward whatever successful P4P strategies emerged, while keeping unintended harms to a minimum. For example, private insurers adopted prescription drug coverage years before Medicare did so, and private plans enjoy more flexibility to innovate and adjust that coverage than Medicare Part D plans.

Preventing CMS from developing P4P incentives for traditional Medicare would be necessary to catalyze this learning process. A P4P scheme in traditional Medicare would apply to thirty-seven million seniors and would effectively crowd out private efforts to develop competing P4P programs. Private plans would be much less likely to incur the costs involved with P4P when they could adopt the Medicare standards at close to zero cost. Moreover, even when private insurers sought to create innovative alternative or supplemental P4P incentives, those efforts would be less likely to influence providers. According to Tom Scully, former administrator of the Centers for Medicare and Medicaid Services, "[i]n many markets Medicare and Medicaid comprise over 65 percent of the payments to hospitals, and more than 80 percent in some physician

specialties."[127] Necessity would force providers to give highest consideration to Medicare's performance measures. Providers might ignore financial incentives offered by other payors, particularly if those incentives applied to small patient populations or entailed high compliance costs (roughly measured by the degree to which a provider would have to deviate from what Medicare already requires). Even where providers complied with alternative private P4P programs, private payors would incur the entire cost of implementing those programs but only reap benefits above and beyond what Medicare's standards would provide for free. For the sake of constantly improving the performance of P4P, it is therefore important not to create a P4P system in traditional Medicare.

One criticism of confining P4P to private Medicare plans is that those plans face incentives to screen out seriously ill seniors, and P4P would give them another tool for doing so. For example, a plan could require strict adherence to CPGs without regard to co-morbidities, which would encourage costly seniors with multiple chronic conditions to avoid that plan. This valid concern arises from a problem similar to the difficulty involved in applying CPGs to atypical patients: In each case, a third-party payor is trying to treat an outlier as though she were the average patient. The solution to such screening is for Medicare to adjust its payments to reflect the expected health care costs of the individual patient. In fact, the Centers for Medicare and Medicaid Services are currently refining Medicare's risk-adjustment capabilities.[128] A further step would be for Medicare to subsidize patients directly, which would encourage plans to compete for outliers by tailoring offerings to those patients.

Another potential criticism of confining P4P to Medicare Advantage plans is that without traditional Medicare's purchasing power, those plans would be less able to change providers' behavior. Although this is true, the fact that Medicare has the market power to influence providers' behavior for the good also means it has the power to influence providers' behavior in ways that harm beneficiaries. Ultimately, P4P schemes will be more effective if they focus on precision first and market power second. Smaller experiments by private insurers are better positioned to deliver that precision, and could build market power by establishing a reputation for quality. Though the evidence is mixed, private P4P efforts have shown some ability to influence provider behavior.[129] Moreover, Medicare's market power derives from the political power of providers and seniors. Though Medicare theoretically has the market power to change providers' behavior, providers often have the political power to change Medicare's behavior. The fact that private plans are not as easily influenced by providers offsets their relatively

127. *Id.* at 169-70.

128. *See generally* Robert A. Berenson, *Medicare Disadvantaged and the Search for the Elusive 'Level Playing Field'*, W4 HEALTH AFF. - WEB EXCLUSIVE W4-572, W4-585 (2004), http://content.healthaffairs.org/cgi/reprint/hlthaff.w4.572v1.pdf.

129. *See generally* DUDLEY ET AL., *supra* note 16.

weaker market position, and leaves open the question of whether private plans or Medicare would have more influence over providers' behavior.

Allowing P4P only in private Medicare plans would confine P4P to a maximum of five million Medicare beneficiaries at present, or twelve percent of enrollees. However, the reach of P4P could be expanded – and the refinement of P4P tools accelerated – by encouraging more Medicare beneficiaries to enroll in private plans. The bipartisan premium support proposals advanced in the late 1990s[130] would encourage greater private plan enrollment and would give individual seniors a stake in evaluating the cost-effectiveness of P4P strategies, as well as health plans overall.

2. Use Patient-Focused Financial Incentives

Provider-focused financial incentives remain an unproven method for improving quality. Much more research is necessary before payors can know whether and where P4P will change providers' behavior and improve patient outcomes. Thus, it is important that payors not focus solely on provider-focused financial incentives. Other measures may also induce providers to improve the quality of care.

One possibility is the use of incentives that increase patients' financial interest in high-quality care. Most P4P initiatives attempt to influence the behavior of providers. A weakness of this approach is that it does not involve the patient – in fact, patients could be completely unaware of the financial incentives that affect the care they receive. Engaging the patient in the pursuit of quality could educate patients about superior modes of care, could conceivably have a greater influence on provider behavior, and would allow patients to avoid the harms that may result from hidden financial incentives targeted to providers.

The same sort of data that third-party payors use to create financial incentives for providers could be used to create financial incentives that encourage patients to demand higher-quality care. Payers could adjust out-of-pocket exposure such that patients who receive recommended care (or who use providers known for delivering recommended care) would face lower out-of-pocket costs, while those who do not would face higher out-of-pocket costs. Patients would know sooner whether a provider was not adhering to the plan's quality guidelines because that deviation would affect their pocketbooks. In such cases, a dialogue between the patient and provider (and perhaps the health plan) could ensue. Both the price signals offered by the plan and the subsequent dialogue would lead to better-educated patients who would help drive quality improvements.

130. *See* Nat'l Bipartisan Comm'n on the Future of Medicare, Building a Better Medicare for Today and Tomorrow (Mar. 16, 1999), *available at* http://thomas.loc.gov/medicare/bbmtt31599.html.

Finally, patient-focused financial incentives would offer protection to patients who might be inadvertently harmed by inappropriate provider-focused incentives. When the financial incentives are targeted to the patient, they are transparent. When a patient and her provider disagree with the health plan's recommendations, they would be free to disregard the recommendations and pay the higher coinsurance. Because such tiered coinsurance would keep the locus of decision making at the level of the patient, it may be more appropriate for traditional Medicare than are provider-focused incentives.

Patient-focused financial incentives would face some difficulties similar to those facing provider-focused incentives. For example, health plans might have to take steps to ensure that patients with co-morbidities and other clinical outliers would not be penalized for choosing appropriate care that happens to deviate from the standard. In addition, patients without the means to pay higher coinsurance would be in the same position as patients whose care is influenced by provider-focused financial incentives that she can neither control nor see. Nonetheless, patient-focused financial incentives are another arrow in the quiver of third-party purchasers (including Medicare) and offer benefits that provider-focused incentives do not.

CONCLUSION

America's health care sector is marked by substantial variations in health care quality. The purchasing power of large third-party payors – such as Medicare – presents an opportunity to encourage low-performing providers to improve the quality of care they deliver. Pay-for-performance offers a way to steer providers toward modes of care that have been demonstrated to improve patient health.

However, P4P is an unproven tool with significant potential pitfalls. As Mary E. Tinetti of the Yale School of Medicine and her colleagues write:

> [O]ne of the hallmarks of quality-assurance programs is a reduction in the variation of practice patterns among providers. It is difficult to separate inappropriate variation due to neglect or ignorance on the part of providers from appropriate variation due to the total disease burden and the preferences of patients.[131]

Developing, implementing, and maintaining the financial incentives required to steer provider behavior are not straightforward tasks. Any number of errors – including false or misinterpreted data and mis-targeted or mis-calibrated financial incentives – could inadvertently encourage low-quality care or reduce access to care. Even when financial incentives are based on accurate data, not all patients

131. Tinetti et al., *supra* note 39, at 2870.

hew to the mean. Encouraging providers to treat each patient as though she were the average patient can harm outliers.

The potential for error that exists in any P4P effort would be magnified if incorporated into traditional Medicare. The political forces that govern Medicare increase the potential for error and would increase the duration of such errors. Many seniors would have difficulty avoiding the resulting harms, given that traditional fee-for-service Medicare is often the only game in town. Moreover, the introduction of P4P into traditional Medicare likely would crowd out private P4P efforts. As they do with regard to coverage determinations and provider reimbursements, private insurers would face strong incentives to follow Medicare's lead. That would unnecessarily constrict experimentation and competition among P4P schemes.

A better approach to introducing P4P into Medicare would be to restrict the use of provider-focused financial incentives to private Medicare plans. Doing so would allow patients to avoid P4P designs that create perverse incentives and would allow private plans to experiment and learn from each other's successes and failures. Moreover, it would offer the benefits of P4P to Medicare enrollees without having traditional Medicare create a de facto national P4P program. If traditional Medicare is to use financial incentives to drive quality, those incentives would be better targeted to individual patients. In either case, the ultimate locus of decision making would be at the level of the individual patient.

The potential risks of broadly applicable P4P systems are serious enough that those adversely affected should have the right to opt out of those systems – and perhaps the responsibility of bearing the cost of that choice. Moreover, P4P holds enough promise that special interests should not be able to stymie its development through political pressure.

The Three Faces of Retainer Care: Crafting a Tailored Regulatory Response

Frank Pasquale*

INTRODUCTION

Retainer care arrangements allow patients to pay a retainer directly to a physician's office in order to obtain special access to care.[1] Practices usually convert to retainer status by focusing their attention on those willing to pay a retainer fee, and dropping the majority of their patients, who are left to be absorbed by other practices.[2] Also known as "boutique medicine," "concierge care," or "innovative practice design," retainer practices have drawn thousands of enthusiastic patients.[3]

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1. Controversies over retainer care extend even to its name. Congress chose the term "concierge care" in the 2003 Medicare Modernization and Prescription Drug Act. 42 U.S.C.A. § 1395cc (West 2006). *See also* U.S. GAO, PHYSICIAN SERVICES: CONCIERGE CARE CHARACTERISTICS AND CONSIDERATIONS FOR MEDICARE (2005) [hereinafter GAO REPORT]. This term is unsatisfactory because opponents have tried to brand retainer arrangements as a mere bauble of the wealthy by using the term "concierge care," or the more common "boutique medicine." At the other extreme, proponents of retainer care choose terms that go beyond euphemism into express approbation (such as "innovative practice design") or misleading synecdoche (such as "personalized preventive care"). *See* Russ Allen, *Doctors on Retainer Catch On*, RISK & INS., Mar. 1, 2005, at 20. "Retainer care" seems to be the best neutral term for discussing the financing arrangements analyzed in this Article.

2. Robert M. Portman, *Concierge Care: Back to the Future of Medicine?*, 15 HEALTH L. 1 (2003); Avram Goldstein, *Doctors on Call – for a Hefty Retainer*, WASH. POST, Jan. 24, 2003, at B1. For a discussion of three models of retainer practices, see John R. Marquis, *Legal Issues Involved in Concierge Medical Practice*, HEALTH LAW. NEWS, Mar. 2005, at 18, 18-19.

3. Nicole C. Brambila, *Paying a Top Price for Health: Patients Giving Docs Retainers for 'Concierge' Medical Service*, DESERT SUN, Feb. 12, 2006, at A1 ("Costs and services differ – from

They have also provoked scrutiny from politicians[4] and consumer groups.[5] Few recent developments in the business of medicine provoke emotional conflicts like retainer care does. Retainer care physicians are thrilled to break out of the vise of managed care, lavishing medical attention where they used to face the stark choice of rationing or involuntarily donating their services. Critics decry an ever-widening gap between haves and have-nots, and view retainer care as one more excess for the wealthy in an age of increasing medical scarcity.[6]

To be sure, there are some irreconcilable ideological differences between the two camps. Retainer care physicians welcome a commodified tiering of primary care that their opponents only grudgingly accept. Yet differences also arise because the opposing sides have not adequately acknowledged the *diversity* of retainer care services. Retainer contracts cover three analytically distinct actions: preventive care, queue-jumping, and amenity-bundling.[7] Most commendably, retainer care physicians are aggressively counseling their patients on how to avoid getting ill, by developing preventive health plans and monitoring problematic behavior. More questionably, they are trading enhanced access for cash – a clear example of queue-jumping relative to their previous business practices and the standard of primary care prevalent in the United States. Most troublingly, they are bundling medical care with unrelated amenity services (such

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as little as $60 a month to $15,000 a year. The peace of mind that comes with having a doctor available 24/7 is money well spent, several of St. Louis' patients said.").

4. *Consumer-Directed Doctoring: The Doctor Is In, Even if Insurance Is Out: Hearing Before the J. Econ. Comm.*, 108th Cong. (2004) [hereinafter *Consumer-Directed Doctoring*]. Both Congress and the Department of Health and Human Services (HHS) have expressed concern about the access issues raised by these practices, and some affected states have responded with investigations and regulation. A recent statute requires the Government Accountability Office (GAO) to study the spread of retainer care and to hold hearings on the topic, spurring interest on the topic at HHS. 42 U.S.C.A. § 1395cc, *supra* note 1; GAO REPORT, *supra* note 1.

5. *See, e.g.*, John Carroll, *Concierge Care by Any Name Raises Ethical Concerns*, MANAGED CARE MAG., Nov. 2003, *available at* http://www.managedcaremag.com/archives/0311/0311.concierge.html; Sidney M. Wolfe, *A New Health Care Gimmick: Concierge Medicine*, HEALTH LETTER, Oct. 2003, at 1, *available at* http://www.citizen.org/documents/hl_oct2003.pdf.

6. Jennifer Russano, *Is Boutique Medicine a New Threat to American Health Care or a Logical Way of Revitalizing the Doctor-Patient Relationship?*, 17 WASH. U. J.L. & POL'Y 313, 329 (2005) ("A huge gap in health care already exists between the wealthy and the poor. Accordingly, many opponents of boutique medicine argue that its 'effect on access' to care – access that is already so disjointed – is the main problem. If a large number of doctors begin charging retainer fees to access their care, access to health care will become a problem. In effect, boutique care will begin to widen the existing gap in the United States health care system, polarizing the wealthy from everyone else."). *See also id.* at 322-23 (describing how practices differ in their willingness to accept Medicare to defray the costs of treatment).

7. *See infra* Section III.A.

as lavish waiting rooms and comfort for the "worried well") in order to avoid legal and regulatory bars on "balance billing" and multiple standards of care.

Each of these "faces" of retainer care deserves a different legal response. Nearly all serious health policy analysts agree that preventive care is underfunded in the United States.[8] To the extent retainer care physicians are closing that gap, they ought to be encouraged. However, retainer care marketing of "queue jumping" – the ability to see one's doctor far more quickly, and for far longer, than the norm – requires state and federal oversight for a number of reasons. Tiering in the health insurance market has already eroded the primary "end" of health insurance: subsidizing the unhealthy, unlucky, and sick with funds from the healthy, lucky, and well.[9] Retainer care threatens to accelerate that process, promoting "exit" from a managed care system where "voice" is ever more necessary.[10]

Medicare policymakers realized the dangers of such a dynamic long ago when they proscribed "balance billing," a practice that allowed doctors to charge

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8. Rebecca J. Cook, *Antiprogestin Drugs: Medical and Legal Issues*, 42 MERCER L. REV. 971, 983 (1991) ("For historic reasons, reinforced by modern jurisprudence, the federal government and state legislatures have resisted funding many health services, including preventive care.").

9. John V. Jacobi, *The Ends of Health Insurance*, 30 U.C. DAVIS L. REV. 311, 315 (1997) ("The origins of health insurance in both the United States and Europe involved pooling funds and sharing risk."); Andrew Stark, *In Sickness and in Health: Health Insurance in America*, DISSENT MAG., Fall 2005, at 47, 47 ("When it comes to private insurance, apparently, Democrats would have the rich subsidize the sick; Republicans seem largely content to have the healthy subsidize the poor.").

10. Albert O. Hirschman categorized responses to crises as either "exit" or "voice":

> [S]ocial actors who experience developing disorder have available to them two activist reactions and perhaps remedies: exit, or withdrawal from a relationship that one has built up as a buyer of merchandise or as a member of an organization such as a firm, a family, a political party, or a state; and voice, or the attempt at repairing and perhaps improving the relationship through an effort at communicating one's complaints, grievances, and proposals for improvement.

ALBERT O. HIRSCHMAN, RIVAL VIEWS OF MARKET SOCIETY 77 (1986). The dichotomy between exit/voice and economics/politics is similar to that of system/lifeworld in Habermas's work; systems coordinate social action "behind the backs" of actors, while "social integration" requires a common lifeworld to ground discussions about a commonly understood course of action. JÜRGEN HABERMAS, 2 THE THEORY OF COMMUNICATIVE ACTION (Thomas McCarthy trans., 1984). Hirschman characterizes exit and voice as complementary "ingredients of democratic freedom" necessary for effective consumption and citizenship. HIRSCHMAN, *supra*, at 79. In the context of health care, those who are buying their way out of a failing managed care system are "exiting"; this Article tries to show the ways in which their "voices" within the current system might be more socially beneficial than the exit strategy.

patients themselves for parts of bills that Medicare did not cover.[11] Both Medicare and private insurers should enforce balance billing rules against retainer care physicians in order to prevent insurance programs from subsidizing further fragmentation of the risk pool.[12]

Finally, retainer care physicians' bundling of medical services with unnecessary amenities presents a troubling dynamic already reflected in the growing demand for cosmetic physical and mental enhancements. Some states have begun taxing or otherwise discouraging these diversions of medical personnel.[13] They should consider similar efforts to discourage retainer care physicians' efforts to bundle the sale of medical care with unnecessary amenities, a practice driven more by marketing efforts and legal concerns than actual medical care.

This Article bases these policy prescriptions on an analysis of current retainer care practices and regulation, in Parts I and II, respectively. Part III suggests a resolution of the leading current legal controversy over retainer care, the applicability of Medicare balance billing rules to retainer payments. Part IV addresses retainer care physicians' complaints about current and proposed regulation, developing a normative framework for further interventions proposed in Part V. Although states have taken some promising steps toward mitigating the worst aspects of retainer care conversions, taxation may be the only policy tool sufficiently targeted to reduce incentives for queue-jumping and amenity-bundling while promoting innovation in and diffusion of preventive care.

I. THE RISE OF RETAINER CARE

Retainer practices did not arise in a vacuum. A variety of pressures on providers and consumers of medical care have led to demand for more intense and personal primary care. The development of cost-containment measures has left many physicians complaining of a lack of autonomy.[14] Patients have

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11. David C. Colby et al., *Balance Billing Under Medicare: Protecting Beneficiaries and Preserving Physician Participation*, 20 J. HEALTH POL. POL'Y & L. 49, 51 (1995) ("Recognizing that many of the poor could not afford to pay medical bills, the original Medicare and Medicaid legislation prohibited physicians from balance billing those Medicare beneficiaries who were also eligible to receive Medicaid benefits.").

12. Jennifer Silverman, *Legal Expert Highlights Potential Risks of Concierge Care*, INTERNAL MED. NEWS, Sept. 1, 2005, at 6 ("Although Medicare is usually the 800-pound gorilla in these situations, it's private insurers that currently pose the biggest risks to these practices.").

13. Minnesota legislators are currently attempting to pass a bill that would extend the sales tax to certain cosmetic procedures. *See* H.F. 2603, 84th Leg. Sess. (Minn. 2006).

14. *See, e.g.*, JAMES WOOD, ROBERT WOOD JOHNSON FOUND., HOW SATISFIED ARE PHYSICIANS AND PATIENTS WHEN MEDICAL GROUPS CONTROL ACCESS TO CARE? (1997),

complained about five-minute office visits, officious staff, interminable waits,[15] and a general lack of concern about their welfare.[16] Even if these concerns lack empirical foundation, *consumer perceptions* of a decline in the availability and quality of primary care have sparked a great deal of anxiety.[17] Retainer care options address this need by providing "Marcus Welby" style medical care to their patients.[18]

Section I.A below describes the background trends in the health care system that have given rise to retainer care, including time pressures on physicians, consumers' demand for more services, and insurers' efforts to placate both groups by offering more à la carte and tiered coverage options. Physician and patient dissatisfaction with the strictures of managed care has led to many important trends in health care financing, including increased tiering and consumer choice in health plans. Section I.B explains how retainer care works, focusing on the ways in which retainer physicians intensify tiering and consumer choice trends.

A. Background Trends: Resistance to Managed Care

After an extraordinary increase in health care spending in the 1960s and 1970s,[19] managed care arose in the 1980s in response to payors' worries over

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http://www.rwjf.org/reports/grr/023332s.htm ("Primary care physicians are significantly less satisfied with the quality of care they are able to deliver to patients covered by capitated contracts than those covered by other payment sources.").

15. Gina Kolata, *Sick and Scared, and Waiting, Waiting, Waiting*, N.Y TIMES, Aug. 20, 2005, at A1 (describing waits to see doctors once in the doctor's office and for follow-up visits).

16. Josh Fischman, *Who Will Take Care of You?*, U.S. NEWS & WORLD REP., Jan. 31, 2005, at 46 ("Research has shown that a good conversation that thoroughly explores problems and possible treatments means better health . . . . [The] relationship [between physician and patient] has clearly been shown to affect diagnostic accuracy, adherence to treatment plans, and patient satisfaction.").

17. Some commentators have suggested that this is merely a matter of perception. *See* Joseph Gottfried & Frank A. Sloan, *The Quality of Managed Care*, 65 L. & CONTEMP. PROBS. 103, 136-37 (2002) ("The empirical evidence from the medical literature does not support the allegations of unsafe practices made against [managed care organizations (MCOs)] by proponents of patient protection legislation. This finding holds despite data suggesting that generalists, who occupy a privileged position as gatekeepers in many MCOs, are less proficient than specialists in the latter's areas of expertise, because such a fact does not appear to translate into worse specialty care for patients in managed care plans.").

18. *See* Internet Movie Database Inc., Plot Summary for "Marcus Welby, M.D.," http://imdb.com/title/tt0063927/plotsummary (last visited Dec. 10, 2006) ("The show is about doctors Marcus Welby, a general practitioner and Steven Kiley, Welby's young assistant. The two try to treat people as individuals in an age of specialized medicine and uncaring doctors.").

19. DAVID DRANOVE, THE ECONOMIC EVOLUTION OF AMERICAN HEALTH CARE 34 (2000) ("At

increasing costs.[20] Insurance plans controlled by doctors and hospitals had few incentives to limit medical care or its attendant costs.[21] Managed care plans promised to reduce waste by leveraging the bargaining power of plan members in negotiations with service providers to drive down the costs of services and to disapprove treatment options with doubtful benefits.[22]

Of course, it is a rare medical procedure that offers *no* benefit.[23] Disputes have arisen, provoking resistance to managed care cost-cutting from physicians (who resent the diminution of their autonomy) and state legislatures (which have begun to force disclosure of physician financial incentives and to require coverage of certain care).[24] Despite this resistance, capitation systems[25] and other pressures to contain costs have already pervasively influenced physicians' interactions with patients.[26] Many primary care physicians must see at least

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the start of the 1990s, before MCOs took over, private sector health spending was rising by more than 10 percent annually, and many experts predicted that health care would account for 20 percent of the GDP by the year 2000 . . . . Thanks to MCO's . . . total spending on health care remains below 14 percent of GDP.").

20. Alain C. Enthoven, *The History and Principles of Managed Competition*, 12 HEALTH AFF. 24, 26 (1993) (describing the economic consequences of a traditional fee-for-service health care system); Clark C. Havighurst, *The Backlash Against Managed Health Care: Hard Politics Make Bad Policy*, 34 IND. L. REV. 395, 400 (2001).

21. Thomas H. Greaney, *Managed Care: From Hero to Goat*, 47 ST. LOUIS U. L.J. 217, 217 (2003) ("At the outset of the [1990's], most observers heralded managed care as the solution to spiraling costs and a guarantor of quality.").

22. Havighurst, *supra* note 20, at 401.

23. The classic health care economics term for this is "flat of the curve" care, which increases expenses but offers virtually no hope of improving outcomes. For such a curve, the *X*-axis measures spending, and the *Y*-axis measures some health outcome, such as Quality-Adjusted Life-Years. *See, e.g.*, ALAIN C. ENTHOVEN, HEALTH PLAN: THE ONLY PRACTICAL SOLUTION TO THE SOARING COST OF MEDICAL CARE 6 (1980).

24. *See* DRANOVE, *supra* note 19, at 62 (objecting to these laws as technology-insensitive and speculating about the technological advances that would have been deterred had "'drive-through' appendectomies and hernia surgery" been outlawed twenty years ago); David A. Hyman, *Regulating Managed Care: What's Wrong with a Patient Bill of Rights?*, 73 S. CAL. L. REV. 221, 247 (2000) (listing examples, such as "drive-through delivery" legislation); Peter Jacobson, *Who Killed Managed Care? A Policy Whodunit*, 47 ST. LOUIS U. L.J. 365 (2003).

25. *See* Stephen Moss, Purchasing Managed Care Services for Alcohol and Other Drug Treatment, 16 Technical Assistance Publications ch. 4 (2002), http://tie.samhsa.gov/TAPS/TAP16/Tap16chap4.html ("Capitation is a method of reimbursement in which a fixed sum of money is paid per enrollee by the purchaser to the provider. This sum of money is expected to cover specified services for every enrollee for a defined period of time."). *See also* MARK A. HALL ET AL., THE LAW OF HEALTH CARE FINANCE AND REGULATION 314-30 (2005) (discussing capitation payment plans).

26. *See* Markian Hawryluk, *Boutique Medicine May Run Afoul of Medicare Rules*, AM. MED.

twenty-five to thirty patients a day[27] in order to clear between $100,000 and $300,000 per year in pre-tax income.[28] Some claim that, in response to many health plans' per-patient payment methodology, doctors are beginning to shun the sickest patients, who take up more of a doctor's time than healthier patients. If a doctor fails to follow this strategy, scheduling may leave her with little more than fifteen minutes per patient visit, regardless of the severity of the problem complained of or the complexity of the patient's health history.

Both empirical evidence and anecdotal accounts suggest that primary care physicians are not happy with these developments.[29] Many consider the strictures of managed care practice at best an inconvenience and, at worst, a reason for leaving the practice of medicine altogether.[30]

Given massive deficits and federal budget cutting, public funding of medical care is likely to become even more "managed" than private insurers' plans. Physicians are frustrated by concomitant government-imposed cost constraints – and since federal and state governments account for at least forty percent of health care spending in the United States,[31] these strictures are becoming

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NEWS, Apr. 8, 2002; William Hoffman, *Fed Up, Some Doctors Turn To 'Boutique Medicine'*, AM. C. PHYSICIANS - AM. SOC'Y INTERNAL MED. OBSERVER, Oct. 2001, *available at* http://www.acponline.org/journals/news/pastobis.htm (click on link for Oct. 2001 issue); Cheryl Jackson, *Premium Practice: When Patients Pay Top Dollar for Exclusive Care*, AM. MED. NEWS, Sept. 17, 2001, *available at* http://www.ama-assn.org/amednews/2001/09/17/bisa0917.htm. *See also Boutique Medicine: Elitist or Egalitarian?*, PHYSICIAN'S WKLY., June 10, 2002, at 10 ("Primary care physicians average between 20 and 30 patient visits each day. But the average number of 'patient contracts,' adding in phone calls and 'paper shuffles,' is over 110. In the last ten years, physician income has declined while the workload has increased.").

27. Katherine Hobson, *Doctors Vanish From View*, U.S. NEWS & WORLD REP., Jan. 31, 2005, at 50. The average primary care physician sees twenty-five people a day. Economic pressure on physicians results from a number of factors, including reduced reimbursement rates, increased overhead costs, and higher premiums for liability insurance.

28. *See* Atul Gawande, *Piecework: Medicine's Money Problem*, NEW YORKER, Apr. 4, 2005, at 44 ("In 2003, the median income for primary-care physicians was $156,902. For general surgeons . . . it was $264,375 . . . .").

29. ROBERT CRUM, ROBERT WOOD JOHNSON FOUND., TIME PRESSURES LEAVE DOCTORS DISSATISFIED (2002), *available at* http://www.rwjf.org/reports/grr/027069.htm; Brian Vastag, *Physician Dissatisfaction Growing*, 286 JAMA 781 (2001) ("If Massachusetts mirrors the nation, physicians' job satisfaction has taken a hit in the past 15 years, according to a study sponsored by the Agency for Healthcare Research and Quality in conjunction with the Robert Wood Johnson Foundation.").

30. AM. ACAD. OF FAMILY PHYSICIANS, 2006 NATIONAL RESIDENT MATCHING PROGRAM, graph 5 (2006), *available at* http://www.aafp.org/match/graph05.html (documenting entry into and exit out of the field).

31. Thomas Bodenheimer & Kevin Grumbach, *Paying for Health Care*, 272 JAMA 634, 638

increasingly important.

Individuals reliant on public health insurance programs, such as Medicaid and Medicare, have had even more cause for concern. Objecting to low reimbursement rates, some doctors refuse to treat Medicaid and even Medicare patients.[32] Each program can be complex and intimidating to beneficiaries. As Medicaid costs continue to rise, federal and state budget cuts are leaving many vulnerable citizens outside the health care system altogether.[33] Auditors eager to penalize over-billing, fraud, and abuse of the system increasingly scrutinize the expenditures of both Medicare and Medicaid.[34] Though necessary, fraud and abuse law has grown so complex that it is becoming a trap for the unwary.[35] These laws may chill not only fraud, but also aggressive care that risks being deemed excessive or abusive in the current legal climate.[36]

Meanwhile, patients are demanding more care and fewer restrictions on their choice of procedures and providers. Although managed care plans have begun to meet this demand by offering subscribers Preferred Provider Options (PPO) plans and other more flexible options, survey evidence reveals dissatisfaction with the health care system as a whole:

> In a nationwide survey of more than 2,000 adults published [in Fall 2004], 55 percent of those surveyed said they were dissatisfied with the quality of health care, up from 44 percent in 2000; and 40 percent said the quality of care had gotten worse in the last five years.[37]

(1994).

32. *See* William Buczko, *Provider Opt-Out Under Medicare Private Contracting*, HEALTH CARE FIN. REV., Winter 2004-05, at 43, 47-49.

33. John Jacobi, *Dangerous Times for Medicaid*, (Seton Hall Pub. L. Research Paper No. 45, 2005), *available at* http://ssrn.com/abstract=845084 (arguing that many Medicaid reforms proposed in 2005 would lessen our commitment to care for the poor and disabled, in some cases pushing vulnerable people out of public coverage).

34. *See, e.g.*, ALICE G. GOSFIELD, MEDICARE AND MEDICAID FRAUD AND ABUSE (2005).

35. James F. Blumstein, *The Fraud and Abuse Statute in an Evolving Health Care Marketplace: Life in the Health Care Speakeasy*, 22 AM. J.L. & MED. 205 (1996) (arguing that the vagueness and breadth of these statutes grant enormous prosecutorial discretion, which is subject to abuse).

36. *See* Jeremy Fine Bollinger, *Doctoring Fraud & Abuse: Enforcement of Stark and the Anti-Kickback Law in Physician Recruitment May Be Bad for Your Health*, 38 LOY. L.A. L. REV. 485, 505-08 (2004) (discussing perverse incentives created by Medicare fraud and abuse laws).

37. Benedict Carey, *In the Hospital, a Degrading Shift from Person to Patient*, N.Y. TIMES, Aug. 16, 2005, at A1. The survey discussed was conducted by Harvard University, the federal Agency for Healthcare Research and Quality, and the Kaiser Family Foundation, an independent nonprofit health care research group.

Patients have even begun to question the utility of hard-won gains in autonomy, such as increased ability to choose treatment options.[38] Opaque and even perverse rationing mechanisms for care, ranging from vaccinations to hospitalization, have raised resentment and concern.[39]

Pressure from payors for cost containment has also riled patients. Worried by increasingly harried or unresponsive doctors, they are demanding change. Insurance plans are now responding to some of these demands. Wary of constantly being cast as the heavy in the drama of health care cost containment, managed care organizations have begun incentivizing cost consciousness instead of imposing strict command and control-style restrictions on coverage.[40] Cost-sharing, PPOs, and other strategies have emerged in order to widen the scope of treatments and personnel available to those who are insured.

Of course, these new options have a price, and they are only available to those who pay for them.[41] Insurers are "tiering" their offerings, providing consumers with more control over the range of services they can demand and the depth of coverage they desire. One of the most important ways of financing new coverage options for consumers is "segmentation of services through financial

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38. *See, e.g.*, BARRY SCHWARTZ, THE PARADOX OF CHOICE: WHY MORE IS LESS 32-33 (2004) ("When it comes to medical treatment, patients see choice as both a blessing and a burden . . . . [T]he prospect of a medical decision has become everyone's worst nightmare of a term paper assignment, with stakes infinitely higher than a grade in a course."); Jan Hoffman, *Awash in Information, Patients Face a Lonely, Uncertain Road*, N.Y. TIMES, Aug. 14, 2005, at A1 ("Dr. Russo, . . . [a] West Orange, N.J., internist who sees 5,000 patients a year, applauds patients who do their homework. But, he noted, especially when patients are researching treatment options, they flop down in his office, feeling inundated.").

39. *See, e.g.*, Mark V. Pauly, *Improving Vaccine Supply and Development: Who Needs What?*, 24 HEALTH AFF. 680 (2005) (describing federal government's repeated recent failures to properly stock and distribute vaccines); Carey, *supra* note 37 (noting rising levels of patient dissatisfaction with hospital visits and unclear admittance criteria). Opaque rationing criteria tend to raise anxieties and opposition to public health measures as they defeat the transparency usually considered a *sine qua non* of legitimate distributive schemes.

40. *See* Henry T. Greely, *Direct Financial Incentives in Managed Care: Unanswered Questions*, 6 HEALTH MATRIX 53 (1996); Mark A. Hall, *Institutional Control of Physician Behavior: Legal Barriers to Health Care Cost Containment*, 137 U. PA. L. REV. 431, 480-504 (1988) [hereinafter Hall, *Institutional Control*]; Mark A. Hall, *Rationing Health Care at the Bedside*, 69 N.Y.U. L. REV. 693, 772-76 (1994); Andrea K. Marsh, *Sacrificing Patients For Profits: Physician Incentives To Limit Care and ERISA Fiduciary Duty*, 77 WASH. U. L.Q. 1323, 1327-34 (1999); David Orentlicher, *Paying Physicians More To Do Less: Financial Incentives To Limit Care*, 30 U. RICH. L. REV. 155, 158-60 (1996).

41. For discussion of a number of articles discussing the cost of these options, see generally *Special Issue: The Managed Care Backlash*, 24 J. HEALTH POL. POL'Y & L. 873 (1999).

incentives."[42] In exchange for greater choice, consumers bear more financial risk in two complementary ways: "[H]orizontal segmentation, in which consumers are induced to choose the richness of coverage based on variable employee cost share, and vertical segmentation, in which consumers within plans are induced to choose providers based on variable employee cost share."[43] Each type of segmentation is designed to encourage cost-consciousness among "consumers" of health care, while opening up new vistas of care options for those able to pay for them. Insured persons act as partners with the plan in calibrating more precise trade-offs of cost and quality.[44]

This growing trend toward "consumer choice" in health care raises the stakes of retainer care regulation.[45] To the extent retainer practices avoid serious regulatory scrutiny, they will likely encourage innovators who want to make health insurance more a defined contribution than a defined benefit system.[46] So far, consumer driven health plans, health savings accounts (HSAs), and cash-only practices have not become widespread.[47] However, congressional and wonkish

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42. John V. Jacobi, *After Managed Care: Gray Boxes, Tiers and Consumerism*, 47 ST. LOUIS U. L.J. 397, 402 (2003) (citing James C. Robinson, *Renewed Emphasis on Consumer Cost Sharing in Health Insurance Benefit Design*, HEALTH AFF. – WEB EXCLUSIVE, Mar. 20, 2002, at W139, W140, http://content.healthaffairs.org/cgi/reprint/hlthaff.w2.139v1.

43. Jacobi, *supra* note 42, at 403.

44. *Id.* ("As the rate of differential and the number of tiers increases, co-payments and co-insurance seem less a gentle nudge to conform to the plan's network design than a mechanism to pass through discounts arranged between the plan and providers.").

45. REGINA E. HERZLINGER, CONSUMER-DRIVEN HEALTH CARE: IMPLICATIONS FOR PROVIDERS, PAYERS, AND POLICY-MAKERS 3-23 (2004) (documenting trend toward consumer choice in health care).

46. A defined benefit pension plan promises a certain level of payments to its members upon its retirement. A defined contribution plan permits members to contribute to various investment plans, and upon retirement the member can draw down these funds. By analogy, a defined benefit health plan specifies a series of services covered (whatever the cost). A defined contribution plan, such as a health savings account, would permit members to contribute to savings accounts (which are usually treated favorably via the tax system) and to then draw them down for medical bills. The Florida Medicaid program has reportedly decided to gradually switch from a defined benefit to a defined contribution model. *See* Robert Pear, *U.S. Gives Florida a Sweeping Right To Curb Medicaid*, N.Y. TIMES, Oct. 20, 2005, at A1. The program contributes a set amount to a managed care program for the recipient, which is then responsible for all covered services to the recipient. The cost reduction is supposed to come from the insurer's freedom to make economical decisions on how to deliver the best care; they have a lot less oversight than the state does.

47. HSAs, usually paired with high-deductible health insurance plans, have been promoted by the current administration and in the Medicare Prescription Drug, Improvement, and Modernization Act of 2003 as a way of encouraging health care consumers to take more responsibility for their medical costs. *See* Medicare Modernization and Prescription Drug Act, Pub. L. 108–173, tit. XII,

enthusiasm for these plans remains high, as evidenced by recent incentives for HSAs embedded in the Medicare Modernization and Prescription Drug Act of 2003.[48] Whether by design or incidentally, health savings accounts will be a great boon to the development of cash-only practices that evade managed care strictures.[49] All of these developments create fertile ground for entrepreneurs seeking compensation for levels of care they deem necessary or desirable for patients.

B. Physician and Patient Experiences with Retainer Care

The trends toward tiered insurance plans and cash-only practices converge in retainer care, which offers patients the chance to contract directly with physicians for services not covered by insurance plans.[50] The services are diverse; they range from "same or next-day appointments" to "private waiting rooms."[51] The fees for

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117 Stat. 2469 (2003) (codified as amended in scattered sections of 26 U.S.C.). Employees can contribute a fixed amount each month to the HSA, then use these funds to cover medical bills. Despite government policy designed to encourage them, HSAs have not yet been particularly popular. *See, e.g.*, Anne Belli, *Health Accounts Slow To Catch on with Employers*, HOUSTON CHRON., Feb. 12, 2006, at B1 ("Employers are 'dabbling, they're all looking' at HSAs . . . . '[b]ut the jury is still out.' Brett Haugh, a principal at Houston-based Employee Benefit Solutions, noted that in a local employer survey conducted by the consulting firm last year, only 8 of the 137 respondents said they were offering their workers health savings accounts. In Houston, interest in HSAs is beginning to emerge, but is still very small, Haugh said. 'Employees just don't gravitate toward HSA plans.'"). *But see* AM. MED. ASS'N COUNCIL ON MED. SERV., UPDATE ON HSAS, HRAS, AND OTHER CONSUMER-DRIVEN HEALTH CARE PLANS (2005), *available at* http://www.ama-assn.org/ama1/pub/upload/mm/372/i-05cmsreport3.pdf [hereinafter AMA CMS REPORT] (suggesting increasing interest in HSAs).

48. Medicare Prescription Drug, Improvement, and Modernization Act of 2003 § 1201.

49. Rhonda L. Rundle, *Pay-as-you-go M.D.: The Doctor Is In, but Insurance Is Out*, WALL ST. J., Nov. 6, 2003, at A1 (describing the advantages of cash-only practices).

50. Retainer care, concierge medicine, and boutique medicine all designate the same phenomenon. When it mandated a study on the topic in 2003, Congress defined retainer care as:

> an arrangement under which, as a prerequisite for the provision of a health care item or service to an individual, a physician, practitioner, or other individual –
>
> (A) charges a membership fee or another incidental fee to an individual desiring to receive the health care item or service from such physician, practitioner, or other individual; or
>
> (B) requires the individual desiring to receive the health care item or service from such physician, practitioner, or other individual to purchase an item or service.

42 U.S.C.A. 1395cc (West 2006). Jennifer Russano provides a good narrative account of various retainer-financed practices. *See* Russano, *supra* note 6, at 321-27.

51. GAO REPORT, *supra* note 1, at 15. The GAO concedes that this survey is not necessarily

retainer care also vary widely, depending on the reputation of the doctors involved and the level of care received. A "top-of-the-line" practice, which accepts no insurance payments, may cost up to $15,000 per patient per year; more modest services may only cost several hundred dollars annually.[52]

Though a small "cash-only" movement has been opting out of the managed care system since its inception, retainer care only emerged in the mid-1990s in Seattle.[53] Since then, it has spread to many, mostly urban, areas.[54] Though "top-of-the-line" retainer practices offer extraordinary amenities, they also tend not to take insurance or to require clients to file their own insurance claims.[55] However, the majority of retainer practices depend on both retainer payments and insurance reimbursement.[56] They market more modest services: preventive care, comprehensive physicals, helpful staff and coordination of care, and guaranteed attention from a dedicated physician within twenty-four hours of a request for care.[57]

The divergence between high- and low-end practices is a difference not only of degree, but also, at least for the law, of kind. By opting out of the insurance system altogether, the high-end practices are purchasing a great deal of

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representative; however, over half the sample responded. *See also* Abigail Zuger, *Before You Buy, Determine What You're Paying For*, N.Y. TIMES, Oct. 30, 2005, at 26.

52. Of the practices surveyed by the GAO, "the amount of the concierge care membership fee ranged from $60 to $15,000 a year for an individual, with about half of respondents charging individual annual membership fees of $1,500 to $1,999." GAO REPORT, *supra* note 1, at 4. Note that the fees follow a classic bell-curve distribution, rather than a bimodal distribution that would be expected if practices were concentrated as high and low-end types. *Id.* at 13.

53. *Id.* at 5 ("The origins of this practice approach are often traced to a medical practice founded in Seattle, Washington, in 1996."). *See also* Gregory M. Lamb, *Gold-Card Health Care: Is It Boon Or Bane?*, CHRISTIAN SCI. MONITOR, May 17, 2004, at 12 (quoting Dr. John Blanchard, president and cofounder of the American Society of Concierge physicians, as stating: "The current model of healthcare delivery, particularly in the primary-care setting, is dysfunctional, to say the least. You're shuttled through offices like cattle. This is not the way healthcare was designed. The quality of healthcare is based largely on the integrity of the patient-physician relationship – and that relationship breaks down in a high-volume healthcare setting.")

54. *See* GAO REPORT, *supra* note 1, at 10, fig. 1 (providing geographical depiction of retainer care prevalence).

55. *See* G. Caleb Alexander et al., *Physicians in Retainer ("Concierge") Practice: A National Survey of Physician, Patient, and Practice Characteristics*, 20 J. GEN. INTERNAL MED. 1079, 1082 (2005) [hereinafter *National Survey*].

56. *See, e.g.*, Concierge Family Medicine, http://www.conciergefamilymedicine.com (last visited Dec. 10, 2006) (indicating that conventional health insurance is still recommended by cash-only practices in order to cover out-of office expenses such as hospitalization, emergency-room visits, and diagnostic tests).

57. "Dedicated" in the sense of "your personal physician," not merely "loyal" or "devoted."

autonomy. However, they also run the risk of being classified as insurers themselves, which would subject them to the whole gamut of state regulation that such classification entails.[58] Lower-end practices can avoid that risk by focusing on insured patients. However, they risk running afoul of Medicare regulations prohibiting balance billing or false claims, or of insurance contracts that condition reimbursements on similar strictures.[59] Part IV below deals with these concerns in more detail.

Retainer care has provoked controversy in part because of the abrupt transition many practices have made to it. Steven Flier's story is typical.[60] Disgruntled by time pressure, falling reimbursement rates, and insurers' interference with treatment options, Dr. Flier and his partners transitioned their practice into Personal Physicians HealthCare in 2000. They cut their number of patients by two-thirds or more, each offering a very high level of primary and preventive care to the first three hundred patients willing to pay a $4000 annual fee. Patients unable to pay the retainer fee were left to find another physician. A similar dynamic has played out in many cities.

The American Medical Association (AMA) has closely followed the retainer care trend and guardedly endorsed physicians' right to convert to retainer practices.[61] The AMA conducted a survey of both retainer- and non-retainer-funded physicians in order to better understand the practice's appeal to some of

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58. *See* Carol M. Ostrom, *'Concierge Physicians' Medical Model Growing*, SEATTLE TIMES, May 28, 2004, at B1; discussion *infra* Section V.A.

59. *See, e.g.*, Mass. Med. Soc'y v. Dukakis, 815 F.2d 790 (1st Cir. 1987) (holding Medicare's "reasonable charge" requirements constitutional).

60. Liz Kowalczyk, *For $4,000, Doctor's Devotion – 2 Boston Internists to Offer More Access*, BOSTON GLOBE, Dec. 13, 2001, at A1 ("With doctors under pressure to see more patients in less time, Dr. Steven Flier and Dr. Jordan Busch want to provide a more personal sort of medical care: long appointments on the same day patients call. Access to the doctors on their cellphones at any hour. And, when a patient needs to see a specialist, they want to go along and interpret. So the two Boston internists have decided to open a medical practice that offers all of these extras - for an annual fee of $4,000 per patient. Reacting against a managed health care system that increasingly stresses volume, Flier and Busch will bring a controversial new brand of medicine to Boston. The two doctors plan to quit their practices with Beth Israel Deaconess Medical Center and open Personal Physicians HealthCare, which will charge individuals $4,000 and families $7,500 a year for amenities and access provided on top of regular medical care. They will reduce their normal patient loads from several thousand to 300 each in order to spend more time with patients. Those who can't afford the fee – or aren't among the first 300 to sign up – must find new physicians.").

61. The CMS report is more positive than the CEJA report, but neither condemns retainer care. *Compare* COUNCIL ON ETHICAL AND JUDICIAL AFFAIRS, RETAINER PRACTICES (2003), *available at* http://www.ama-assn.org/ama1/pub/upload/mm/369/ceja_3a03.pdf [hereinafter CEJA REPORT], *with* F. MAXTON "MAC" MAUNEY, COUNCIL ON MED. SERV., SPECIAL PHYSICIAN-PATIENT CONTRACTS (2002), *available at* http://www.ama-assn.org/ama1/pub/upload/mm/372/cms902.doc.

its members.[62] According to this survey, "50% of the retainer physicians said they thought they were offering more diagnostic and therapeutic services than traditional practices," and "70% of retainer physicians said they were doing better [financially] in this type of practice than they had in traditional practice."[63] It is not hard to see why, given the numbers: "Retainer physicians saw an average of 11 patients per day; non-retainer physicians saw an average of 22 patients."[64] As the GAO report notes, these patients' retainer payments in excess of insurance reimbursements average between $1500 and $2000 per year.

The only downsides for doctors mentioned in the AMA survey and GAO report are the disapproval of colleagues[65] and the legal uncertainty surrounding this new method of health care finance.[66] Scholars of law and norms would likely be quick to note the mutually reinforcing character of concerns about morality and legality.[67] Far from operating in separate spheres, perceptions of legality and morality often interrelate and mutually reinforce one another, particularly in the

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62. Jennifer Silverman, *Retainer Practices Reporting Better Care,* FAM. PRAC. NEWS, June 1, 2005, at 71 ("The AMA mailed out surveys to 144 physicians from retainer practices – also known as concierge or boutique medicine practices – and received 83 responses. As a control group, researchers mailed surveys to 463 primary care physicians in nonretainer practices from the AMA's master list, and received 231 responses. Data were collected between December 2003 and February 2004."). As of late 2006, the primary source data had not yet been released; they are "still unpublished and have been in review since January 2005."

63. *Id.* The only apparent downsides were legal worries and reputational concerns. *See id.* at 72 ("When queried about the potential risks of a retainer practice, respondents from both groups expressed concern that society and their peers would disapprove of their decision to start a retainer practice.").

64. *Id.*

65. *See id.* at 74 ("You risk having people 'look down their noses at you,' Dr. Wynia said. In a surprising statistic, '5% of people in retainer practices thought they should be discouraged' from pursuing this approach. Indeed, several participants at the meeting told this newspaper that their employer or practice partners did not know that they were attending a conference on concierge care. More than half of retainer physicians and 80% of nonretainer physicians thought that concierge care created a risk of a more tiered system of access to health care. Loss of patient diversity and insurance contracts and legal challenges were other concerns cited by the survey respondents.").

66. *Id. See also* Steven M. Goldstein, The Legal Risks of Boutique Medicine (July 2003), http://www.sackstierney.com/articles/boutique.htm (emphasizing the legal uncertainty of boutique medicine practices).

67. *See, e.g.*, Kristin Madison, *Government, Signaling, and Social Norms*, 2001 U. ILL. L. REV. 867, 879-80 (reviewing ERIC A. POSNER, LAW AND SOCIAL NORMS (2000)) (discussing how normative order serves as an extralegal mechanism for influencing behavior); Cass R. Sunstein, *Social Norms and Social Roles*, 96 COLUM. L. REV. 903, 944-47 (1996) (describing the contextual basis of judgments on norms).

highly regulated field of health care finance.[68]

For example, the GAO reports repeated pleas from doctors for guidance from the Department of Health and Human Services (HHS) on the legality of their practice, or a list of "safe harbor" practices that will not provoke regulators' scrutiny.[69] These pleas relate not only to the doctors' legal concerns, but also amount to lobbying for a governmental imprimatur on retainer care. Widespread disapproval of retainer practices may rest on the conflation of a legal with a normative definition of good medical practice – i.e., a sense of the "wrongness" of the project may be driven by its perceived lack of legality.[70] If legal concerns are quickly cleared up, normative concerns may diminish, leading retainer care to spread much more quickly.

Neither the GAO nor the AMA surveyed the *patients* of retainer practices.[71] Perhaps their names were unavailable or retainer physicians were unwilling to encourage scrutiny of a delicate new financing arrangement. There are essentially two views of patient experiences. Skeptics charge that these health care consumers are merely buying the appearance of better care, without any objective contribution to their health. Proponents of retainer care tend to view market demand as revelation and proof of the value of the service.[72] There is some empirical evidence for the claim; according to one reporter, "patients buying these higher levels of personal care have been renewing on a better-than-90-percent annual basis in many practices."[73]

Of course, there is some downside: Where do the patients unable or unwilling to afford the retainer care premium go? Hundreds of patients are often

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68. *See* TIMUR KURAN, PRIVATE TRUTHS, PUBLIC LIES: THE SOCIAL CONSEQUENCES OF PREFERENCE FALSIFICATION (1995) (discussing the interrelation of laws and norms and developing a "cascade model" of their interrelation).

69. GAO REPORT, *supra* note 1, at 17-20.

70. Here, again, Sunstein, *supra* note 67, at 944-47, is helpful. As Sunstein notes, the social meaning of an action is driven by context, and by what other similarly situated actors are doing. In a society of generous individuals, actions that appear entirely natural in our society might seem downright avaricious. By contrast, in a society of avaricious individuals, generosity may look like a sign of weakness. If HHS quickly gives its imprimatur to retainer practices, it risks artificially accelerating retainer care conversions by affirming their legitimacy, and thereby setting off a chain reaction of new perceptions of their normality.

71. However, another study did focus on the demographic mix of patients at retainer practices. According to a recent survey, "Retainer physicians . . . reported caring for few patients on Medicaid compared to non-retainer physicians . . . . [and] minority patients were also under-represented in most of these practices." *National Survey*, *supra* note 55, at 1081.

72. *See Shop Talk on Boutique Medicine*, N.Y. NEWSDAY, Jan. 1, 2005, at B2.

73. Allen, *supra* note 1, at 20.

dropped by a practice in its transition to the retainer model.[74] Both the AMA and the GAO report that nearly all of these individuals are "absorbed into nearby practices," particularly because retainer care is now only prevalent in urban areas where there are plenty of doctors.[75] Despite these assurances, concerns about access to care and public insurance budgets have led to increasing regulatory and journalistic scrutiny of retainer practices.

II. CONTROVERSY OVER FEDERAL REGULATION

State and federal policymakers are slowly beginning to realize the potentially corrosive distributive impact of retainer care.[76] The federal Medicare program is the most important factor here, as it has construed the retainer as a charge to patients beyond the normal rate in at least one case.[77] Sections II.A and II.B below describe extant efforts to regulate retainer care. Federal regulation currently has the perverse incentive of inducing physicians to bundle retainer

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74. Susan H. Thompson, *Doctors Always in for Members of Practice*, TAMPA TRIB., Feb. 16, 2003, at 1 ("When doctors convert their practices, they may cut caseloads, dropping hundreds of patients.").

75. *See* MAUNEY, *supra* note 61, at 2. *See also* GAO REPORT, *supra* note 1, at 14-15.

76. *See, e.g.*, Uwe E. Reinhardt, *Doctors are More Interested in Having Higher Incomes than Providing Better Health Care*, 324 BRIT. MED. J. 1335 (2002); Sandi Doughton, *State Looks Askance at Extra Fees for Doctors*, SEATTLE TIMES, Aug. 12, 2003, at B1; Howard Gleckman, *Want a Doctor Who Treats You Like Royalty?*, BUS. WK. ONLINE, May 6, 2002, http://www.businessweek.com/magazine/content/02_18/b3781606.htm; Carol M. Ostrom, *'Retainer Fees' Spark Warning*, SEATTLE TIMES, Apr. 14, 2004, at B1.

77. *See* OFFICE OF INSPECTOR GEN., OIG ALERTS PHYSICIANS ABOUT ADDED CHARGES FOR COVERED SERVICES (2004), *available at* http://www.oig.hhs.gov/fraud/docs/alertsandbulletins/2004/FA033104AssignViolationI.pdf [hereinafter OIG ALERT] ("[T]he OIG recently alleged that a physician violated his assignment agreement when he presented to his patients – including Medicare beneficiaries – a 'Personal Health Care Medical Care Contract' asking patients to pay an annual fee of $600. While the physician characterized the services to be provided under the contract as 'not covered' by Medicare, the OIG [Office of the Inspector General] alleged that at least some of these contracted services were already covered and reimbursable by Medicare. Among other services offered under this contract were the 'coordination of care with other providers,' 'a comprehensive assessment and plan for optimum health,' and 'extra time' spent on patient care. OIG alleged that based on the specific facts and circumstances of this case, at least some of these contracted services were already covered and reimbursable by Medicare."); Pam Belluck, *Doctors' New Practices Offer Deluxe Service for Deluxe Fee*, N.Y. TIMES, Jan. 15, 2002, at A1 ("Concierge practices say they adhere to the law by ensuring that their fees pay only for services not covered by insurance or Medicare."). *See also* Editorial, *Shop Talk on Boutique Medicine*, N.Y. TIMES, Jan. 17, 2002, at A28 (arguing that doctors should not feel the need to charge more to give high quality care). Critics believe this may be evasion (and not mere avoidance) of balance billing rules.

care with amenities, in order to characterize the retainer as a charge for amenities, rather than a second charge for services covered by Medicare. Unfortunately, the double-billing rules designed to enhance access to medical care in the 1980s are now encouraging tiering in the service of their evasion.

A. An Ambiguous Federal Stance

Some members of Congress have claimed that retainer billing practices are crude evasions of balance billing rules.[78] According to these legislators and some consumer advocates,[79] retainer practices violate the balance billing rules by effectively getting paid twice for the same service.[80] The basic contention here is that Medicare beneficiaries with retainer plans are not only being charged the normal fee for services (which is basically limited, and paid for, by Medicare), but are also being charged whatever fraction of their annual retainer care fees that can be reasonably allocated to the service. For example, consider a hypothetical retainer patient with Medicare who visits her physician five times a year and pays a retainer fee of $3000 annually. If Medicare sets a $200 reimbursement limit, which the physician collects, it appears that the patient is not simply being billed for that $200, but also for $400 additionally for each visit (with an amount of the retainer proportionally applied to each visit).[81]

Conditions on Medicare funding provide important leverage for the federal

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78. Letter from Representative Henry Waxman to Tommy Thompson, Sec'y of Health and Human Servs. (Mar. 4, 2002) (on file with author) [hereinafter Waxman Letter] ("In 1989, as part of the Omnibus Budget Reconciliation Act (OBRA), Congress legislated that '[n]o person may bill or collect an actual charge for the [Medicare] service in excess of the limiting charge.' This 'limiting charge' now stands at 115% of the Medicare rate. By conditioning the receipt of all Medicare services on an annual fee, however, 'exclusive' physician practices seem to violate this law.").

79. *See* Anthony J. Linz et al., *Impact of Concierge Care on Healthcare and Clinical Practice*, 105 J. AM. OSTEOPATHIC ASS'N 515, 517 (2005) ("Medical ethicists and consumer advocates have voiced ethical concerns regarding the creation of a two-class system of medicine based on willingness and ability to pay."); Rachel Brand, *'Concierge' Docs Cater to Service-Minded Patients; Membership Fees Raise Questions Among Regulators*, ROCKY MTN. NEWS, Sept. 11, 2004, at 1C ("Some states prohibit 'balance billing,' where patients must pay the difference between what an insurer pays and the doctor charges. The Office of Inspector General warned in a March letter that concierge medicine may constitute just that for Medicare patients."); Wolfe, *supra* note 5.

80. Brand, *supra* note 79.

81. Paul Ginsburg, President of the Center for Studying Health System Change, has claimed that this strategy is "the equivalent of an end run around Medicare rules." *See* Michael Romano & Laura B. Benko, *These Doctors and Their Affluent Patients Find Themselves in Exclusive Company*, MOD. HEALTHCARE, Oct. 22, 2001, at 38.

government to influence the American health care system.[82] Participating providers must follow a complex set of rules for reimbursement.[83] Over seventy percent of retainer care physicians contacted by the GAO participate in Medicare, so the program provides some leverage over the development of retainer care. Medicare regulation may also provide a model for large private insurers to assure that they are not subsidizing the tiering of the health care system.[84]

Though HHS officials were initially skeptical of critics of retainer care, they have since issued some warnings to providers about potential violations of the law.[85] The Center for Medicare and Medicaid Services ("CMS") and the Office of the Inspector General ("OIG") of HHS are currently developing a regulatory response designed to protect the interests of Medicare beneficiaries.

> CMS outlined its position on retainer care in a March 2002 memorandum to CMS regional offices that CMS officials told us remains current as of June 2005. The memorandum states that physicians may enter into retainer agreements with their patients as long as these agreements do not violate any Medicare requirements. For example, retainer care membership fees may constitute prohibited additional charges if they are for Medicare-covered items or services. If so, a physician who has not opted out of Medicare would be in

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82. For a similar discussion regarding the federal government's ability to influence Medicaid funding, see BARRY R. FURROW ET AL., HEALTH LAW: CASES, MATERIALS & PROBLEMS 736 (4th ed., 2001).

83. *Id.*

84. According to one journalist:

> Private insurers, which often follow Medicare's lead, may also join the fray. Anthem Blue Cross Blue Shield has barred Virginia doctors from soliciting or accepting additional payments from patients insured by the company. Most insurers in the state say they're waiting to see if the insurance commissioner comes up with new rules.

Ostrom, *supra* note 76.

85. *See id.* The federal government is warning physicians they could face penalties or even expulsion from Medicare if they charge those patients for covered services. What are these services? Medicare's fraud alert is not spelling it out, but a Minneapolis doctor was busted for charging a fee for services such as "coordination of care" and "extra time" with patients: "'Medicare beneficiaries are entitled to certain services from their physician,' said Greg Demske, a chief in the Office of the Inspector General. 'If the physicians are asking for extra money for those services, then that's a problem.'" *See also* Ctrs. for Medicare & Medicaid Servs., OIG Alert About Charging Extra for Covered Services, Medicare Learning Network Matters, *available at* http://www.cms.hhs.gov/MLNMattersArticles/downloads/SE0421.pdf ("Participating physicians, suppliers, and providers who consider charging Medicare patients additional fees should be mindful that they are subject to civil money penalties if they request any payment for already covered services from Medicare patients other than the applicable deductible and coinsurance."). The Medicare Learning Network Matters bulletin on the topic appears to be a re-affirmation of the 2004 OIG Alert on covered services, which it cites.

violation of the limits on what she or he may charge patients who are Medicare beneficiaries.[86]

The "additional charges" mentioned are prohibited by "balance billing rules," which prevent doctors from charging an amount above Medicare care limits, getting reimbursement from Medicare, and then charging patients for the balance remaining.[87]

The balance billing rules arose out of congressional concerns about potential barriers to access to care for poor and lower middle class Medicare beneficiaries.[88] Without such rules, physicians could condition services to Medicare patients on the payment of additional charges that would undermine the programs' efforts to provide reasonably-priced health care to all. Under Medicare balance billing rules, participating physicians' charges are limited by the fee schedule prescribed by the program.[89] Under the relevant statute, physicians who accept assigned claims are prohibited "from charging more than the Medicare fee schedule amount."[90] Physicians who "do not accept assignment are prohibited from charging more than 115% of the fee schedule amount."[91]

To the extent that they implicate balanced billing concerns, retainer practices could also violate the False Claims Act.[92] The congressional sponsors of

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86. GAO REPORT, *supra* note 1. *See also* Portman, *supra* note 2, at 4 ("The Medicare statute requires physicians to submit claims for all procedures performed on Medicare patients, even if they do not accept assignment. It also prohibits physicians who accept assignment of a patient's claim from charging more than the Medicare fee schedule amount. Those who do not accept assignment are prohibited from charging more than 115% of the fee schedule amount.").

87. Hawryluk, *supra* note 26 (citing 42 U.S.C. § 1395w-4(g)(2)(C) (2000)). *See also* Russano, *supra* note 6, at 322 (discussing the legal consequences of such arrangements).

88. *See* David C. Colby et al., *Balance Billing Under Medicare: Protecting Beneficiaries and Preserving Physician Participation*, 20 J. HEALTH POL. POL'Y & L. 49, 51 (1995) ("Recognizing that many of the poor could not afford to pay medical bills, the original Medicare and Medicaid legislation prohibited physicians from balance billing those Medicare beneficiaries who were also eligible to receive Medicaid benefits. For all others, however, Medicare allowed physicians to bill more than the Medicare payment for services on a claim-by-claim basis until 1983. Since 1983, physicians have been given the choice to participate or not to participate under the Participating Provider (PAR) Program, for which they are given several incentives to enroll.").

89. *See* 42 U.S.C.A. § 1395w-4(g)(2) (West 2005); Portman, *supra* note 2, at 4.

90. Portman, *supra* note 2, at 4.

91. *Id.*

92. According to the False Claims Act:

Any person who–

(1) knowingly presents, or causes to be presented, to an officer or employee of the United States Government . . . a false or fraudulent claim for payment or approval;

legislation to keep retainer care practitioners out of the federal Medicare system claim that these physicians "knowingly submit erroneous bills" to the government.[93] To return to the hypothetical scenario above, they insist that the bill for each visit of the retainer care patient is actually $600, not $200, and that its representation to the government as the latter is merely a fiction designed to avoid the strictures of balance billing rules.[94] Retainer care proponents respond to this accusation by claiming that Medicare does not cover the services they offer, so they are not properly billed as Medicare claims.[95]

B. Covered or Non-covered Services?

A leading retainer care trade association claims that the retainer is a payment for better service, not better medical care.[96] This characterization is important, because "[i]f participating physicians decide they want to charge patients additional fees they should be mindful that they are subject to civil money penalties if they request any payment for already covered services from Medicare patients other than the applicable deductible and coinsurance."[97] Medicare-covered services include all "items and services . . . reasonable and necessary for

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> (2) knowingly makes, uses, or causes to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the Government . . .
>
> . . .
>
> is liable to the United States Government for a civil penalty of not less than $5,000 and not more than $10,000, plus three times the amount of damages which the Government sustains because of the act of that person.

31 U.S.C. § 3729 (2000). Critics of retainer care characterize the bill to the government as a false claim that has already been paid for by the retainer. *See* Waxman Letter, *supra* note 78, at 3.

93. Waxman Letter, *supra* note 78, at 3.

94. *See* GAO REPORT, *supra* note 1, at 27 ("OIG has addressed the consequences of noncompliance with Medicare billing requirements. In March 2004, HHS OIG issued an alert 'to remind Medicare participating physicians of the potential liabilities posed by billing Medicare patients for services that are already covered by Medicare.'"). The alert stated that "charging extra fees for already covered services abuses the trust of Medicare patients by making them pay again for services already paid for by Medicare." *Id.* As an example, the alert referred to a Minnesota physician who paid a settlement and agreed to stop offering personal health care contracts to patients for annual fees of $600. *Id.*

95. AM. SOC'Y OF CONCIERGE PHYSICIANS, PATIENT FINANCED MEDICINE: PAST, PRESENT AND FUTURE 12 (2004) (on file with author).

96. Waxman, *supra* note 78, at 2.

97. CORRIGAN MEMORANDUM, *supra* note 77 (quoting Acting Principal Deputy Inspector General Dara Corrigan, implying that the concierge amenities at issue fall outside the scope of Medicare covered services and thus should not be subject to balance billing scrutiny).

the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member."[98]

The distinction between covered and non-covered services is a term of art of federal health care financing. Medicare tends to follow the diagnosis and management codes developed by the AMA.[99] Unfortunately, neither regulations nor guidance documents appear to clarify application of this legal distinction to retainer care.[100] However, a close examination of the lists of services offered by retainer care practices discloses that at least some of them are likely covered Medicare services, as HHS itself determined in at least one case in Minnesota.[101] In that case, the OIG provided three examples of potentially covered services illicitly charged for by a retainer care physician: "coordination of care with other providers, a comprehensive assessment and plan for optimum health, and extra time spent on patient care."[102] Unfortunately, the alert did not specify how many of these services were covered under Medicare.

In the case of the one-third or so retainer care practices with retainer fees below $1000 per year, it is perhaps believable that patients would be willing to pay such a fee for more courteous staff, a nicer waiting room, monogrammed

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98. 42 U.S.C. § 1395y (2000). There is, of course, a long list of exceptions, codified in subparagraphs appearing after this portion of the statute. Most important for our purposes are the many preventive services that Medicare is now covering, including "prostate cancer screening; bone mass density measurement; diabetic self-management; mammography screening; glaucoma screening; pap smears; an initial physical examination; cardiovascular screening blood tests; diabetes screening tests; and hepatitis B, pneumococcal, and flu shots." *See* FURROW ET AL., *supra* note 82, at 684.

99. The statute establishes a substantive legal standard for Medicare coverage. *See* 42 U.S.C. 1395y(a)(1)(A) (2000). There are also regulatory criteria for National Coverage Determinations. *See* 65 Fed. Reg. 31,124 (May 16, 2000) (citing 42 U.S.C. 1395y(a)(1)(A) for authority to avoid coverage of services "not reasonable and necessary").

100. *See* Joan R. Rose, *A Caution Light for Concierge Practices*, MED. ECON., May 21, 2004, at 22. Each "improper request" to a patient for payment can result in a $10,000 fine, plus treble damages. *See* Ostrom, *supra* note 76.

101. *See* OIG ALERT, *supra* note 77, at 2 ("For example, the OIG recently alleged that a physician violated his assignment agreement when he presented to his patients – including Medicare beneficiaries – a 'Personal Health Care Medical Care Contract' asking patients to pay an annual fee of $600. While the physician characterized the services to be provided under the contract as 'not covered' by Medicare, the OIG alleged that at least some of these contracted services were already covered and reimbursable by Medicare. Among other services offered under this contract were the 'coordination of care with other providers,' 'a comprehensive assessment and plan for optimum health,' and 'extra time' spent on patient care. OIG alleged that based on the specific facts and circumstances of this case, at least some of these contracted services were already covered and reimbursable by Medicare.").

102. *Id.* (internal quotation marks omitted).

slippers, and other non-care-related amenities.[103] However, as fees mount, such a sharp distinction between care and customer service is harder to defend.

III. RESOLVING THE BALANCE BILLING CONTROVERSY BY DISAGGREGATING RETAINER CARE

In order to resolve the controversy over whether retainers are prohibited payments for covered services or permitted payments for non-covered services, it is important to disaggregate the range of services provided by retainer care physicians. Section III.A below develops a taxonomy, while Section III.B applies that categorization to the legal issues at hand.

A. Three Faces of Retainer Care

Retainer care physicians offer a wide range of services, as this survey from the GAO shows:

Table 1: Features Offered by Concierge Physicians, October 2004[104]

Feature	*% Offering Feature*
Same- or next-day appointments for non-urgent care	99
24-hour telephone access	99
Periodic preventive-care physical examination	99
Extended office visits	96
Access to physician via e-mail	94
Access to physician via cell phone or pager	93
Wellness planning	93
Nutrition planning	82
Coordination of medical needs during travel	82
Patient home or workplace consultations	78
Smoking cessation support	77
Preventive screening procedures	72
Newsletter	71
Stress reduction counseling	67

103. *See* Russano, *supra* note 6, at 336 ("If boutique medical practices provide their patients with bonuses such as 'heated towel racks, free hotel rooms, [and] special bathrobes,' these amenities could violate the federal anti-kickback statute or the Health Insurance Portability and Accountability Act prohibiting such inducements. However, since these amenities are offered after payment of a retainer, it is likely that they will be seen as services provided in exchange for payment and not as an 'inducement.'") (internal citations omitted).

104. GAO REPORT, *supra* note 1, at 15 tbl.2.

Private waiting room	63
Mental health counseling	60
Online or other electronic access to personal records	42

Though many commentators have directed praise or blame at retainer care *as a whole,* these statistics show that there are many distinct services offered by retainer care physicians. They may be usefully categorized as:

(1) Preventive care (designed to prevent illness or moderate the effects of chronic illness);
(2) Queue-jumping (designed to grant privileged access to superior health care); and
(3) Amenity-bundling (designed to enhance the value of queue-jumping and preventive care by combining them with comforts, luxuries, and positive experiences).

Each of these categories is described below.

1. Preventive Care

Nearly all retainer care practices responding to the GAO survey offer "periodic preventive-care physical examinations."[105] High percentages also offered "wellness planning" and "nutrition planning."[106] Retainer care physicians are particularly proud of this dimension of their practice. Bernard Kaminetsky, a retainer care physician who has testified before Congress and been profiled in the *New York Times* has frequently argued that his practice *saves* the health care system money by minimizing hospitalizations and emergency room visits via careful monitoring of patients and constant availability.[107] He and other retainer care physicians claim that, after years of feeling they could never meet their own high standards due to pressures from managed care, they can finally rest assured that they have provided all potentially helpful primary medical care that their

105. *Id.* at 15 (reporting that periodic preventive care and physical examinations, along with same or next-day appointments and twenty-four-hour telephone access, were the most frequently reported features by retainer care physicians who responded to a survey).

106. Ninety-three percent offered wellness planning, and 82% offered nutrition planning. *Id.* Other practices report the following preventive measures: "smoking cessation support" (77%), "preventive screening procedures" (72%), "stress reduction counseling" (67%), and "mental health counseling" (60%). *Id.* at 15 tbl.2.

107. *See Consumer-Directed Doctoring, supra* note 4, at 46 (statement of Bernard Kaminetsky), (testifying that only fifty-five percent of recommended preventive care and fifty-two percent of recommended screening is administered, presumably leading to increased out-patient care and health care costs).

patients need.[108]

Beyond any particular preventive intervention, the availability and constancy of retainer care also promises significant preventive effects. A retainer physician can keep closer tabs on an array of potentially troublesome developments in a patient's weight, habits, or bloodwork. Advice on prevention from a trusted physician may also be far more effective than a rote catechism of self-care offered by a harried practitioner.[109]

Retainer care deserves to be encouraged to the extent that retainer payments fund the type of preventive health care that many public and private insurers have so far been unable or unwilling to fund. Cancer screenings, vaccinations, cardiac rehabilitation, and anti-obesity and anti-smoking behavioral modification techniques undoubtedly occur at suboptimal rates.[110] Many harried primary care physicians simply do not have the resources to provide them. If some entrepreneurs among them can inspire patients to pay for these socially beneficial programs, regulatory agencies should not stand in their way.

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108. *See id.* at 51 ("Because of the time I now have for preventive care, and the trust engendered, I am not subject to . . . fear [of malpractice suits]. My patients and I recognize that whatever the outcome, I gave them my best."); Soc'y for Innovative Med. Practice Design, Why Should Physicians Join This Movement? (2006), http://simpd.org/physicians.htm ("Since 1996, physicians in the United States have been experimenting with new practice structures that take them out of the treacherous waters of third party controlled care and allow them to once again take care of their patients directly, with decisions controlled by doctors and patients, not by spreadsheet mavens and government bureaucrats. The key principle that allows these practices to exist is the notion that when patients buy their care directly from their physician, high quality care becomes possible, often at far lower prices than the existing healthcare market will permit.").

109. *See* Claude Solnik, *Doctors Give Patients the Boca Raton, Fla.-Based MDVIP Treatment*, LONG ISLAND BUS. NEWS, May 19, 2006, at 1 ("'[Patients at retainer-care practices] probably do get better care, because the physician spends more time with [them],' said Lawrence Lioz, a partner at accounting firm Margolin, Winer & Evans in Garden City. 'The patient care probably is a step up. But there's a cost.'").

110. *See Consumer-Directed Doctoring*, *supra* note 4, at 46-47 (statement of Bernard Kaminetsky) (suggesting that normal-sized medical practices do not have the time needed to provide basic preventive care to patients); Kimberly S.H. Yarnal et al., *Primary Care: Is There Enough Time for Prevention?* 93 AM. J. PUB. HEALTH 635 (2003) (reporting that basic preventive services at [the U.S. Preventive Services Task Force (USPSTF)] recommended frequencies are commonly missed in a traditional primary care setting under the present health care scheme). *See also* Barnaby J. Feder, *New Priority: Saving Feet of Diabetics*, N.Y. TIMES, Aug. 30, 2005, § F5 ("[R]esearch suggests that anywhere from fifty percent to eighty-five percent of [the roughly 50,000] diabetic foot amputations [that occur each year] are preventable.").

2. Queue-Jumping

Beyond preventive care, retainer care physicians also offer far quicker and lengthier access to ordinary care. Nearly all of those responding to the GAO survey offer "same- or next-day appointments for nonurgent care," "24-hour telephone access" to physicians, and "extended office visits."[111] Nearly as many offer access to physicians via e-mail, cell phones, or pagers.[112] Many retainer care physicians coordinate medical needs during travel, or visit their patients at their home or workplaces.[113] A smaller number offer "priority for diagnostic tests in affiliated medical facilities."[114]

Given most retainer care physicians' commitment to a unitary standard of care, such patients are not "skipping in front of" other patients within retainer practices.[115] However, they only attained this level of care by effectively outbidding those unable or unwilling to pay the required retainer. Moreover, considering the baseline of primary care availability, they are far "ahead" of those in non-retainer practices. The average American waits several days for an

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111. GAO REPORT, *supra* note 1, at 15 tbl.2. These features are often reported as the most important features distinguishing retainer care practices from more traditional primary-care practices.

112. *Id.*

113. *Id.*

114. *Id.* at 16 tbl.2 (stating that twenty-seven percent of retainer care physicians offer this service).

115. The AMA's Council on Ethical and Judicial Affairs has mentioned that retainer care physicians ought to provide the same standard of care to the patients in their practice who are incapable of paying the retainer. *See* CEJA REPORT, *supra* note 61, at 5 ("Physicians who engage in mixed practices, in which some patients have contracted for special services and amenities and others have not, must be particularly diligent to offer the same standard of diagnostic and therapeutic services to both categories of patients."). *See also* Sandra J. Carnahan, *Law, Medicine, and Wealth: Does Concierge Medicine Promote Health Care Choice, or Is It a Barrier to Access?*, 17 STAN. L. & POL'Y REV. 121, 139-40 (2006) ("[P]hysicians who have split their practices may be violating their provider agreements when they give preferences to their concierge patients. For example, a standard Blue Cross Blue Shield provider agreement provides: 'Physician shall provide Covered Services to Members in the same manner, quality and promptness as services are provided to Physician's other patients.' Physicians provide their concierge patients an expedited appointment process, often a waiting room for the exclusive use of concierge patients, and other amenities that regular patients would not receive. Even assuming the quality of medical services was the same for both categories of patients, concierge physicians are essentially contractually bound to their access-fee patients to 'prefer' them over their regular patients with respect to appointment preference and amount of time spent, which may violate the anti-discrimination provision of the provider agreement."); Hoffman, *supra* note 26 ("[P]hysicians like Dr. Kaminetsky, who sees both types of patients at his practice in Boca Raton, Fla., insist that all their patients are treated equally . . . .").

office visit, is subjected to more delays once at the doctor's office, and more than half of such visits last less than twenty minutes.[116] By contrast, retainer patients get near-immediate access through traditional visits, house-calls, and even e-consultations and phone calls.[117]

The term "queue-jumping" usually refers to individuals' effort to spend their way past the "lines" for rationed care in order to get immediate attention. The term has been most commonly used in analyses of "parallel" public and private health care systems, such as those prevailing in the United Kingdom, where the ten percent or so of the population that buys private insurance can use it to fund access to physicians whose attention they would normally need to wait weeks or months to get.[118]

Given that the overall mix of public and private spending in the United States has led to waits, on average, for primary care[119] there is a rather direct analogy between queue-jumping via retainer care in the United States and queue-jumping via private insurance or private payment in primarily public systems. But to be analytically rigorous, it is helpful to distinguish between jumping the queue to get *rapid access* and jumping ahead to get more *intense, longer, or more expert* office visits. The latter issues raise interesting problems, which might be developed by thinking about the *extant,* somewhat random, distribution of above-average primary care.

Before retainer care, we may assume that *some* doctors were giving care as

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116. *See generally* Fischman, *supra* note 16, at 46 (discussing difficulties in the physician-patient relationship).

117. *See* Bill Sonn, *Concierge Medicine: Physicians Weigh Financial, Ethical Issues*, PHYSICIANS PRAC. ONLINE, Feb. 2004, http://www.physicianspractice.com/index.cfm?fuseaction=articles.details&articleID=483.

118. *See* Michael Calnan, *The NHS and Private Health Care*, 10 HEALTH MATRIX 3, 16 (2000) (discussing parallel public and private health systems in the United Kingdom).

119. In 1999, a Kaiser Family Foundation survey of insured adults younger than sixty-five years found that twenty-seven percent of people with health problems had difficulty gaining timely access to a clinician. KAISER FAMILY FOUND., NATIONAL SURVEY OF CONSUMER EXPERIENCES WITH HEALTH PLANS: SUMMARY OF FINDINGS AND CHART PACK (2000), *available at* http://www.kff.org/insurance/loader.cfm?url=/commonspot/security/getfile.cfm&PageID=13510. From 1997 to 2001, the percentage of people reporting an inability to obtain a timely appointment rose from twenty-three to thirty-three percent. BRADLEY C. STRUNK & PETER J. CUNNINGHAM, CTR. FOR STUDYING HEALTH SYS. CHANGE, TREADING WATER: AMERICANS' ACCESS TO NEEDED MEDICAL CARE, 1997-2001 (2002), *available at* http://www.hschange.com/CONTENT/421/. In 2001, forty-three percent of adults reporting an urgent condition were occasionally unable to receive care as soon as they desired. JANET GREENBLATT, AGENCY FOR HEALTHCARE RESEARCH & QUALITY, STATISTICAL BRIEF NO. 08: ACCESS TO URGENT MEDICAL CARE: 2001 (2002), http://www.meps.ahrq.gov/mepsweb/data_files/publications/st8/stat08.pdf.

intense, expert, and dedicated as retainer care physicians. However, the distribution of such doctors was somewhat random. Perhaps some clung to an older standard of care, limiting their number of patients even as managed care squeezed effective compensation per patient. Some were in rural areas where there just weren't that many patients to treat. Some were just exceptionally energetic. Getting such a doctor was desirable, but left to chance and individual initiative, as people sought out recommendations of a "good" physician from family, friends, and coworkers. The sick (and perhaps the worried well) could be counted on to expend real energy in finding an exceptional primary care physician; those needing less care would probably not find the effort worth their while.

Admittedly, the informal "sorting" of doctors has always tracked class distinctions in the United States.[120] The better-off are more likely to have the time, connections, and skills necessary to find quality primary care. Some of the best-off have long opted for "cash-only" practices, upon which the toniest retainer care practices have been modeled. Retainer care promises to expand the scope of the commodification of primary care quality. No longer do merely those wealthy enough to go "cash only" have the opportunity to command the attention of retainer doctors. As the buying power of this class expands, the doctors most capable of taking advantage of it via retainer care are likely to be the best doctors, or at least those with a superior reputation.[121] Retainer patients are likely

120. *See* INST. OF MED., UNEQUAL TREATMENT: WHAT HEALTHCARE PROVIDERS NEED TO KNOW ABOUT RACIAL AND ETHNIC DISPARITIES IN HEALTHCARE (2002), *available at* http://www.iom.edu/Object.File/Master/4/175/Disparitieshcproviders8pgFINAL.pdf ("[M]any recent news reports indicate that racial and ethnic minorities receive lower healthcare quality than whites, even when they are insured to the same degree and when other healthcare access-related factors, such as the ability to pay for care, are the same."). The correlation between primary care and class distinctions was evidenced by a 2002 survey which found that minority adults, whether they had insurance or not, were less likely than whites to have a regular doctor. For more information, see *Coverage and Access: Minorities More Likely than Whites to Report Difficulty Communicating with Care Providers, Face Other Barriers, Survey Says*, DAILY HEALTH POL'Y REP., Mar. 7, 2002, *available at* http://www.kaisernetwork.org/Daily_reports/rep_index.cfm?DR_ID=9888.

121. *Consumer-Directed Doctoring, supra* note 4, at 45 (statement of Robert A. Berenson, Senior Fellow, Healthy Policy Ctr., The Urban Inst.) ("[I]t is likely that relatively healthy, affluent individuals would be the group most likely to opt out of comprehensive insurance products, leading to high insurance costs for those whose health problems give them no choice but to remain in the basic health insurance pool. As healthier families and individuals opt out of traditional insurance coverage, those remaining in comprehensive health plans would be more expensive to insure. This will lead to destructive market segmentation, driving up premiums for traditional coverage even further and setting off a spiral of adverse selection. The comprehensive health insurance option would become unaffordable precisely for those who need its protection."). *See also* Martin

to want, not merely more time from a physician, but also *quality* time with a *quality* physician.

These likely dynamics point to distinct facets of the "queue-jumping" so important to the retainer care model. Retainer payments guarantee a) quicker access to care – the classic definition of queue-jumping familiar from countries with parallel public and private systems. But they also promise b) better health care, when they permit payors to leverage buying power into access to more skilled or dedicated physicians.[122] Retainer patients are thus relatively advantaged (vis-à-vis non-retainer patients) by gaining *quicker* access to *better* care.

3. Amenity-Bundling

Yet just how far can retainer care physicians' standard of care diverge from the normal standard? Virtually any decent primary care practice will provide patients with a call service and quick attention (or a referral to a emergency room) in case of a serious problem. As mentioned above, several commentators suggest that current levels of dissatisfaction with managed care relate more to perception than reality.[123] Perhaps a great deal of the dissatisfaction stems from

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Solomon, *The Doctor Will Not See You Now*, GATHER.COM, Aug. 5, 2006, http://www.gather.com/viewArticle.jsp?articleId=281474976772872 (asserting that a patient searching for a new doctor will have to settle for a young doctor who is new to the community because the more experienced doctors have either converted to the retainer model, or have stopped accepting new patients).

122. A simple economic model of the quality of physician services would project that the best physicians would be the best paid. While this is obviously not true universally, it is likely probabilistically true enough to warrant these concerns. There is some empirical evidence that retainer care physicians are disproportionately more experienced and more expert. *See* Solomon, *supra* note 121. We can, for instance, assume that only an established practice can convert to the retainer model, since usually only that practice would have a base of customers it could solicit for retainer fees.

123. *See* Robert J. Blendon et al., *Understanding the Managed Care Backlash*, 17 HEALTH AFF. 80, 84, (1998) ("A majority (55 percent) of people in managed care say that they are at least 'somewhat worried' that if they were sick, their health plan would be more concerned about saving money than about what is the best medical treatment; 34 percent of those with traditional health insurance feel this way. When asked about specific examples, taken from news stories, of dramatic events that might be considered statistical outliers, the public's perception is that these are fairly common occurrences. For example, two-thirds of Americans believe that a health maintenance organization (HMO) holding back on a child's cancer treatment is something that happens 'often' (26 percent) or 'sometimes' (40 percent); only 23 percent think that this happens 'rarely.' Two in five (39 percent) think that newborn babies are often sent home after just one day because of a managed care plan's policy, in spite of mothers' concerns about their children's health; another third (34 percent) think that this occurs 'sometimes'; only 18 percent think that this happens

the near-automatic anxiety generated for many by today's health care system.[124] For those already sick, the prospect of grappling with billing disputes and officious staff might be enough to keep them away from the doctor altogether.[125]

As their moniker suggests, concierge care physicians try to make the interactions with the health care system more like the lavish treatment at a fine hotel. Over half of those responding to the GAO survey offered a "private waiting room."[126] Thirty-one percent offered "home delivery of medication by physician or office staff."[127] Retainer practices generally pride themselves on making interactions between staff and patients as amenable and productive as possible.

Some sensationalistic media reports have also focused on the more extravagant "perks" of retainer patients: monogrammed bathrobes, heated towels, and slippers.[128] Although these reports probably do not accurately represent the

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'rarely.' These perceptions of managed care are reflected in the ratings of the industry compared with other health care groups.").

124. A June 2005 Lake Snell Perry Mermin survey revealed that "[r]ising health care costs are voters' number one *economic* concern at 27 percent, followed by wages not keeping up with costs (18%), a secure retirement (14%), higher taxes (12%), rising gas prices (9%), paying off debt (7%), losing your job (5%), and expenses like child care and college (4%)." CELINDA LAKE & DANIEL GOTOFF, LAKE SNELL PERRY MERMIN DECISION RESEARCH, OVERVIEW OF RECENT RESEARCH ON THE ECONOMY 2 (2005), *available at* http://www.ourfuture.org/docUploads/lake_poll_july2005.pdf. *See also* Ross Douthat & Reihan Salam, *The Party of Sam's Club: Isn't it Time the Republicans Did Something for Their Voters?*, WKLY. STANDARD, Nov. 14, 2005, *available at* http://www.weeklystandard.com/Content/Public/Articles/000/000/006/312korit.asp (stating that the country's health care system may be the greatest source of anxiety for many families).

125. *See* Jean P. Fisher, *Pinched by Medical Bills*, NEWS & OBSERVER, Jul. 11, 2004 ("But families reported situations such as being contacted by collection agencies, postponing a major household purchase such as a car or borrowing money to pay health-care bills. Consumers also said they had to forgo doctor's visits or leave prescriptions unfilled because they had no money to pay or feared racking up additional medical bills."). For reporting on patients' perspectives of excessive wait times in doctors' offices and their inability to obtain timely appointments, see GREENBLATT, *supra* note 119; KAISER FAMILY FOUND., *supra* note 119; STRUNK & CUNNINGHAM, *supra* note 119; and Michael Goitein, *Waiting Patiently*, 323 NEW ENG. J. MED. 604 (1990).

126. *See* GAO REPORT, *supra* note 1, at 15 tbl.2 (reporting that 63% of respondents claimed to offer this feature).

127. *Id.* Admittedly, this is not a "luxury" for those unable to get to a pharmacist. Unfortunately, the GAO survey does not reveal what percentage of retainer patients taking advantage of this service were not able to get to the doctor.

128. Carnahan, *supra* note 115, at 121-22 ("['Concierge'] patients receive a varying array of services that are not typically covered by insurance, such as access to their personal physician twenty-four hours a day, seven days a week, immediate or same-day appointments, their

patient experiences at most retainer care practices,[129] they suggest the direction of competition in the future. Health care often is characterized by economists as an "experience good" – a service whose value is hard to judge critically until after it has been rendered – or a "credence good," whose value really only can be judged by experts.[130] To the extent discriminating consumers want to compare retainer care practices, they often will have little to go by other than the appearance of doctors' offices and the perks they provide.

Would competition on amenities be a good development? There are several reasons to doubt that. Amenity bundling, like many statutory and regulatory requirements for managed care coverage that stymie the provision of more "cut-rate" offerings, can be deeply inegalitarian. Clark Havighurst's critique of "managed care mandates" (which require health plans to cover procedures like in vitro fertilization) applies *a fortiori* to amenity bundling:

> [T]he elite classes, including many self-proclaimed consumer representatives as well as organized professional groups . . . design and maintain a system that meets their own particular needs but leaves less privileged citizens who are not qualified for publicly financed care with a Hobson's choice: either coverage for "Cadillac" care or no health coverage at all. Ruled as it is by and for dominant elites, the U.S. health care system imposes large, unfair, and unnecessary economic burdens on ordinary working people.[131]

Scholars outside health law also raise concerns about amenities. As Lior Strahilevitz has demonstrated, "exclusionary amenities" are widely used by

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physician's personal cell phone number and e-mail address, extensive executive-type annual physicals, some preventive care services, and, in some cases, spa-like amenities such as robes, slippers, and refreshments."). *See also Shop Talk on Boutique Medicine*, *supra* note 77 (stating that some retainer care practices provide patients with monogrammed bathrobes and heated towel racks).

129. Since most retainer care practices now charge fees between $1500 and $2000 annually, they probably cannot afford such amenities. *See* GAO REPORT, *supra* note 1, at 13. Since the GAO Report does not even mention them in its survey of services offered by retainer care practices, they are likely rare. *Id.* at 15-16.

130. *See* William M. Sage & Peter J. Hammer, *A Copernican View of Health Care Antitrust*, 65 LAW & CONTEMP. PROBS. 241, 270 n.104 (2002) ("Many health care services are what economists call credence goods, meaning that consumers cannot necessarily assess their quality even after consuming them.") (citing Kenneth J. Arrow, *Uncertainty and the Welfare Economics of Medical Care*, 53 AM. ECON. REV. 941, 951-52 (1963)). With "credence goods, consumers are never sure about the extent of the good they actually need." Winand Emons, *Credence Goods and Fraudulent Experts*, 28 RAND J. ECON. 107 (1997).

131. Clark C. Havighurst, *How the Health Care Revolution Fell Short*, 65 LAW & CONTEMP. PROBS. 55, 86 (2002).

housing developers in order to discourage "unwanted" groups from affecting the character of the neighborhood, without running afoul of antidiscrimination laws.[132] For example, a condominium association that only wants childless singles and couples to join may write into the relevant covenant a requirement that all residents subsidize a variety of amenities such families are unlikely to use.[133] Luxurious amenities may be valuable to those who can afford them, but also tend to increase already troubling trends toward economic apartheid.[134] Though this trend may be inevitable in the housing market, health care should not be conditioned on one's ability to purchase lavish services unrelated to therapeutic ends. Whatever one thinks of Havighurst's critique of managed care mandates, it fits amenity bundling in retainer care exceptionally well.

The problem lies not only in the substance of amenity-bundling but also in its form. Bundling has provoked antitrust scrutiny in certain industries.[135] Since the rest of retainer care services often are not available outside a package including amenities, they are offered in a particularly tight type of bundling.[136] Admittedly, it would be difficult to apply recent doctrine on "bundled discounts" to retainer practices given their lack of market power and their failure to market the components of retainer care separately in the past.[137] Yet perhaps the very difficulty of such an analysis suggests the need for valuing the component part of retainer care more carefully.[138] As Section III.B below shows, often amenities are

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132. *See* Lior Jacob Strahilevitz, *Exclusionary Amenities in Residential Communities*, 92 VA. L. REV. 440 (2006) ("People interested in residential homogeneity inevitably will try to thwart integration using creative substitutes for overt discrimination.").

133. *See id.* at 441.

134. CHUCK COLLINS & FELICE YESKEL, ECONOMIC APARTHEID IN AMERICA 31 (2000) (discussing inequality and public health).

135. David S. Evans & Michael Salinger, *Why Do Firms Bundle and Tie? Evidence from Competitive Markets and Implications for Tying Law*, 22 YALE J. ON REG. 37 (2005); Daniel L. Rubinfeld, *3M's Bundled Rebates: An Economic Perspective*, 72 U. CHI. L. REV. 243 (2005) (discussing leading case LePage's Inc. v. 3M, 324 F.3d 141 (3d Cir. 2003)).

136. Bruce H. Kobayashi, *Does Economics Provide a Reliable Guide to Regulating Commodity Bundling by Firms? A Survey of the Economic Literature*, 4 J. COMPETITION L. & ECON. 707, 708 n.2 (2005) (charting six types of bundling, based on whether components are available separately or not).

137. Thomas A. Lambert, *Evaluating Bundled Discounts*, 89 MINN. L. REV. 1688, 1689 (2005) (explaining that leading recent antitrust cases addressed "bundled discounts," which occur "when a seller offers a collection of different goods for a lower price than the aggregate price for which it would sell the constituent products individually."). Since the retainer care physicians are not presently selling amenities separately, it would be very difficult to determine whether suspected "bundled discounting" actually occurred.

138. And, perhaps, the chilling effects of antitrust liability here. A rational seller might decide to vigorously resist any decomposition of a package of goods it sells in order to avoid liability for

emphasized not simply for their own sake, but to provide "something else to bill for" to avoid liability for double billing for covered services.

B. What Are the Retainer Payments For?

Amenity-bundling is likely to persist because amenities play an important role in the business model of retainer care physicians by providing a legal basis (however tenuous) for the assertion that retainer payments are only compensation for non-covered services. Strategic retainer care physicians tend to assure that their contracts specify that retainer payments only are made in consideration for uncovered amenity and preventive care.[139] For example, Personal Physicians HealthCare (PPHC) hired attorney Michael Blau to legally restructure their practice in order to distinguish payments for ordinary medical services and those for preventive and amenity care:

> Personal Physicians HealthCare PC was formed to provide healthcare services and contracts with all of the various insurance payers. Its structure was almost identical to that found in the average physician's office; and as a corporation, it was authorized to offer all medically necessary covered services.
>
> Personal Physicians HealthCare LLC was formed as a client services corporation that charges the $4,000 annual fee. This umbrella of services would also cover PPHC's in-house nutritionist and personal trainer, the doctor-patient communication system of email and cell-phone access and other PPHC custom-designed patient services.[140]

One of the founders of this "dual structured" practice explains that the

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bundling if it later decides to sell them together. Just as balance billing rules may unintentionally promote the bundling of amenities into retainer care packages, so too might potential antitrust liability for bundling unintentionally chill the constructive efforts of sellers to break a package of retainer services into its component parts. Worries over the unintended consequences of regulation drive the conclusion, stated *infra* in Part V, that targeted taxation of the troubling parts of retainer care probably amount to the best regulatory response at this time.

139. *See, e.g.*, Personalized Primary Care Membership Agreement, *available at* www.personalizedprimarycare.com/membership_reg/membership_form.pdf (last visited Dec. 10, 2006) (section entitled "Medical Care Services Excluded from Annual Membership Fee").

140. GREGORY L. STOLLER & CHRISTOPHER FERRARONE, THE PATIENT IS ALWAYS RIGHT: PERSONAL PHYSICIANS HEALTHCARE 8 (2004), *available at* www.bc.edu/schools/csom/bcbi/meta-elements/pdf/persphy.pdf. The "dual structure" was also used for accounting purposes. As retainer care physician Steven Flier explains in the piece, "[M]ost insurance plans cover medically necessary house calls. However, if the house call is for the patient's convenience, then it is not covered under insurance and would be 'paid for' by the patient's annual fees from the LLC." *Id.*

arrangement works in part because "LLC buys time from the PC so that our doctors are not busy."[141]

Groups like PPHC would like to characterize all these LLC payments as being "for" non-covered preventive and amenity care, even if they dwarf the amount paid directly for insurance-covered medical care and the relevant doctors spend more time on the latter than the former. The mere legal form or labeling of payments should not dispose of questions about what they are actually for.[142] Some of the amenities offered by retainer physicians are merely "better services," but it is unlikely that retainer patients paying several thousand dollars annually are merely paying for monogrammed bathrobes or friendlier office staff. Rather, these are payments for medical care itself.

Retainer care services may be categorized usefully as amenity, preventively therapeutic, and directly therapeutic. Given extant patterns of Medicare funding, we can predict that those services falling into the last category would likely qualify for Medicare coverage, and those in the first would likely fall outside the program's purview. Certainly the categories do not map directly onto coverage decisions, which are inevitably idiosyncratic given the degree of discretion vested in the Secretary of HHS by the statute.[143] However, given the number of retainer care services that reasonably fall into the "directly therapeutic" category, the OIG reasonably could presume that at least part of the retainer fee charged at many practices is supplementing Medicare payment for covered services.[144]

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141. *Id.* (internal quotation marks omitted).

142. *See* Michael Romano, *If You Have To Ask, You Can't Afford It; Boutique Practices Getting a Hard Look From Government, Doctors' Group*, MOD. HEALTHCARE, Mar. 25, 2002; *Lawmakers Challenge Legality of "Boutique Medicine"*, 12 CLINICIAN REV., May 2002, at 32 (noting that leading Democratic Congressmen "requested a review of the legality of these practices," because "[c]urrent law states that providers who do not accept the Medicare fee schedule can charge no more than 115% of the Medicare rate for a covered service.").

143. *See* Goodman v. Sullivan, 712 F. Supp. 334, 338 (S.D.N.Y. 1989) ("Congress delegated to the Secretary the authority to promulgate regulations for administering the medicare [sic] program, 42 U.S.C. § 1395hh(a), and provided the Secretary with great discretion in determining what items or services will be covered under Medicare Part B.").

144. GAO REPORT, *supra* note 1, at 18 n.26. HHS has issued a memorandum stating that retainer agreements could be problematic if they attempt to substitute for Medicare supplemental insurance policies. CMS officials reported encountering problems with physicians offering unregulated supplemental policies in the mid-1990s. In June 2005, CMS officials told [the GAO] that, while such substitutions are not allowed, they are no longer concerned that retainer arrangements are being used as substitutes for Medicare supplemental insurance." *Id.* The GAO unhelpfully fails to cite to the date or title of the memo it refers to, and a search of the HHS website for the document has proven fruitless. *See* KENNETH T. BOWDEN II & LAWRENCE L. FOUST, ADVANCED ISSUES IN PROVIDER/PAYER MANAGED CARE CONTRACTING AND NEGOTIATIONS 12 (2005) (copy on file with author).

Many defenders of retainer care claim that the retainers only pay for "better service," not better health care. This nomenclatural smoke screen has obscured what is really objectionable about retainer care: the bidding away of primary care resources by those whose wealth permits them to opt out of the rationing mechanisms of managed primary care. To the extent retainer care physicians are bundling amenities with retainer care in order to avoid legal liability for double billing, law is encouraging the worst distributive consequences of the retainer care trend. Bundled amenities only tend to make retainer care more unaffordable and serve little to no therapeutic purpose.[145]

Admittedly, the valuation of each facet of retained services will be difficult. But to the extent the distinction is a sham, insurers should step in to avoid subsidizing the type of struggle for positional advantage (in access to care) that queue-jumping is likely to encourage. For patients with insurance, retainer payments raise the type of "double payment" concerns addressed by Medicare's balance billing rules, the False Claims Act, and similar provisions in private insurance contracts. The relevant authorities should scrutinize these arrangements in order to minimize the extent to which public and private insurers are subsidizing retainer conversions primarily designed to provide priority access. These conversions serve only to fragment the risk pools that insurance is designed to unify.

The Medicare program can be a powerful policy lever for encouraging retainer practices to concentrate on preventive care and to avoid promoting the kind of wasteful competition that "queue-jumping" for ordinary medical care may cause.[146] A majority of retainer physicians responding to the GAO's survey participate in the Medicare system, and retainer patients skew toward the elderly.[147] By cutting out reimbursements for ordinary medical care already paid

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145. Some theorists of positional goods have suggested that this diversion of health resources away from those unable to afford them actually amounts to a competitive advantage for the diverters. *See* Harry Brighouse & Adam Swift, *Equality, Priority, and Positional Goods*, 116 ETHICS 471, 479 (2006) ("[H]ealth . . . . [may] indeed have a competitive, and hence positional, aspect. The value to me of my health does depend on how healthy others are. In the land of the blind, the one-eyed man is king. This is a case of a latent positional good."). On this Darwinian account, the diverters of the primary care are the "one-eyed men," and the rest of the system is left "blind."

146. Admittedly, if Medicare requirements get too burdensome, HHS risks losing influence over them to the extent that retainer practices exit the public insurance program altogether (and perhaps become "cash only"). *See* Buczko, *supra* note 32, at 43. There are many anecdotal accounts of physicians about to opt out of the system entirely due to insurers' burdensome administrative requirements. However, a recent study suggests that few providers give physicians the option to opt-out of Medicare. *Id.* at 57.

147. "On average, Medicare beneficiaries represented about thirty-five percent of the total

for by retainer fees, HHS could reduce the financial appeal of the retainer model, as well as its potential to increase queue-jumping. Part V below suggests some methods of decomposing the value of the different facets of retainer care.

IV. SHOULD RETAINER CARE BE FURTHER REGULATED?

Though Medicare has great influence over the U.S. health care system, it does not exhaust the potential range of regulatory responses to retainer care. Balanced billing rules may also prove to be too blunt an instrument to simultaneously diminish queue-jumping and promote preventive care. Other options, including state regulation, may achieve health policy goals in a more nuanced way.

Before examining these options, it is important to address the normative question – *should* retainer care be further regulated? Any fair approach to this question requires a careful airing of the concerns of retainer care physicians and their patients.

Retainer care physicians' complaints about regulation break down into four main types. First, many argue that retainer care is simply too insignificant a phenomenon to merit sustained attention from regulators.[148] Second, they argue that gains in time and compensation from retainer care will encourage more medical students to become primary care physicians.[149] Third, retainer care physicians argue that they treat some of the sickest patients, and should be praised instead of penalized for developing long-standing care relationships.[150] Finally, libertarians believe it is unconscionable to deny treatment options to those willing and able to afford them.[151]

Sections IV.A through IV.D below elaborate these concerns and critically examine them. Although advocates of retainer care make some compelling arguments for permitting it in a certain range of cases, a tailored regulatory response is essential to mitigate its worst effects.

A. A Self-Limiting Phenomenon?

Proponents of retainer care have tried to deflect regulation by insisting that it is a "self-limiting" phenomenon that would only threaten access to care if it were

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number of patients – retainer and non-retainer – that responding retainer care physicians reported having in their care as of October 2004." GAO REPORT, *supra* note 1, at 21.

148. *See infra* Section IV.A.

149. *See infra* Section IV.B.

150. *See infra* Section IV.C.

151. *See infra* Section IV.D.

to become widespread.[152] A nascent phenomenon in health care finance, retainer care has not yet affected the vast majority of providers or patients. The GAO's report, one of the most comprehensive so far, stated that "[t]he small number of retainer care physicians makes it unlikely that the approach has contributed to widespread access problems."[153] Some predict that is likely to remain the case for the foreseeable future. According to one leading academic and policy advisor, "[c]oncierge care may remain attractive to a limited number of high income-individuals . . . [i]t is not likely to become an important component of the American health care system."[154]

This characterization of retainer care is essential to its current justification. As the AMA's Council on Ethics and Judicial Affairs warns, if retainer care were to become widespread, or even to "take over" a certain market, it would certainly raise concerns about access.[155] But the AMA's Council on Medical Service downplayed such concerns, and both advisory groups claimed that the value of pluralism in consumer and provider options outweighs any negative effects of retainer conversions.

As of mid-2005, about 250 physicians have retainer practices.[156] The largest retainer care network, MDVIP, based in Boca Raton, Florida, "has 85 doctors in 14 states serving 27,000 patients."[157] The GAO reports a continuous growth in retainer practice since its inception in 1996.[158] Nevertheless, the same report concludes that "[t]he small number of retainer care physicians makes it unlikely that the approach has contributed to widespread access problems."[159] The Council on Medical Service of the AMA goes further on the prevalence question, deeming retainer care an "inherently self-limiting" phenomenon:

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152. Troyen Brennan summarizes these responses (from health lawyers and the AMA) in a seminal article on the topic. Troyen A. Brennan, *Luxury Primary Care – Market Innovation or Threat to Access?*, 346 NEW ENG. J. MED. 1165, 1167 (2002).

153. GAO REPORT, *supra* note 1, at 24.

154. *Concierge-Style Health Care Perks Not Likely To Revolutionize Medical Services Field, Says Stuart Altman*, BRANDEIS NEWS, Jan. 10, 2002, *available at* http://my.brandeis.edu/news/item?news_item_id=100466 (describing a speech by Stuart Altman, a leading health care economist and co-chairman of The Massachusetts Governor's and Legislative Health Care Task Force).

155. CEJA REPORT, *supra* note 61, at 4.

156. Amy Zipkin, *The Concierge Doctor is Available (at a Price)*, N.Y. TIMES, July 31, 2005, at C6.

157. *Id.*

158. *See* GAO REPORT, *supra* note 1, app. II (charting the rate of prevalence of retainer practices).

159. *Id.* at 17. The GAO was directed to study retainer care pursuant to the Medicare Prescription Drug, Improvement, and Modernization Act of 2003.

> The phenomenon of retainer practice is inherently self-limiting. The more physicians charge for their services, the smaller the demand for their services. Retainer practices will generate higher costs for those patients who are willing and able to pay for higher levels of service, but not necessarily for those patients who cannot afford those higher levels of service. These economic realities limit any potential for widespread adoption of retainer practice and any potential for growth in retainer practice to adversely impact patient access to care.[160]

This analysis suggests that, like most other luxury goods, retainer care will simply be enjoyed by a small elite and will not divert resources from others. Or if it becomes widespread, physicians will flood into the market and increased supply will bring costs down.

This simple model of supply and demand ignores several peculiarities of the market for professional services in general, and medical care in particular. On the supply side, the number of doctors available cannot rapidly increase simply because a new model of financing increases demand for their services. Supply is rigidly limited by restrictions imposed both on the number of medical schools and on the number of residencies available after undergraduate medical education.[161] On the demand side, the dynamics of positional goods and auction effects are poised to push retainer care toward a "tipping point" of ever-increasing bidding for physician services.[162] The economics of positional goods suggests the rapidity with which bidding wars for superior professional services can escalate in response to changes in the financing patterns of markets for knowledge-based services.[163] It is odd to hear proponents of retainer care use its rarity as a rationale for not regulating it, since legal controls (or uncertainty over their application) may themselves be the *reason* for its rarity. Much health care financing innovation is driven by the legal system – including the statutes governing Medicare, state insurance law, and the mass of regulations and

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160. MAUNEY, *supra* note 61, at 2.

161. *See* KENNETH M. LUDMERER, A TIME TO HEAL: AMERICAN MEDICAL EDUCATION FROM THE TURN OF THE CENTURY TO THE ERA OF MANAGED CARE 214 (1999) (discussing the role of the Liaison Committee on Medical Education, "established in 1942 as a cooperative effort of the Association of American Medical Colleges and the Council on Medical Education and Hospitals of the American Medical Association.").

162. ROBERT H. FRANK, CHOOSING THE RIGHT POND: HUMAN BEHAVIOR AND THE QUEST FOR STATUS 7 (1985) (noting that positional goods are "sought after . . . because they compare favorably with others in their own class"); FRED HIRSCH, SOCIAL LIMITS TO GROWTH 1-12 (1976) (positing that the pursuit of self-interest to advance "to a higher place among one's fellows" results in an over consumption of private goods, reducing the overall net social utility).

163. *See, e.g.*, ROBERT H. FRANK & PHILIP J. COOK, WINNER TAKE ALL SOCIETY 96-97 (1995) (discussing the polarization of incomes among dentists).

guidance documents that interpret those laws. It is no surprise that physicians, uncertain of the legal status of retainer care, have not rushed to embrace the idea.[164] But if the relevant authorities were to decisively adopt a laissez-faire position, they would greatly diminish the marginal cost of conversion to the retainer model caused by legal uncertainty. Legal uncertainty is itself a major cause of the current scarcity of retainer practices, and it is simply disingenuous to argue that the former should be eliminated on account of the latter.

Supporters of retainer care have argued that retainer arrangements are not significant enough to regulate because they will only affect a small number of providers.[165] However, regardless of the degree of diversion of resources *now* occurring, retainer care is likely to prove much more attractive to upper and middle class consumers of health care as it gains in notoriety.[166] As soon as one person in a reference group purchases retainer care, their peers are likely to ask: "How can I deny this to myself? Or my children?"[167] Given the special significance of health care, there are many consumers who will accept nothing less than the "best" available. As retainer care creates new opportunities to break through extant "ceilings" (upper limits) of care generated by public and private insurance systems, it generates new channels for the wealthy to bid away resources from pooled risk purchasers.

For example, when considering several brands of insurance with similar patterns of coverage, a rational consumer would naturally consider the reimbursement policies of each and the degree of access to doctors they permit. Few would want to be part of an aggressively cost-containing plan, if only because doctors would be more likely to avoid them as patients.[168] To the extent the plan limited or delayed reimbursement, their attractiveness as a patient *relative to* other insured persons would drop.[169] Conversely, to the extent the plan

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164. Reporting on its survey of retainer physicians, the GAO reported that various strategies for concierge care practice design have been developed to help concierge physicians avoid potential problems with Medicare compliance, but most GAO survey respondents expressed a desire for more information from HHS to guide them. *See* GAO Report, *supra* note 1, at 17.

165. *See* MAUNEY, *supra* note 61, at 4.

166. *See* Mike Norbut, *Boutique Care Goes Mainstream*, AM. MED. NEWS, Aug. 4, 2003, at 18 .

167. For an economic analysis of the spread of spending norms, see, e.g., DAVID BROOKS, BOBOS [BOURGEOIS BOHEMIANS] IN PARADISE (2000); JULIET SCHOR, THE OVERSPENT AMERICAN (1998); THORSTEIN VEBLEN, THEORY OF THE LEISURE CLASS 35-36 (1992); NICHOLAS XENOS, SCARCITY AND MODERNITY 85 (1989) (discussing competitive consumption). For a critical analysis of the limits of parental obligation to children, see ADAM SWIFT, HOW NOT TO BE A HYPOCRITE: SCHOOL CHOICE FOR THE MORALLY PERPLEXED (2003).

168. FURROW ET AL., *supra* note 82, at 595-97.

169. Mark O. Hiepler & Brian C. Dunn, *Irreconcilable Differences: Why the Doctor-Patient Relationship is Disintegrating at the Hands of Health Maintenance Organizations and Wall Street,*

guaranteed quick or generous reimbursement for procedures, an insured person's *relative* attractiveness as a patient would increase.[170]

Since most large insurance companies' business plans require them to spread risk over thousands of subscribers for each particular product they offer, they do not yet offer a very wide variety of specifically tailored plans to subscribers.[171] The average large employer, for instance, only offers a few different plans to its employees.[172] However, with the rise of retainer care, medical practices are cutting out the middleman and offering a tailored version of insurance directly to their patients.[173]

In this way, retainer care permits consumers to distinguish themselves even further in the pool of insured patients. Whereas before one could only buy the best health plan one's employer offered, retainer care permits one to leverage such a plan into extraordinary primary care and lavish related services.[174] Meanwhile, the retainers collected by those offering this level of service allow them to treat fewer patients while making the same (or, often, more) income than they made when only third-party insurers paid.[175]

Therefore, retainer care intensifies the pressures for relative position already present in the insurance market. As more consumers opt for the retainer model, fewer doctors are available to the rest of the market. The resulting scarcity makes the retainer model all the more *relatively* attractive, foreshadowing a self-reinforcing exodus from third-party insurance *simpliciter* to the type of third-party-payor plus retainer-payment model.

The combined effects of supply restrictions and positional competition (by physicians, for income, and patients, for care) raise the possibility that retainer care conversions may be a self-reinforcing, rather than a self-limiting,

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25 PEPP. L. REV. 597, 606 (1998).

170. Deven C. McGraw, Note, *Financial Incentives to Limit Services: Should Physicians Be Required To Disclose These To Patients?*, 83 GEO. L.J. 1821, 1839 (1995).

171. *See* BARRY R. FURROW ET AL., THE LAW OF HEALTH CARE ORGANIZATION AND FINANCE 201 (4th ed. 2001).

172. *See* FURROW ET AL., *supra* note 82.

173. *See* Hoffman, *supra* note 26. In order to avoid state regulation of insurance plans, many retainer practices dispute this characterization of the fee, claiming that it is simply a fee for "better service," not for "medical care" itself. I give some reasons for skepticism about that characterization in Part V of this Article (discussing the recent history of state insurance regulation applicable to provider-sponsored organizations (PSOs)).

174. *See* Vasilios J. Kalogredis, *Should You Consider Concierge Medicine?*, PHYSICIAN'S NEWS DIG., Feb. 2004, *available at* http://www.physiciansnews.com/business/204.kalogredis.html.

175. *See* Andrew Haeg, *Top-Shelf Health Care – If You Have the Money* (Minnesota Public Radio broadcast June 24, 2002), *available at* http://news.minnesota.publicradio.org/features/200206/24_haega_conciergecare/.

phenomenon. Looking back on the literature on the conversion of non-profit hospitals to for-profit status over the past decade or so, it is remarkable how often the terms "rapid," "sudden," and "revolutionary" are used to describe the development.[176] Of course, commentators had several explanations for the apparent inevitability of the trend once it was well-established. The for-profit chains skimmed off the most profitable work; they had far more access to capital necessary for technology-intensive care, and thereby initiated a competitive dynamic that severely disadvantaged non-profits.[177] The same trends are now fueling the rise of specialty hospitals, which only perform surgeries with very high profit margins.[178] These market dynamics may also direct the most profitable patients toward retainer care.

Doctors feel increasingly pressed for time with their family or outside-work interests, and for money to pay off education debt and malpractice insurance.[179] Few will reject an opportunity to increase income *and* leisure simultaneously

176. *See* ROBERT KUTTNER, EVERYTHING FOR SALE: THE VIRTUES AND LIMITS OF MARKETS 126 (1996) ("Historically, one segment of the hospital industry was for-profit, but such hospitals were invariably locally owned. In less than a decade, the vast majority have now become owned by absentee companies, usually the result of merger-and-acquisition binges orchestrated by entrepreneurs.") (citing Zachary Schiller, *Balance Sheets that Get Well Soon*, BUS. WEEK, Sept. 4, 1995, at 80-84).

177. *See id.*

178. David Armstrong, *A Surgeon Earns Riches, Enmity by Plucking Profitable Patients*, WALL ST. J., Aug. 2, 2005, at 1 ("The debate . . . [over surgeon Larry Teuber's Black Hills Surgery Center] mirrors national concerns about specialty hospitals, which are typically doctor-owned for-profit facilities that focus on a narrow range of services . . . . Critics say specialty hospitals harm hospitals that serve poorer and sicker patients, and lead to waste of health care dollars by driving people to get unneeded surgery.").

179. *See* Linz et al., *supra* note 79, at 516 ("Physician dissatisfaction with the typical selective contracts used in HMOs, or managed care programs, have emerged as an impetus in the development of the concierge care model. Standard contracts often impose discounted fees that require physicians to rapidly increase their number of patient visits per day, compelling brief visits that are typically limited to an average of five to ten minutes per person . . . . Many physicians note that the managed care contracts cause much frustration for them as they attempt to deliver competent care to their growing number of patients, counteract rising financial costs, preserve personal and family time, and cope with the legal constraints and malpractice threats that are common with managed care."); Ken Carlson, *Loan Repayment Carrot Helps Keep Doctors: Awards in Exchange for Staying in Area*, MODESTO BEE, May 20, 2006, at B1 ("Young physicians may have as much as $200,000 in education debt, while trying to pay for malpractice insurance and other startup expenses for a practice. 'That kind of debt burden is actually dissuading young physicians from choosing a practice in primary care, pediatrics and family medicine,' said Dr. Peter Broderick, director of the Stanislaus Family Medicine Residency Program. 'Those practices tend to be the lowest compensated.'").

without serious thought. MDVIP appears so confident of the trend that it has even attempted to franchise its business model.[180] More subtle – but just as powerful – pressures are also important. Any given primary care physician's frame of reference for her "correct" or "fair" compensation will usually include the other doctors in her area who work approximately as many hours as she does.[181] Once one retainer care practice begins reporting extraordinarily high incomes, it should not be surprising if others follow suit. Indeed, if retainer care were to become widespread, insurance practices may start taking the compensation into account in their reimbursement levels, much as restaurant owners depend on waiters' tips to supplement inadequate wages.[182]

Thus, retainer care threatens to intensify already-existing trends toward polarization of incomes in professional services. Previous tiering made specialty practice more remunerative than primary care; now primary care itself is becoming more stratified. Consider the story of dentists, health professionals whose reliance on "out-of-pocket" payments has been greater than that of physicians for some time.[183] Among dentists in the 1980s, there

> was a dramatic shift in the distribution of their earnings about the median. Whereas fewer dentists earned incomes in the moderately high range of $60,000 to $120,000, the numbers increased sharply at both the low and high

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180. *See* Allen, *supra* note 1 ("Retainer medicine has spread beyond select markets on the east and west coasts. Boca Raton-based MDVIP has helped to set up about 60 physicians in retainer-medicine franchises in 10 states – offering the doctors expensive assistance in transitioning to, maintaining, and building such practices. Using the MDVIP identity as part of their marketing, the practices agree to a maximum of 600 patients per physician and a charge of $125 per month, per person.").

181. *See* Robert H. Frank, *The Frame of Reference as a Public Good,* 107 ECON. J. 1832 (1997). Frank discusses how satisfaction is often directly related to one's relative position. In a society where nearly all doctors work long hours, no one doctor doing so is likely to feel dissatisfied about his or her situation. However, once a sector within the profession begins to work less, at the same (or greater) pay, dissatisfaction is likely to arise.

182. *See* Michael Kinsman, *Gratuity Mystery*, SAN DIEGO UNION-TRIB., Nov. 12, 2006 ("Tips are the lifeblood of minimum-and low-wage workers in service industries. Without the promise of tips, restaurant and bar owners say they would be hard-pressed to pay high enough wages to attract workers for many jobs.... [S]ome companies attempt to use tips to drive down labor costs. Restaurant owners often use tips to subsidize the low salaries of employees who don't interact with the public.").

183. *See* FRANK & COOK, *supra* note 163, at 97 ("Although we cannot measure the precise extent to which growing inequality among dentists is the result of [processes of positional competition], this much seems clear: The available data rule out changes in human capital as a significant explanation.").

ends of the earnings spectrum.[184]

Robert Frank gives a number of explanations for the trend, including the decline in demand for "primary dental services" (due to increased fluoride use), the rise in demand for cosmetic dentistry, and a decline in the number of students accepted annually to dental school (from around 6,000 in 1982 to 4,000 in 1994).[185] Each of these has parallels in a primary medical care field affected by retainer care: consumers increasingly seeking direct access to specialists (via Preferred Provider Options) and "cosmetic" amenities like better waiting rooms and staff treatment, and a declining number of primary care hours available. A practitioner aware of trends in fields like dentistry, sales, and law would be cautious about missing out on a chance not only to enhance her current position, but also to avoid consignment to the bottom of the physician income scale (where those who fail to entrepreneurially market their services seem increasingly likely to go).[186]

B. Physician Shortage?

Advocates of retainer care may accept all the arguments in Section IV.A above, and turn them into another, more forward-looking argument for retainer practices. Even if rapid increases in primary care physician incomes cause painful adjustments now, they will eventually draw more doctors to the field. To the extent they improve doctors' salaries and living conditions, retainer practices may divert health care dollars to a cash-strapped primary care system and, presumably, away from the specialty care that has come to dominate both medical school curricula and the professional aspirations of the most ambitious medical students.

Several sources have documented a decline in the number of new physicians choosing primary care (although there appeared to be a slight increase in the late 1990s as managed care began directing funds to these frontline doctors as

184. *Id.* at 89.

185. *Id.* at 96-97 ("Jim Bader, editor of the *Journal of Dental Education* . . . notes that although the demand for primary dental services has declined slightly as a result of fluoride use, there has been strong growth in the demand for cosmetic, consumer-oriented dentistry . . . . Taken together these changes appear to have created ample opportunity for self-reinforcing [winner-take-all effects], like the ones that have characterized competition for top positions in other fields, to have expressed themselves in dentistry as well.").

186. Positional competition for income can include both a desire to get ahead of others, and a desire not to fall behind. Each motivation can lead to self-reinforcing dynamics that polarize income. *See* Brighouse & Swift, *supra* note 145, at 475.

gatekeepers).[187] Presumably, opportunities for a "lifestyle" practice in primary care may cause some would-be dermatologists and radiologists to reconsider their specialization.[188] More pointedly, those who are strongly motivated by monetary gain may be led away from traditional specialty choices back to primary care.

This Article does not attempt to assess the wisdom of drawing more physicians away from specialty practice and into primary care.[189] However, even if one concedes the desirability of this goal, the spread of retainer care seems a singularly inefficient way of achieving it. Physicians in the United States already earn two to three times as much as their counterparts in Europe.[190] To the extent retainer care incentivizes physician training by reducing workload, it would tend to exacerbate the primary care physician shortage. Retainer doctors see between one-tenth and one-half of the patients borne by their non-retainer peers.[191] Moreover, they primarily serve the type of sophisticated, wealthy health care

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187. 2001 was the fourth straight year that the number of medical school seniors choosing primary care dropped. AM. ACAD. OF FAMILY PHYSICIANS, *supra* note 30.

188. Those concerned with controlling their hours often choose these very competitive residencies. *See* Sid Kircheimer, *Fewer People Want To Be Doctors: Med Students More Likely to Choose Specialties Based on Lifestyle*, WEBMD MEDICAL NEWS, Sept. 2, 2003, http://my.webmd.com/content/article/73/82011.htm.

189. There has been a great deal of controversy over the proper number of physicians in the United States. There were alarming reports of an impending physician shortage in the 1960s. *See* LUDMERER, *supra* note 161, at 398. The federal government responded by increasing funding of undergraduate and graduate medical education. *Id.* at 401. Proponents of managed care claim that the program "worked too well," producing a glut of overcapacity that third-party payers have only begun to wring out of the system. *See* DRANOVE, *supra* note 19, at 54. Commenting on the decline in medical school applications in the mid-1990s, Dranove later admits that "with the complex combination of incentive problems in the market, it is impossible to determine whether we have too few or too many physicians, or receive too few or too many services." *Id.* at 129.

190. *See* Gawande, *supra* note 28; Paul Krugman, *The Medical Money Pit*, N.Y. TIMES, Apr. 15, 2005, at A16 (noting that American physicians earn two to three times as much as their European counterparts).

191. John D. Goodson, a primary-care physician and associate professor at Harvard Medical School, puts it this way:

> Think about this in a macro way . . . . Say you lose ten or fifteen percent of your doctors. In the overall system, you end up reducing by a significant percentage the patient-hours of care, and everyone else who's left behind is suddenly working harder. There is already a shortage of primary-care docs. What's to prevent any doctor from starting to charge fees? The whole thing could mean the Balkanization of American medicine.

Devin Friedman, *Dr. Levine's Dilemma*, N.Y. TIMES MAG., May 5, 2002, at 23 (internal quotation marks omitted).

consumers who seem best able to navigate the health care system on their own.[192] Finally, there appear other, less stratifying alternatives available – such as expanding the number of medical schools, the number of doctors they train, or the number of foreign nationals permitted to practice in the United States.[193]

Despite these options, groups like the AMA would likely point to falling medical school applications as evidence that the present level of compensation, prestige, and leisure available to physicians is not enough to incentivize the lengthy and costly educational investment medical practice now demands.[194] However, given the limited number of patients that retainer doctors see, it seems very inefficient to use this type of financing arrangement to counteract the trend. Since retainer care is primarily being adopted by more established practices, it seems just as likely the physician-hours brought "off line" by retainer conversions will swamp the putative wave of new applicants drawn to practice by retainer care. The retainer care model only permits doctors to increase income and leisure time by reducing the number of patients they see – sometimes quite dramatically.[195] Finally, and most importantly, the number of slots in undergraduate and graduate medical education are fixed, and there are far more applicants than slots for each.[196] Even if retainer care somehow motivated a

192. *See National Survey*, *supra* note 55, at 1082 ("[W]e found that retainer physicians have smaller proportions of patients with diabetes, and perhaps other chronic diseases, than do their non-retainer counterparts and they care for fewer African-American and Hispanic patients. Given that minorities are already underserved and at risk for worse health outcomes, our findings suggest that retainer practices could contribute to tiering of health care and to disparities in health care according to race as well as wealth.").

193. *See, e.g.*, Bollinger, *supra* note 36, at 513 (discussing the Mexico Physician Pilot Program).

194. *See* Randal C. Archibold, *Applications To Medical Schools Decline For Second Straight Year*, N.Y. TIMES, Sept. 2, 1999, at A23 (noting that factors in the decline include "a more difficult job market for medical school graduates, and complaints by doctors of excessive paperwork and a loss of autonomy brought on by the growth of managed care." Additionally, "Jordan Cohen, president of the American Association of Medical Colleges, agreed that the economy might explain the decline but also blamed the growth of managed care.").

195. *See National Survey, supra* note 55, at 1079 ("Retainer physicians have much smaller patient panels (mean 898 vs, 2303 patients, $P<.0001$) than their non-retainer counterparts, and care for fewer African-American (mean 7% vs. 16%, $P<.002$), Hispanic (4% vs, 14%, $P<.001$), or Medicaid (5% vs. 15%, $P<.001$) patients.").

196. "U.S. medical schools graduate roughly 17,000 new physicians every year, out of over 45,000 students a year who apply." *The Doctor Quota*, J. COM., Mar. 4, 1997, at 8A (describing a "campaign" by U.S. doctors to "restrict the number of foreign-trained physicians in the United States."). The AMA strictly controls the number of medical schools, and "[t]here are still two applications for every opening at medical school, and, on average, the academic qualifications of applicants hasn't changed. So there is still a cadre of highly qualified, dedicated, and smart people going to medical school." Kircheimer, *supra* note 188 (quoting Barbara Barzansky, author of a

massive increase in the number of medical school applications, its proponents identify no mechanism that would lead to a commensurate increase in the capacity of medical schools to educate them.[197]

C. Treating the Sickest Patients?

Proponents of retainer care may claim that it takes upon itself a reverse moral hazard that ultimately alleviates pressures on the health care system. Under traditional moral hazard analysis, asymmetric information between purchasers and providers of health insurance can permit the former to take advantage of the latter.[198] Given a simple model mapping demand for health care to willingness to pay, only those patients needing the most attention from the health care system should be willing to pay for retainer care. This is a potentially powerful argument given the concentration of health care costs among the chronically ill (i.e., the sickest 10% of the population).[199] If retainer physicians are treating the sickest patients, they may well be reducing demand for health care to the same extent their retainer care conversions reduce the supply of primary care physician-hours.

There are several reasons to doubt this possibility. Although health care

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study indicating that applications to the nation's medical schools have decreased since 1997).

197. Indeed, the medical profession's tight control over the number of doctors is the main cause of the current primary care physician shortage. *See* Uwe E. Reinhardt, *The Economic and Moral Case for Letting the Market Determine the Health Workforce*, *in* THE U.S. HEALTH WORKFORCE: POWER, POLITICS, AND POLICY 8 (Ellen Osterweis et al. eds., 1996) (arguing that "advocate[s] for artificial limits on entry into the profession ought to be able to explain . . . [to] the thousands of qualified and highly motivated American youngsters who have vainly sought entry into medical school and who quite probably would have been willing to practice medicine at incomes much below those now customary in the profession [why] their rejection serves the nation's best interest.").

198. *See* Malcolm Gladwell, *The Moral Hazard Myth*, NEW YORKER, Aug. 29, 2005 ("'Moral hazard' is the term economists use to describe the fact that insurance can change the behavior of the person being insured .... Insurance can have the paradoxical effect of producing risky and wasteful behavior. Economists spend a great deal of time thinking about such moral hazard for good reason. Insurance is an attempt to make human life safer and more secure. But, if those efforts can backfire and produce riskier behavior, providing insurance becomes a much more complicated and problematic endeavor.").

199. *See* John V. Jacobi, *Consumer-Directed Health Care and the Chronically Ill*, 38 U. MICH. J.L. REFORM 531, 572 (2005) ("Consider how consumer-driven care will affect spending for those on the upper end of the consumption curve – the ten percent accounting for seventy percent of the cost. Those with severe acute and chronic illnesses will incur costs that dwarf their HSA contribution and deductible. Despite the savings gained by transferring these initial costs to the sickest members, sponsors gain no cost-saving value from HSAs for the lion's share of annual health expenditures.").

costs *in general* may be concentrated among the chronically ill, there is little evidence that primary care demand is similarly focused on this group.[200] More directly, given the high percentage of retainer physicians reporting more leisure time after the transition to retainer care, it seems incongruous to attribute to them the assumption of the burden of the sickest. As the most recent comprehensive study of retainer practices noted:

> [C]ritics of retainer practices have argued that these practices might attract wealthier and healthier patients (the "worried well") rather than sick patients with complex illnesses, who tend to be less wealthy but who might benefit most from the additional attention retainer practices can offer. . . . [W]e found that retainer physicians have smaller proportions of patients with diabetes, and perhaps other chronic diseases, than do their non-retainer counterparts and they care for fewer African-American and Hispanic patients.[201]

To understand demand for retainer care, we should focus less on the concentration of care on the chronically ill and more on the concentration of resources in the hands of the wealthiest.

D. Freedom of Contract?

In the face of these challenges, retainer care advocates are likely to fall back on freedom of contract. To the extent that powerful private insurers have attempted to perform the roles of rationing and cost-containment required of national governments, it is not surprising that consumers are attempting to contract around their strictures in order to purchase care.[202] Even if retainer care has doubtful positive social impact, why shouldn't individual patients and doctors have the right to contract with each other for retainer services?[203]

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200. *See id.*

201. *National Survey, supra* note 55, at 1082. The authors of the study do concede that their "data are limited to physicians' estimates of their patients' demographic and illness characteristics and therefore do not allow for examination of case-mix severity in detail." *Id.*

202. *See* Timothy Stoltzfus Jost, *Why Can't We Do What They Do? National Health Reform Abroad*, 32 J.L. MED. & ETHICS 433, 434 (2004) ("Access to health care would no longer depend on belonging to a social insurance plan (which was usually, in some sense, employment-related), but rather would be free at point-of-service to all residents. Thus, universal coverage was created independent of the economic or employment status of any individual.").

203. Eugene Volokh goes so far as to characterize this as a constitutional right to "medical self-defense." Eugene Volokh, *Medical Self-Defense, Prohibited Experimental Therapies, and Payment for Organs*, 120 HARV. L. REV. (forthcoming 2007). However, he notes that distributive concerns could lead to a qualification of the right via regulatory price ceilings. *Id.* at 25 ("The 'rich outbidding others' concern . . . only supports capping payments at the level that all funders would

Retainer care advocates take some comfort in the existence of "parallel private systems" of health care that exist in nearly all nations with a dominant national health care system.[204] As Timothy Jost has observed:

> In countries with universal public health services (the Beveridge model), persons who purchase private health insurance do so in order to obtain health services more quickly and conveniently, in more pleasant settings, or from more prestigious professionals than is possible under the public system to which they also have access.[205]

Even the Quebec health care system, which had long attempted to discourage "contracting around," has now been forced to permit it due to a recent Canadian Supreme Court ruling.[206]

Given that even the most egalitarian national insurance systems permit the wealthy to purchase either more immediate access to health care or better health care, restrictions on retainer care in the United States' highly privatized system might seem incongruous. If the Canadian Supreme Court has decreed a fundamental right to purchase health care above and beyond that provided by the

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pay, likely the level at which they'll still be saving money by getting an organ instead of paying for long-term dialysis."). *See also* Frank Pasquale, Medical Self-Defense or Bidding War, Concurring Opinions, Nov. 13, 2006, *available at* http://www.concurringopinions.com/archives/2006/11/notes_on_medica.html.

204. *See* Jost, *supra* note 202, at 435 ("Countries that have national health insurance programs cover all of their citizens and long-term residents, although in most countries individuals can choose to carry private insurance and obtain services privately. Some countries with social insurance funds, such as France or Austria, cover their entire populations as well. Others, however, such as Germany and the Netherlands, only require people whose income falls below a certain level to be part of the social insurance program.").

205. Timothy Stoltzfus Jost, *Managed Care Regulation: Can We Learn From Others? The Chilean Experience,* 32 U. MICH. J.L. REFORM 863, 864 (1999) (citing Deborah J. Chollet & Maureen Lewis, *Private Health Insurance: Principles and Practice, in* INNOVATIONS IN HEALTH CARE FINANCING: PROCEEDINGS OF A WORLD BANK CONFERENCE 104-09 (George J. Schieber ed., 1997)) (describing the role of private health insurance in ten Organisation for Economic Co-operation and Development (OECD) and thirty-six non-OECD countries). *See also* Jost, *supra*, at 864 ("In the United Kingdom, for example, persons rely on private insurance normally to permit queue-jumping for certain kinds of surgery, while in Australia private insurance pays for hospital care in private facilities. In some countries with social health insurance systems (the Bismark model), on the other hand, private health insurance is limited to persons, usually with high incomes, who are not legally obligated to participate in the national social insurance program. This is the situation, for example, in Germany and the Netherlands.").

206. Chaoulli v. Attorney General of Quebec, [2005] S.C.R. 791 (Can.) (holding that sections of the Health Insurance Act which outlawed private medical insurance violated the right to personal inviolability as guaranteed by the Quebec Charter of Human Rights and Freedoms).

state, even at the cost of diverting suppliers away from the system overall,[207] how can a sensible American commentator propose to limit the same process here? There are three main reasons why retainer care in these single payer systems poses less of a concern than it does in the United States.

First, all of the nations that permit tiering also provide universal insurance. Though the United States has a patchwork of law, charity, and government assistance that assures *eventual* care to everyone once their condition reaches a certain level of seriousness (or once they are impoverished enough), this patchwork does not assure the same level of social provision for the neediest prevalent in more social democracies.[208] Therefore, concerns about diversion of care are not nearly as pronounced in these countries as they are in the United States. And recent studies have demonstrated that even in these systems, there are significant diversionary concerns.[209]

Second, nearly all of these countries enjoy lower levels of "background inequality" than the United States. As Robert Frank has argued, positional bidding dynamics are most pronounced in countries with high levels of

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207. This diversionary impact is a well-documented phenomenon. *See, e.g.*, Calnan, *supra* note 118, at 16 (2000) (noting that parallel private system in the United Kingdom "redistribute[d] access to resources and manpower in favour of better off patients of working age who live in London and South East England" as "[t]he more privileged sick (in terms of income, class and power) have been 'substituted' for the less fortunate sick who remain on NHS lists").

208. *See* Jacobi, *supra* note 9, at 315 ("While many European countries maintain pockets of private insurance or are experimenting with competitive components to a statutory health insurance system, only the United States relies on a competitive private marketplace and voluntary coverage to provide health insurance to the majority of its citizens.").

209. *See, e.g.*, John Cullis, *Waiting Lists and Health Policy*, *in* RATIONING AND RATIONALITY IN THE NATIONAL HEALTH SERVICE 23-27 (S. Frankel & R. West eds., 1993); Calnan, *supra* note 118, at 17 ("[T]he introduction of market economy principles into the NHS in 1991 has led to a two-tier system of care (patients registered with fund holding practices have easier access to care than those in non-fund holding practices). This might have been one of the reasons why the new Labour government has abolished the internal market and fund holding."); Stephen J. Duckett, *Private Care and Public Waiting*, 29 AUSTL. HEALTH REV. 87 (2005), *available at* http://proquest.umi.com/pqdlink?Ver=1&Exp=1032011&FMT=7&DID=814702051&RQT=309&cfc=1#fulltext (reaching the conclusion that private care leads to longer public waits); Can. Health Servs. Research Found., Myth: A Parallel Private System Would Reduce Waiting Time in the Public System (2005), *available at* http://www.chsrf.ca/mythbusters/pdf/myth17_e.pdf (arguing that England and Australia both have private systems, and that it has been determined that waits for public health care are longest in areas that have the most private coverage); JEREMIAH HURLEY ET AL., PARALLEL PRIVATE HEALTH INSURANCE IN AUSTRALIA: A CAUTIONARY TALE AND LESSONS FOR CANADA, INST. FOR THE STUDY OF LABOR, Discussion Paper No. 515 (2002), ftp://repec.iza.org/RePEc/Discussionpaper/dp515.pdf (reaching the conclusion that a second, private tier creates more problems than it solves, notably it decrease in public access to health care).

inequality.[210] There is more discretionary income to spend on health care, leading to greater potential diversion of resources once the wealthy start bidding on enhanced access to a pool of primary care physicians whose supply is relatively fixed in the short and medium term.[211]

Finally, more progressive income taxation in these universal systems dampens supply-side pressures toward retainer care as well.[212] As advocates of laissez-faire never tire of reminding us, higher income tax rates reduce the incentive to maximize one's income.[213] We can therefore expect the higher income tax rates in social democracies to diminish physicians' incentive to switch to a retainer model.

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210. *See* FRANK & COOK, *supra* note 163, at 213 (proposing progressive taxation to reduce the inequality that exacerbates positional pressures).

211. *See* Joseph P. Newhouse & Charles E. Phelps, *New Estimates of Price and Income Elasticities of Medical Care Services*, *in* THE ROLE OF HEALTH INSURANCE IN THE HEALTH SERVICES SECTOR 261 (Richard N. Rosett ed., 1976) ("Estimates suggest that as one's income increases by some percentage, the demand for health insurance also increases, but at roughly half that rate."). "Medical tourists" from the first world are promoting the segmentation of the health sector in many countries. *Health Care Systems and Approaches to Health Care Report*, *in* GLOBAL HEALTH WATCH 2005-2006: AN ALTERNATIVE WORLD HEALTH REPORT 55, 63 (Claudia Lema et al. eds., 2006), *available at* http://www.ghwatch.org/2005report/B1.pdf ("Health care systems in some countries are being segmented even further by the processes of globalization – in India, Mexico and South Africa private providers cater to foreign 'medical tourists' from high-income countries or from high-income groups in low- and middle-income countries. The assumption behind these policies is that it is more efficient and equitable to segment health care according to income level – a public sector focused on the poor and a private system for the rich that allows the public sector to focus on the poor. But there is no evidence that such a system is more equitable or efficient. The greater likelihood is that it would result in increased inequality as the middle-classes opt out of public sector provision, take their financial resources and stronger political voice with them, and leave the public service as a 'poor service for poor people.'").

212. For a good list of countries providing more comprehensive insurance than the United States, see DANIEL CALLAHAN & ANGELA A. WASUNNA, MEDICINE AND THE MARKET 89 (2006). *See also* Chiara Bronchi & Flip de Kam, *The Income Taxes People Really Pay*, OECD OBSERVER, Apr. 1999, at 13, *available at* http://www.oecdobserver.org/news/fullstory.php3?aid=77 (in the chart provided, only South Korea and Hungary had lower income taxation than the U.S.); Timothy Stoltzfus Jost, *Our Broken Health Care System and How to Fix It: An Essay on Health Law and Policy*, 41 WAKE FOREST L. REV. 537, 538 (2006) ("[T]he quality of the health care Americans receive is no better, and in some respects worse, than that provided in many other countries that spend far less on health care and yet provide it for all of their citizens.").

213. *See* Christine Jolls, *Behavioral Economics Analysis of Redistributive Legal Rules*, 51 VAND. L. REV. 1653, 1655 ("[T]he animating feature of both lawyers' and economists' analyses of tax schemes is their potential to distort people's work incentives.").

V. CRAFTING A TAILORED REGULATORY RESPONSE

The concerns raised in Part IV suggest that retainer care deserves more, not less, regulation. Part III suggested a principled way for the Medicare program to discourage retainer care by applying balanced billing rules. The federal government could also seek to apply the False Claims Act. Since the fee is flat, a patient seeking to "amortize her investment" might go to the doctor very frequently. Unnecessary visits might constitute "services substantially in excess of the patient's needs," which cannot be compensated in accordance with that Act.[214] Finally, if retainer services are offered to Medicare beneficiaries at below-market rates, they may constitute "inducements" forbidden under the relevant fraud and abuse laws.[215]

Yet there is a cost to such federal regulation. Overly aggressive federal interventions could squelch all forms of retainer care. Most of the physicians pioneering retainer practices are committed professionals whose first priority is providing quality health care. They are pioneering innovative preventive care, and at least that aspect of retainer care deserves to be encouraged.

Is there a way to craft a more tailored regulatory response? In conditions of uncertainty, policymakers often turn to the states as "laboratories of democracy." Concentrated in big cities on the coasts, retainer care practices have already attracted some scrutiny from state regulators.[216] These embryonic interventions provide a good starting point for discussion of future regulation of retainer care.

The real challenge for policymakers is to craft a *tailored* regulatory response to retainer care that discourages queue-jumping and amenity-bundling while promoting preventive care. Washington state began to do so by characterizing

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214. GOSFIELD, *supra* note 34, at (paraphrasing 42 U.S.C.A. § 1320a-7(b)(6) (West 2006)).

215. *See* 42 C.F.R. 1003.101 (2004). For a brief account of the inducement provisions, see OFFICE OF INSPECTOR GEN., SPECIAL ADVISORY BULLETIN: OFFERING GIFTS AND OTHER INDUCEMENTS TO BENEFICIARIES (2002), *available at* http://www.oig.hhs.gov/fraud/docs/alertsandbulletins/SABGiftsandInducements.pdf. *See also* Russano, *supra* note 6, at 336 ("If boutique medical practices provide their patients with bonuses such as 'heated towel racks, free hotel rooms, [and] special bathrobes,' these amenities could violate the federal anti-kickback statute or the Health Insurance Portability and Accountability Act prohibiting such inducements. However, since these amenities are offered after payment of a retainer, it is likely that they will be seen as services provided in exchange for payment and not as an 'inducement.'").

216. Carnahan, *supra* note 115, at 122 ("[C]oncierge physicians face numerous legal obstacles from state insurance regulators, private insurers, and the federal government."). *See also National Survey*, *supra* note 55, at 1080 (stating that retainer care practices continue to form across the country, with the greatest concentration found in large cities and coastal states, particularly Washington and Florida).

retainer practices as insurance providers.[217] However, given the legal complexity of this strategy, insurance regulation may not prove an effective way of tailoring regulation. Rather, taxation targeted at the queue-jumping and amenity-bundling aspects of retainer care would provide a more effective response. Already applied to cosmetic surgery and specialty hospitals, such taxation of retainer care – particularly when directed at achieving access for the poor – would assure some principled results from the tiering that retainer care is intensifying.[218]

A. Retainer Care Agreement as Insurance Contract?

Since they sell unlimited amounts of physician time in return for a flat fee, retainer care agreements have been deemed a form of insurance in several states.[219] As the Deputy Insurance Commissioner in Washington stated, "[t]he critical element of the transaction is that risk of the patient's utilization of health-care services during the period is transferred from the patient to the provider for a set amount."[220] Even if a doctor purposely limits her patients to a low number,

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217. *See* Carnahan, *supra* note 115, at 132-34 ("In Washington State, the Office of the Insurance Commissioner (OIC) became concerned that this model may run afoul of state laws that required insurers of health care to have a certificate of registration. The OIC's position was that the arrangement whereby patients paid a fixed fee for the receipt of all primary care services, including future services, transferred risk from the patient to the provider."); Office of the Ins. Comm'r of Wash., Engaging in Activities Requiring a Certificate of Registration, 1 Technical Assistance Advisory Draft (2003), *available at* http://www.insurance.wa.gov/special/accessfees/removed/provider_plans_draft_taa.doc.

218. Note that even advocates of retainer care concede this tiering effect. *See, e.g.*, AMA CMS REPORT, *supra* note 47, at 2 ("Although critics appear to suggest that retainer practice is a radical departure from the way care is currently financed and delivered, a multitiered system of care already exists in the United States, with higher levels of service going to those patients whose health benefit plans offer a wider array of benefits or less parsimonious rates of payment.").

219. *See, e.g.*, Doughton, *supra* note 76 ("Doctors who require insured patients to pay retainer fees for routine medical care are violating state law, says a draft ruling from the Washington Insurance Commissioner's Office. And 'concierge' health services, under which clients pay a flat rate for personalized medical care, may be illegal if they're not licensed as health insurers, the commissioner's office says.").

220. Peter Neurath, *Medical Retainer Fees Violate Law, Ruling Says*, PUGET SOUND BUS. J., August 1, 2003, *available at* http://seattle.bizjournals.com/seattle/stories/2003/08/04/story6.html. Deputy Insurance Commissioner Beth Berendt said that "[t]he fee is paid by the patient regardless of the amount of services provided [and] even if no services are provided. These arrangements result in a transfer of risk and, in essence, are insurance agreements." *Id. See also* Office of Ins. Comm'r for the State of Wash., Forum for Review of Draft Technical Advisories to Health Carriers and their Participating Providers (2003), *available at* http://www.insurance.wa.gov/special/accessfees/removed/public%5Fforum%5Fpresentation.ppt.

she risks simultaneous demands for care from two or more patients.[221] Furthermore, retainer practices might go out of business before they can fulfill their promise to provide care.[222] Each of these risks is reminiscent of the types of problems insurers often have to bond or reinsure against.[223]

Washington[224] and New Jersey[225] have been most aggressive, issuing rules and interpretations that discouraged retainer care. Other states have issued warnings and guidance, but have done little to actually intervene.[226] If they were regulated as insurers, retainer practices would have to satisfy potentially onerous

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221. Steven Flier and Jordan Busch did this when they began PPHC, intentionally limiting themselves to about 300 patients per physician. STOLLER & FERRARONE, *supra* note 140, at 7 (quoting Flier and Busch). Some retainer practices may contract with even fewer families per physician. *Id.* at 13-14.

222. Though I have not yet found examples of large upfront fees paid in exchange for "lifetime care," it is interesting to note that one of the earliest insurance plans involved the exchange of an assurance of a lifetime of care in return for investment in its infrastructure.

223. *See* Portman, *supra* note 2, at 4 ("To the extent that concierge practices charge their members a fixed, prepaid amount for a bundle of guaranteed services, they could be found to be providing insurance in violation of state law."). Any insurance provider must be registered with the state and bonded against the possibility it cannot provide the services/coverage purchased in advance in consideration for the premium.

224. *See id.* at 5 (indicating that according to Portman, "the Washington Insurance Commissioner has issued a pair of draft technical assistance advisories in which it has determined that health care providers entering into arrangements to provide a package of health care services for a fixed, pre-paid fee must first obtain a certificate of registration from the state as either a health care service contractor or health maintenance organization. In a separate draft advisory, the commissioner concluded that health care providers that require patients to pay access fees to receive services covered by their health insurance are acting in violation of state laws requiring providers and plans not to charge more than the covered amount and to hold patients harmless from any amounts not covered by insurance.")

225. BOWDEN & FOUST, *supra* note 144 ("During the summer of 2003 insurance regulators in Washington State circulated two draft advisories warning against 'access' fees and regulators in New Jersey issued a bulletin ordering providers to immediately terminate charging patients access, retention, or service fees.").

226. Some appear to tacitly, if not explicitly, endorse retainer care as a legitimate new method of health care financing. *See, e.g.*, Portman, *supra* note 2, at 5 ("The Massachusetts Department of Insurance investigated Personal Physicians Health Care for discriminating against patients who couldn't afford its annual fee but apparently found no violation of state insurance laws as long as beneficiaries were advised that insurance would not cover the extra fees. The Massachusetts Board of Registration in Medicine, which licenses Massachusetts physicians, also reportedly found nothing illegal about concierge practices."). According to Flier, he repeatedly met with insurance providers and state officials before launching the pioneer Boston retainer practice, Personal Physicians HealthCare, and currently retains lobbyists to assure favorable regulatory treatment. *See* STOLLER & FERRARONE, *supra* note 140, at 15-16.

capitalization requirements, and could not be as flexible in choosing their group of patients.[227] Retainer practices have aggressively lobbied for exceptions or favorable interpretations of the relevant laws, and appear to have stalled legal interventions in two states.[228]

For example, the state of Washington initially moved to characterize retainer practices as insurers,[229] thereby requiring them to certify that they are financially prepared to deal with the "risks" of the practice.[230] One regulator has also attempted to undermine the legal basis of conversions to retainer care, stating that "it's illegal to force patients who have health insurance to pay a retainer fee simply to keep their existing doctor or to get services their health-care policy already guarantees."[231] After retainer physicians and clients registered their vehement opposition to such rules, the "draft technical assistance advisories" announcing the agency's position disappeared from the state government's website, and officials have announced an effort to find "common ground."

New Jersey regulators also began with an aggressive approach, but failed to garner support from politicians. The New Jersey Department of Health and

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227. *See* Doughton, *supra* note 76 ("[I]f doctors want to provide a broad range of medical services for a set fee, they may need to be licensed and regulated as insurers. The state requires insurers to prove they are financially healthy and not likely to go out of business and leave consumers with no medical care, [Washington Deputy Insurance Commissioner Beth] Berendt said. The state also makes it difficult for insurers to kick out patients.").

228. *Id.*

229. *Id.* ("Seattle Medical Associates doesn't get any money from Medicare or other insurance companies. If patients are referred to specialists outside the group, those specialists bill insurance or Medicare separately. But according to the commissioner's preliminary rulings, the group may require a state insurance license, because it operates somewhat like an insurance company.").

230. *See* BOWDEN & FOUST, *supra* note 144, at 7 (stating that the Insurance Commissioner permitted retainer care "if the services offered for the fee were truly noncovered and the fees were optional. Mandatory fees could be charged when the patient is uninsured, the provider is non-participating, or the patient is covered under an indemnity policy that does not require use of a participating provider. The draft advisories have been withdrawn before being finalized. In addition, the Insurance Commissioner withdrew the pursuit of H.B. 2815 in the 2004 Washington Legislature in order to "develop legislation that would address the needs of everyone."). *See also* Marquis, *supra* note 2, at 18 (implying that the Washington Insurance Commissioner is currently trying to develop a consensus on regulation of retainer care, due to the Washington State Medical Society's successful opposition to the Insurance Commissioner's effort to get the legislature to "codify the content" of its advisories as a statute).

231. Romano & Benko, *supra* note 81, at 38 ("Paul Ginsburg, president of the Center for Studying Health System Change, a Washington-based research group, says there's nothing to stop a physician from charging wealthy, fee-for-service clients whatever they choose. The problem, he says, arises when companies such as MDVIP offer services only to members, thus denying access to many longtime patients either unwilling or unable to pay the annual fees.")

Human Services and Department of Banking and Insurance issued a memorandum prohibiting insurers from contracting with doctors who require patients to pay fees for access, even when fees are for additional services.[232] The Departments asserted that New Jersey's "non-discrimination" laws prevent practitioners participating in managed care networks from conditioning access to their clinic on retainer-like payments.[233] However, it is difficult to assess the legal force of this document, and it is hard to find evidence that retainer care has been eliminated in New Jersey.[234]

Regulation of retainer practices as insurance may be on shaky ground legally as well as politically. Such regulation hinges on an assertion that retainer practices bear risk in a manner similar to that of traditional insurers.[235] However, it is easy to imagine ways of contracting out of such risk. For example, a retainer contract might promise 24/7 attention, *unless* another member of the plan demanded the physician's attention immediately before one calls. Or it might shift the risk of insolvency onto the patient, or effectively disguise the transfer of risk by having the patient pay in arrears instead of in advance. Finally, even though sick patients may be very demanding of their primary care physician's *time,* the physician is not promising the broad range of services traditionally packaged by insurers. If the baseline contract for additional services is legal, it is difficult to see how these limitations on service would be forbidden. Professor Thomas Mayo has questioned Washington State's application of its insurance laws to retainer practices:

> In what sense do the doctors take on risk? The care isn't pre-paid with the retainer; only access is pre-paid. The patient's health insurer is going to be tapped for the care, and no part of the insurer's risk is being shifted

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232. Holly Bakke, Dep't of Banking & Ins. State of N.J. (DOBI), & Clifton Lacy, Dept. of Health & Senior Services (DHSS), State of N.J., DOBI/DHSS Bulletin 2003-02 (Aug. 8, 2003), *available at* http://www.state.nj.us/dobi/bullet03.shtml [hereinafter DOBI/DHSS Bulletin].

233. *Id.* at 2 ("Rather, the Departments' position is that retainer agreements are inconsistent with the requirement that all provider agreements subject to New Jersey law assure that in-network providers do not discriminate in treatment of members or covered persons.").

234. Silverman, *supra* note 12, at 6 ("Health departments and insurance commissioners pose another credible risk to [retainer] practices. In 2003, New Jersey's health department found that physicians who already had contracts with HMOs were requiring HMO patients to pay an annual fee to get into their practices. . . . New Jersey asserted that this requirement was illegal, even though the fee in these practices was limited to services that were clearly not covered by the health plan. 'They're stating, 'We don't care if the service is covered by the health plan or not. It's illegal if you charge that 'poll tax' for a patient to get into the practice,' Mr. Marquis said.'").

235. This is an attractive "peg" to hang regulation on, since many retainer practices contract for an unknown amount of care for a fixed annual fee. The retainer physician risks taking on extraordinarily demanding patients who may well demand far more care than average.

> downstream to the physician. Granted, there is some risk that the demand for services at any given time might outstrip the physician's ability to schedule, but that's not a financial risk, is it?[236]

Some mid-1990s guidelines regarding the regulation of "provider sponsored organizations" echoed this distinction, noting that providers could commit to potentially unlimited amounts of their own time (in return for a fee), and this would not represent financial risk.[237]

B. Targeting Queue-Jumping and Amenity-Bundling via Taxation

Given the legal uncertainty surrounding the regulation of retainer care agreements as insurance, another tool of legal intervention is likely necessary. An indisputably positive facet of extant retainer care practices provides an important clue on where to look. Some retainer care practitioners use the time gained from retainer practice to provide pro bono care – a model that is well established in legal practice.[238] Moreover, some large retainer practices, such as one based at Tufts University, directly subsidize access to care for the disadvantaged. Instead of passing the retainer fee from wealthy patients to wealthy physicians, the hospital is using the money "to subsidize the hospital's primary care practice."[239]

To the extent these countervailing, socially conscious practices arise out of

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236. Thomas Mayo, Medical Retainer Fee (a/k/a "Boutique Medicine") Nixed in Washington, HealthLawBlog (Aug. 5, 2003), http://healthlawblog.blogspot.com/2003_08_01_healthlawblog_archive.html. Nevertheless, one practitioner warns that any retainer practice which "provides unlimited physician office visits" might end up being regulated as an insurer. *See* Portman, *supra* note 2, at 4-5 ("Unlike physician networks or IPAs [Independent Practice Associations], which have generally been found not to be insurance companies because there is another risk bearing entity in the chain of treatment and payment – *i.e.*, a health insurer or HMO – [that] is subject to state insurance regulations, concierge practices that do not accept insurance and provided prepaid medical care may be perceived as the only risk bearing entity in the patient's chain of care.").

237. *See* John S. Conniff, *Regulating Managed Health Care: Provider Sponsored Organizations*, 16 J. INS. REG. 377 (1998); Edward B. Hirshfeld et al., *Structuring Provider-Sponsored Organizations: The Legal and Regulatory Hurdles*, 20 J. LEGAL MED. 297 (1999); Allison Overbay & Mark Hall, *Insurance Regulation of Providers That Bear Risk*, 22 AM. J.L. & MED. 361 (1996). Federal regulation has also sparked academic commentary. *See, e.g.*, Michael O. Spivey & Jeffrey G. Micklos, *Developing Provider-Sponsored Organization Solvency Standards Through Negotiated Rulemaking*, 51 ADMIN. L. REV. 261 (1999).

238. *See* Silverman, *supra* note 62 ("Charity care for retainer physicians averaged 9.14 hours per months versus 7.48 hours per month for nonretainer practices.").

239. This is the Tufts-New England Medical Center plan featured in Steve Smith, *The Boutique Medicine Boom: Perspectives on the Growth of a Controversial Trend*, PRAC. BUILDERS, Sept.-Oct. 2003, at 1.

retainer care, we might say that it causes "difference principled" tiering, after the famous proviso of Rawls' *A Theory of Justice*, which stipulates that any increase in inequality is acceptable to the extent it raises the welfare of the least well off.[240] It is doubtful that such "difference principled" tiering currently outweighs the "brute tiering" that denies the services of retainer doctors to those who cannot afford their fees. However, states can begin using targeted taxation to alleviate brute tiering and promote "difference principled" tiering arising out of retainer care.

For example, states have already addressed the diversion of medical resources to non-medical ends via tax policy in the context of plastic surgery. New Jersey has imposed a six percent tax on cosmetic plastic surgery procedures.[241] Illinois has been considering a similar effort with redistributive designs – funds from a "vanity tax" would be earmarked for medical research.[242] A similar tax on the amenities bundled into retainer care agreements would help assure that some portion of the money spent to divert medical resources to non-medical ends would itself be diverted back toward genuine health care.

Admittedly, valuation problems are sure to arise. Just as New Jersey regulators have been skeptical about retainer physicians' ability to distinguish between ordinary medical care (meriting insurance reimbursement) and retainer services (paid for by retainer fees), critics of my proposal may charge that retainer clients are paying for the entire experience of retainer care and that no particular aspect of that experience can be disaggregated from the whole and given a market value. However, as the diversity of retainer practices increases, it should be easier to perform the type of hedonic pricing that has allowed economists to, for example, price the value of an eighth-story view of a park.[243]

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240. JOHN RAWLS, A THEORY OF JUSTICE 54 (1999) ("All social values – liberty and opportunity, income and wealth, and the social bases of self-respect – are to be distributed equally unless an unequal distribution of any, or all, of these values is to everyone's advantage."). I have coined the term "difference principled" to designate tiering that is both principled and in accord with Rawls's theory of justice.

241. N.J. STAT. ANN. § 54:32E-1 (West 2006) ("There is imposed and shall be paid a tax of 6% on the gross receipts from a cosmetic medical procedure, which shall be paid by the subject of the cosmetic medical procedure . . . ."). *See* Susan Jones, New Jersey Taxes Cosmetic Surgery, CNSNews, July 1, 2004, http://www.cnsnews.com/ViewNation.asp?Page=%5CNation%5Carchive%5C200407%5CNAT20040701a.html.

242. Beth Kapes, *Vanity Tax Would Fund Stem Cell Research*, COSMETIC SURGERY TIMES, May 1, 2005.

243. *See* Maureen L. Cropper & Wallace E. Oates, *Environmental Economics: A Survey*, 30 J. ECON. LIT. 675, 703-10 (1992) (discussing how "the price of a house or job can be decomposed into the prices of the attributes that make up the good, such as air quality," and assessing methods of such decomposition, including wage-amenity studies, hedonic labor markets, and hedonic travel

No one sells "eighth-story views of parks" on eBay, but economists can compare the prices of very similar apartments with and without such views and develop a rough sense of how much the view itself contributes to the value of the property.[244] Similarly, we can begin to assess the value of a given retainer perquisite by comparing the cost of joining that practice with the cost of joining a practice that offers all but that perquisite.

Less ambitiously, regulators may just ask for an accounting of the cost of the amenities provided by the retainer practice. Personal Physicians HealthCare of Boston has spent at least a million dollars on its office's infrastructure, including a luxury waiting area appointed with fine furniture and art.[245] A rough accounting of the practice resources and physician time devoted to amenity services should provide some basis for a tax on them.

Some forward-looking retainer practices have begun to recognize and counteract their negative effects on access to care. For example, Tufts University hospital, a teaching hospital in Massachusetts, has used retainers to fund its charity care.[246] To the extent a retainer practice takes on this type of redistribution itself, it might be exempted from taxation designed for the same ends.[247] Furthermore, a state may decide not to tax retainer revenues that support

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costs). *See also* Brian R. Binger et al., *The Use of Contingent Valuation Methodology in Natural Resource Damage Assessments: Legal Fact and Economic Fiction*, 89 NW. U. L. REV. 1029 (1995); Frank B. Cross, *Natural Resource Damage Valuation*, 42 VAND. L. REV. 269 (1989); David A. McKay, *CERCLA's Natural Resource Damage Provisions: A Comprehensive and Innovative Approach to Protecting the Environment*, 45 WASH. & LEE L. REV. 1417 (1988).

244. *See* DAVID PEARCE & DOMINIC MORAN, THE ECONOMIC VALUE OF BIODIVERSITY 71 (1994) (stating that in the hedonic pricing method, "an attempt is made to estimate an implicit price for environmental attributes by looking at real markets in which these characteristics are effectively traded. Thus, 'clean air' and 'peace and quiet' are effectively traded in the property market since purchasers of houses and land do consider these environmental dimensions as characteristics of property.").

245. *See* STOLLER & FERRARONE, *supra* note 140, at 10.

246. *See* Russano, *supra* note 6, at 323.

247. Another example is a cataract clinic in India mentioned in an article generally supportive of retainer care. The author mentions

> [a] scenario whereby the profits from the boutique practice were used to finance a second practice that provided the same service, same world-class technology and cutting edge methods, minus a few of the red carpet frills to the population of poor patients. A fantasy? Hardly, it exists right now, in India in a practice founded by Dr. Govindappa Venkataswamy over twenty five years ago. His Aravind Eye Hospital is now . . . performing 180,000 cataract operations a year, 70 percent of them for free.

Justin C. Matus, Am. Acad. of Med. Adm'rs, Boutique Medicine: Good Medicine With a Bad Taste or Just Bad Medicine?, http://www.aameda.org/MemberServices/Exec/Articles/winter03/boutiquemedMatus.pdf (citing JOAN MAGRETTA, WHAT MANAGEMENT IS (2002)) (last visited Dec.

preventive care services not covered by insurance.

Taxation is an important policy tool here because increasing numbers of retainer physicians may evade insurance-leveraged regulation by becoming "cash-only."[248] This latter development may raise even more serious concerns regarding access to care, since cash-only practices often consist of a very small number of clients paying a very large retainer. For example, under one Seattle plan, each physician takes on fifty families per year, at a cost of $20,000 per family, grossing one million dollars per year. Because of their extremely restricted scope, these practices raise concerns similar to those raised by amenity services: namely, the diversion of medical resources to non-medical ends.[249]

CONCLUSION

The appeal of retainer care arrangements to physicians is undeniable. Unfortunately, what is professionally and personally rewarding for retainer care physicians may harm society as a whole. Retainer care raises difficult policy questions because it combines positive incentives (for more primary care physicians providing a higher quality of care) with financing methods that further stratify access and threaten to generate a bidding war for supplemental, provider-sponsored insurance.

Legal disputes over retainer care have tended to focus on whether retainer payments constitute "balance billing" for services covered by Medicare. This Article has suggested a way to resolve that issue, by disaggregating retainer

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10, 2006).

248. Specialty hospitals have raised concerns because they divert the most lucrative cases to specialized centers that usually do not provide the levels of community services expected from general hospitals. *See* FURROW ET AL., *supra* note 82, at 217-18 (discussing state taxation and regulation of specialty hospitals); U.S. GEN. ACCOUNTING OFFICE, SPECIALTY HOSPITALS: GEOGRAPHIC LOCATION, SERVICES PROVIDED, AND FINANCIAL PERFORMANCE, GAO REP. NO. 04-167, at 4 (2003); William J. Lynk & Carina S. Longley, *The Effect of Physician Owned Surgicenters on Hospital Outpatient Surgery*, 21 HEALTH AFF. 215 (2002).

249. The non-medical end here is the *absolute* assurance of the retainer customers that they will be able to call on their retained physician in case of illness. Steven Flier of PPHC reports that, even with a panel of 300 patients, he has never had two conflicting demands on his time in his three years of retainer practice. *See* STOLLER & FERRARONE, *supra* note 140, at 12. Demanding a panel of less than this size makes the physician retained less a doctor than a courtier, whose primary value derives not from the medical services offered but rather from the sense of assurance and superiority flowing from the client's ability to "reserve" the time of a skilled professional so absolutely. *See* Friedman, *supra* note 191 ("[I]sn't there a decreasing rate of return on the amount of time spent with a single patient? At some point, paying more attention to someone won't really make him or her healthier; it will just satisfy a desire to be pampered. The new practice could end up being more about extravagant service for relatively wealthy people than about effective medical care.").

services into preventive care, queue-jumping, and amenity-bundling. To the extent a retainer practice can plausibly claim that its patients' retainers are funding non-covered preventive care and amenities, they should be safe from liability for balance billing. But to the extent the retainer is funding quicker access to better care, it is a second charge for services already covered by insurance.

Given the importance of queue-jumping to the retainer care business model, most retainers would constitute violations of balance billing under the approach proposed in this Article. Federal regulators could leverage such violations into more aggressive efforts to discourage retainer practices, including prosecution under the False Claims Act. For now, though, such a strategy appears ill-advised. Regulation of retainer care should instead focus on a targeted discouragement of queue-jumping and amenity-bundling via taxation. Such an approach would only raise the price of retainer care, and not ban it outright. Moreover, it could be neutral toward (or perhaps even subsidize) personalized preventive care.

Of course, a nuanced approach should not be a complacent one. Left unregulated, the battle between cost-cutting insurers and revenue-maximizing doctors may result in inefficiencies bordering on cruelty. As budgetary crises lead to further cuts in Medicaid, the uninsured third-class of American health care consumers is sure to suffer more privations.[250] Managed care has made the second-class insured uncomfortable enough to find the blandishments of first class retainer care appealing, even at a price tag of several thousand dollars annually. Given positional pressures to "keep up with the Joneses," the well-off (or those who would like to appear so) are likely to find retainer care a necessary accoutrement of their social station – or at least a way of controlling their schedule in a manner expected of contemporary professionals.

There is no doubt they will be getting value for their money: Most retainer physicians are committed to providing the highest quality of primary care. But as those fortunate enough to opt for retainer care exit the dominant system, those left behind lose a powerful voice for reform within it. Those who pay retainer fees "jump the queue" of rationing tacitly imposed by managed care, and provide a market for the bundling of basic or preventive health care with luxurious amenities. Targeted regulation may not eliminate these effects, but can check them.

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250. *See* Bob Herbert, *Curing Health Costs: Let the Sick Suffer*, N.Y. TIMES, Sept. 1, 2005, at A23 (describing cuts to TennCare program); Gardiner Harris, *Gee, Fixing Welfare Seemed Like a Snap*, N.Y. TIMES, June 19, 2005, § 4, at 3; Robert Kuttner, *Taming the Medicaid Monster*, BOSTON GLOBE, Feb. 16, 2006, at A19; John Jacobi, *supra* note 33 (arguing that many proposed Medicaid reforms would, in addition to weakening Medicaid, also weaken the safety net for the uninsured.).

Fluconomics: Preserving Our Hospital Infrastructure During and After a Pandemic

Vickie J. Williams*

> *There is a bitter little pill of a joke currently circulating among infectious disease experts. It is short: The nineteenth century was followed by the twentieth century, which was followed by the . . . nineteenth century.*
>
> *– Alfred Crosby*[1]

INTRODUCTION

Would an infectious disease pandemic overtax our hospitals to the extent that conditions for treating infectious disease would revert back to those prevalent in the nineteenth century? The United States is not immune to naturally occurring outbreaks of deadly diseases. The United States Centers for Disease Control (CDC) and the World Health Organization (WHO) are currently monitoring a strain of avian influenza, or "bird flu," that has infected 236 people in Asia, Turkey, and Iraq, and has a mortality rate of fifty-eight percent.[2] If this virus mutates to become easily transmissible from person to person, it could

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1. ALFRED W. CROSBY, AMERICA'S FORGOTTEN PANDEMIC xiii (2d ed. 2003).

2. WHO, Cumulative Number of Confirmed Human Cases of Avian Influenza A/(H5N1) Reported to WHO (Aug. 9, 2006), http://www.who.int/csr/disease/avian_influenza/country/cases_table_2006_08_09.

become a pandemic[3] even more deadly than the legendary Spanish flu[4] that swept through the United States and the world in 1918.[5]

The Spanish flu infected more than twenty-five percent of the United States population, and killed 500,000 in the United States alone.[6] It lowered the average life span of an adult in the United States by twelve years.[7] Estimates of the total number of deaths from the Spanish flu worldwide range from 20 million to more than 100 million, with most occurring within the span of twenty-four weeks.[8] If a similar pandemic occurred today, with a similar mortality rate, 1.5 million Americans would die.[9] Virtually all experts agree that it is not a question of *if* but *when* another influenza pandemic as deadly as the Spanish flu will occur.[10] The

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3. A pandemic is "an epidemic of unusual extent and severity," "occurring over a wide geographic area," and "affecting an exceptionally high proportion of the population." WEBSTER'S THIRD NEW INTERNATIONAL DICTIONARY (UNABRIDGED) 1629 (1993).

4. The label "Spanish Flu" is most likely a misnomer. Most epidemiologists and public health experts now believe that the pandemic influenza of 1918 originated in Kansas, or possibly in China. JOHN M. BARRY, THE GREAT INFLUENZA 452-56 (2004). The moniker "Spanish flu" came about because there was heavy press censorship in 1917 and 1918 of anything that could be construed as detrimental to public morale and the war effort in World War I in the United States and most of Europe. Therefore, the American and most of the European press failed to report the alarming number of persons stricken with the flu and the high mortality rate associated with it. *Id.* at 171. Spain did not censor its press heavily during this time. Therefore, the first reports of what became the influenza pandemic came from Spain, giving rise to the moniker of "Spanish flu" for the disease that was sweeping the world. GINA KOLATA, FLU, THE STORY OF THE GREAT INFLUENZA PANDEMIC OF 1918 AND THE SEARCH FOR THE VIRUS THAT CAUSED IT 10 (1999).

5. *See* Marc Santora, *When a Bug Becomes a Monster*, N.Y. TIMES, Aug. 21, 2005, at A29.

6. KOLATA, *supra* note 4, at 6-7. The mortality rate from the Spanish Flu was estimated at 2.5%. *Id.* at 7. In a normal flu year, only one-tenth of one percent of flu victims die. *Id.*

7. *Id.*

8. *See id.*; BARRY, *supra* note 4, at 450. By contrast, through 2004, AIDS had killed 24.8 million people worldwide, but over a period of twenty-four years. *Id.* The toll of the Spanish flu far exceeds the combat deaths experienced by the United States in World War I, World War II, the Korean War, and the Vietnam War combined. Elizabeth Brainerd & Mark Siegler, *The Economic Effects of the 1918 Influenza Epidemic* (Ctr. for Econ. Policy Research, Discussion Paper No. 3791, 2003), *available at* http://ssrn.com/abstract=394606.

9. KOLATA, *supra* note 4, at 7.

10. BARRY, *supra* note 4, at 449. Influenza pandemics occur regularly, although they are usually not as deadly as the 1918 Spanish flu pandemic. The Asian influenza pandemic of 1957 and the Hong Kong influenza pandemic of 1968 were not as deadly as the 1918 Spanish flu pandemic, but did engender high rates of social disruption. The Asian influenza pandemic of 1957 killed 70,000 people in the United States, and the Hong Kong influenza pandemic of 1968 killed 34,000 people in the United States. *Influenza Pandemic—Challenges Remain in Preparedness; Hearing Before the H. Subcomm. on Health, Comm. on Energy and Commerce*, 109th Cong. 1 n.2 (2005) [hereinafter *Challenges Remain*] (testimony of Marcia Crosse, Dir., Health Care, GAO).

United States and the world are engaging in new pandemic preparedness efforts because of the recent emergence of the H5N1 avian flu as a human infection.[11]

The massive outbreak of a disease like avian flu would impose severe economic costs on the health care industry. The CDC estimates that the direct and indirect medical costs in the United States associated with a "medium-level" influenza pandemic would range from $71 billion to $167 billion.[12] Hospitals and other health care providers will absorb a large portion of these costs.[13] Most hospitals in the United States are privately owned, and an increasing number are for-profit enterprises.[14] The current shift from non-profit to for-profit hospital status is coupled with a fragmented American health care financing system. Therefore, we must consider costs of care and compensation well in advance of a public health emergency to avoid the collapse of this important part of our health care safety net.[15]

The broad impact that such a pandemic would have raises a litany of questions: How will the nation's hospitals fair when faced with the financial demands imposed during and after a pandemic? Even if they can withstand the immediate fiscal impact of the pandemic, will they ultimately survive the ordeal? Will they act in the best interests of the public's health, even if it causes them potentially fatal economic injury? Or will they follow the old adage that those who turn and run away, live to fight another day? Will they protect their bottom lines, even if it means a less-than-optimal response to a pandemic? How can we ensure that hospitals comply with, rather than resist, the orders of public health authorities that may be adverse to their economic interests during the next pandemic?

This Article addresses all of these questions. Part II discusses the likely economic consequences of an infectious disease pandemic on our nation's hospitals. Recent examples of health care provider behavior during limited outbreaks of infectious disease demonstrate that guarantees of monetary assistance sufficient to ensure a health care provider's economic health—both

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11. *See, e.g.*, HOMELAND SEC. COUNCIL, NATIONAL STRATEGY FOR PANDEMIC INFLUENZA IMPLEMENTATION PLAN (2006), *available at* http://www.whitehouse.gov/homeland/pandemic-influenza-implementation.html; WHO, WHO GLOBAL INFLUENZA PREPAREDNESS PLAN (2005), *available at* http://www.who.int/csr/resources/publications/influenza/WHO_CDS_CSR_GIP_2005_5/en/index.html.

12. *Challenges Remain*, *supra* note 10, at 2.

13. *See generally* Martin I. Meltzer et. al., *The Economic Impact of Pandemic Influenza in the United States: Priorities for Intervention*, 5 EMERGING INFECTIOUS DISEASES 659 (Sept.-Oct. 1999).

14. Am. Hosp. Ass'n, Fast Facts on U.S. Hospitals (Oct. 23, 2006), *available at* http://www.aha.org/aha/content/2006/pdf/fastfacts2006.pdf.

15. *See* MARK A. ROTHSTEIN ET AL., UNIV. OF LOUISVILLE SCH. OF MED., INST. FOR BIOETHICS, HEALTH POLICY AND LAW, QUARANTINE AND ISOLATION: LESSONS LEARNED FROM SARS 11 (2003).

during and after such an outbreak—are crucial to ensuring quick and complete compliance with the orders of local public health officials. Part III demonstrates that existing law fails to address the economic needs of hospitals dealing with a pandemic. Additionally, it argues that failing to assure hospitals that they will emerge from a public health emergency relatively unscathed acts as a disincentive for hospitals to comply with the orders of public health officials, and endangers the public interest. Part IV proposes legal measures designed to assure the nation's hospitals that they will survive the economic effects of a pandemic. Such measures include reinterpreting the Takings Clause of the United States Constitution, establishing federal reserves to pay for the immediate effects of a pandemic on our nation's hospitals, and legislating a public-private partnership with casualty insurers to insure hospitals against the financial risks of pandemics.

I. THE ECONOMIC EFFECTS OF AN INFECTIOUS DISEASE PANDEMIC ON THE NATION'S HOSPITALS

Although it is impossible to predict precisely how a pandemic will impact American hospitals, it is indisputable that a pandemic would have both an immediate impact on hospital finances and a lingering negative economic effect.[16] While past pandemics did not have catastrophic effects on the health care industry, this was due to the relative scarcity of treatment options. Because of the way that the modern health care industry is financed, the costs of personnel, and the greater number of treatment options, the impact on modern hospitals is likely to be much greater. Finally, a pandemic's long-term damage to hospital finances could be even more devastating than the pandemic's immediate economic effect on them. Adequate planning efforts must consider both immediate and long-term economic damage to our hospitals to be effective.

A. Historical Care of Pandemic Victims—Isolation and Quarantine

When the public thinks of what it will cost hospitals to respond to a pandemic, it thinks of the direct costs of using hospitals and their associated medical personnel to isolate and care for sick individuals, or to quarantine exposed persons. Nevertheless, because of massive advances in medicine since the last large-scale pandemic in the United States, a historical review of the costs incurred by hospitals in caring for isolated and quarantined individuals during an

16. *See, e.g.*, Kristin Choo, *The Avian Flu Time Bomb*, A.B.A. J., Nov. 2005, at 36, 40 (noting that American hospitals operate on slim profit margins and rely on highly compensated procedures to break even that will likely not be available if the hospital is treating victims of an epidemic); Stephen D. Gravely & Erin S. Whaley, *Emergency Preparedness and Response: Legal Issues in a Changing World*, 17 HEALTH LAW. 1, 3 (2005).

infectious disease outbreak has limited, if any, value in estimating the current or future costs of a pandemic. Until the discovery of antibiotics in the mid-twentieth century, people were relatively helpless to treat infectious disease. Therefore, it was not necessary to isolate sick individuals in a place where they could receive skilled medical care, such as the equivalent of the modern hospital. At most, isolated persons suffering from infectious disease received palliative care, which required little medical skill or technology.[17] Rather than using hospital-like facilities, public health authorities generally enforced isolation and quarantine in the location where the infected or exposed person first appeared within their jurisdiction, such as an arriving ship.[18] Even when hospital facilities were used for isolation, as was the case for persons debarking from ships in New York City in the nineteenth century, the facilities were usually dedicated specifically to isolation and palliative care, rather than active treatment of disease.[19] Society isolated patients suffering from infectious diseases and forced them to live in places known widely as "pesthouse[s]," which upstanding citizens avoided at all costs.[20]

Some of the earliest uses of general hospital facilities in the United States to isolate and treat sick patients occurred during the Spanish flu pandemic of 1918. For example, within weeks of the first report of the Spanish flu in San Francisco, the chief of San Francisco's Board of Health and the superintendents of the city's hospitals decided to move all of the patients not suffering from Spanish flu out of the San Francisco Hospital, and use the hospital to isolate Spanish flu patients.[21] Ultimately, the San Francisco Hospital admitted 3509 pandemic victims.[22] Despite their hospitalization in an acute care facility, twenty-six percent of them died.[23]

The Spanish flu pandemic occurred at a time when hospitals in the United States were changing from repositories for the poor who received long-term treatment into the acute-care facilities actively treating disease and illness that we know today.[24] Nevertheless, many Spanish flu victims were treated in makeshift isolation centers. These isolation centers did not have the amenities that we generally associate with a hospital, such as a sterile environment, advanced

17. ROTHSTEIN, *supra* note 15 at 19.

18. *Id.*

19. *Id.*

20. *See, e.g.*, Kirk v. Wyman, 65 S.E. 387, 387-88 (S.C. 1909) (concerning a woman with leprosy who sued government officials to avoid being isolated in a facility formerly used to house smallpox victims).

21. CROSBY, *supra* note 1, at 94.

22. *Id.*

23. *Id.*

24. *See* PAUL STARR, THE SOCIAL TRANSFORMATION OF AMERICAN MEDICINE 157-61 (1982).

medical equipment, and pharmacies. For example, San Francisco set up improvised emergency hospitals in available large, empty, and dry buildings.[25] In Philadelphia, many of the sick were placed in "emergency hospitals" that opened in armories in the city and in parish houses elsewhere.[26] Because the pandemic occurred during World War I, many victims were treated in military facilities, where conditions were even more makeshift than in the civilian world.[27] At Camp Devens, Massachusetts, the first place in the United States to experience a wide-scale outbreak of the Spanish flu, the base hospital was designed to hold 1200 men.[28] In September 1918, at the height of the pandemic, more than 6000 men were at the base hospital, in every corridor, spare room, and porch.[29]

Americans today would find the type of care rendered to Spanish flu pandemic victims in these makeshift and temporary hospital settings inadequate and unacceptable.[30] The Spanish flu swept the world in the days before antibiotics and antiviral drugs were available. Because the vast majority of care given to Spanish flu victims was palliative, victims' chances of survival were not greatly affected by whether they were in an acute care hospital, a makeshift emergency hospital, a military field hospital, or at home. The public did not expect Spanish flu victims to be treated in a hospital intensive care unit, or to be treated with life-support equipment or any of the other technologically advanced (and expensive) life-sustaining advances we now associate with a modern hospital.[31] It is likely that the public today would expect all pandemic victims to

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25. CROSBY, *supra* note 1, at 95.

26. *Id.* at 75.

27. The United States Army and Navy reported a total of 24,330 deaths from influenza and pneumonia in the autumn of 1918, which was during the height of the pandemic in the United States. *Id.* at 58-59.

28. BARRY, *supra* note 4, at 189.

29. *Id.*

30. Nevertheless, the Congressional Budget Office recently noted that an influenza pandemic may require American communities to increase hospital bed capacity by setting up "field hospitals" and using shelters, schools, religious facilities, nursing homes, hotels, and day care centers to treat pandemic victims. CBO, A POTENTIAL INFLUENZA PANDEMIC: POSSIBLE MACROECONOMIC EFFECTS AND POLICY ISSUES 29 (2006) [hereinafter, CBO REPORT], *available at* http://www.cbo.gov/ftpdocs/69xx/doc6946/12-08-Birdflu.pdf.

31. Scientists now believe that one reason the Spanish flu was so deadly, particularly to young, otherwise healthy adults, was because it caused a phenomenon called Acute Respiratory Distress Syndrome (ARDS). ARDS is a process of disintegration in the lungs. Even today, the only care available for an ARDS victim is to keep her alive until her lung tissue regenerates and she can recover. BARRY, *supra* note 4, at 250. This requires respirators, skilled nursing, and all of the other technology available in a modern intensive care unit. *Id.* If the Spanish flu struck today, it simply would not be possible to properly treat severely affected pandemic victims in warehouses, schools, and other public buildings.

receive life-sustaining technology that is typically administered in hospital intensive care units.

B. The Current State of Hospital Financing—Cost-Shifting, Diagnosis-Related Groups, and Hospital Margins

Health care financing has also changed dramatically since 1918. In 1918, hospitals were financed mostly by charitable donations, public funds, patients paying out-of-pocket, and a steadily increasing but still relatively small proportion of privately insured patients.[32] Today, the American health care delivery system is financed by a hodge-podge of public and private sources.[33] In 2001, 34.8% of personal health care costs were covered by private health insurance, 45.4% of personal health care costs were paid by the federal and state governments through programs such as Medicare and Medicaid, and 14.4% of personal health care costs were paid out-of-pocket by patients.[34] As part of this system, one payor group (usually private health insurers) may systematically pay substantially higher prices to offset lower prices paid by another payor group (usually the federal and state governments, or patients paying out-of-pocket).[35] This "cost-shift hydraulic" is very prominent in the hospital payment system.[36] In 2002, private insurers paid on the average 122% of costs for hospital services, while the federal and state governments paid approximately 90% of costs for the same services.[37] This cost-shifting allows hospitals to provide social benefits to

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32. Between 1911 and 1921, the proportion of paying patients in New York hospitals increased from eighteen to forty-five percent. STARR, *supra* note 24, at 161. Before the 1930s, the only significant private health insurance plans were direct service plans offered to employees of certain industries. *Id.* at 294.

33. John K. Iglehart, *Business and Government: Striking New Balances*, 21 HEALTH AFF. 7, 7 (2002).

34. BARRY R. FURROW ET AL., THE LAW OF HEALTH CARE ORGANIZATION AND FINANCE 194 (5th ed. 2004).

35. Allen Dobson et al., *The Cost-Shift Payment 'Hydraulic': Foundation, History, and Implications*, 25 HEALTH AFF. 22, 22 (2006).

36. Apparently, this "cost-shift hydraulic" is not a new phenomenon. A 1909 guide to hospital administration noted that a medical staff with large and profitable practices could realize enough money to defray the entire operating expenses of a hospital, not only for private patients, but for charity care patients as well. STARR, *supra* note 24, at 166.

37. Dobson et al., *supra* note 35, at 24. The importance and extent of this cost-shifting varies over time. For example, in the early to mid-1980s, the public payors covered their costs, while in the mid to late 1990s the increase in the prevalence of managed care drove down the percentage of costs that private insurers paid for hospital services by as much as fifteen percent. *Id.* at 27. Nevertheless, the American health care financing system seems to depend upon the existence of cost-shifting to ensure coverage for all. *Id.* at 24.

the community, such as teaching, research, standby capacity, and charity care.[38]

The social disruption caused by even a mild outbreak of a deadly disease carries serious short-term economic consequences for an affected area. Severe Acute Respiratory Syndrome (SARS), a disease that emerged from Asia in 2003, infected approximately 8000 people world-wide, killing 800.[39] Yet it was estimated that even this comparatively small disease outbreak would cut Hong Kong's gross domestic product by over 1.5%.[40] In Singapore, SARS resulted in a 75% decline in visitors, a 50% decline in hotel occupancy, and a sharp decline in the stock market.[41]

In the United States, the federal government is planning for an influenza pandemic with the assumption that up to forty percent of the staff of any business entity may be absent a period of two weeks.[42] The United States Congressional Budget Office (CBO) estimates that the economic effect of a severe influenza pandemic would be greater than recent recessions and akin to an average post-war recession.[43] A severe pandemic would lead to an initial drop in the stock market and would reduce gross domestic product by approximately 4.25% in the subsequent year.[44] "[E]conomists know little about how large population and labor force shocks affect economic growth."[45] Nevertheless, in the event of a severe pandemic, it appears likely that a significant number of Americans would lose their jobs, and their employment-based private-payor health insurance.[46] This would increase the number of people enrolled in publicly funded health plans or with no insurance at all. This, in turn, would disrupt hospitals' normal payor mix and their ability to cost-shift. A large-scale pandemic that decreases the number of patients covered by private insurers and increases the number of

38. *Id.* at 23.

39. CBO REPORT, *supra* note 30, at 13.

40. MARK A. ROTHSTEIN ET AL., *supra* note 15, at 84.

41. *Id.* at 95. The Singapore government also instituted a Home Quarantine Order Allowance Scheme, which was designed to compensate self-employed persons and small business that had to close because of SARS. Singapore spent about $3.2 million Singapore dollars on this program. Mah Bow Tan, Minister for Nat'l Dev., Remarks at the Grassroot Club (July 11, 2004), *available at* http://www.cdc.org.sg/data/speeches/speeches16.html.

42. HOMELAND SEC. COUNCIL, *supra* note 11, at 165.

43. CBO REPORT, *supra* note 30, at 10.

44. *Id.* at 1, 10.

45. Brainerd & Siegler, *supra* note 8, at 3.

46. The most important immediate economic effect of a pandemic is likely to be a sharp decline in demand for products and services, as people avoid congregating in shopping malls, restaurants, and other public spaces. CBO REPORT, *supra* note 30, at 9. Travel-related industries would also see large declines in usage, and attendance at sporting events and museums would decline precipitously. *Id.* at 10.

publicly funded or self-pay patients, even for a short period of time, is likely to have long-reaching negative effects on hospitals. Hospitals will have no choice but to sharply reduce the amount and availability of important social benefits we rely on them to provide.[47] This loss of social benefits, such as training of new physicians, research on new treatments and technologies, and standby capacity for emergencies, will reverberate through the community for months or years after the pandemic has ended, detrimentally affecting public health.

Hospitals' reserves would quickly be depleted if their revenue stream was disrupted or delayed. Although federal, state, and local governments have provided enhanced funding for emergency preparedness since the terrorist attacks of September 11, 2001—including funds to develop hospital surge capacity for outbreaks of infectious disease[48]—the question of who will pay for each individual pandemic victim's care is uncertain. Although the public and private insurers of persons who are actually ill should pay for the treatment, if the insurer does not have a pre-existing contractual relationship with the isolation center and the pandemic victim is at that particular institution because of the orders of public health authorities, the insurer may balk at paying for the hospital stay. Likewise, the government, knowing that a patient is privately insured, is likely to insist that the private insurer pay for the patient's care.[49] This inevitable debate between insurers, the government, and the hospital about payment rates will be a significant distraction at a time when health care resources should be directed at dealing with the public health emergency. Hospitals may be tempted to avoid this quandary by doing everything in their power to avoid being designated as an isolation center, even if they are the most suitable places to treat pandemic

47. Although Hurricane Katrina's direct hit on the Gulf Coast of the United States was not a pandemic, the disaster illustrates the weaknesses in our health care system's ability to withstand the long-term impact of a major disaster. *See* Sara Rosenbaum, *U.S. Health Policy in the Aftermath of Hurricane Katrina*, 295 JAMA 437 (2006). Because the major providers of charity care in New Orleans, Charity Hospital and University Hospital, have remained closed since Katrina, the private hospitals that have reopened in the surrounding area have seen major increases in uninsured cases. Jessica Zigmond, *Still in Recovery*, MOD. HEALTHCARE, Aug. 21, 2006, at 6, 27. Since Katrina, Touro Infirmary in New Orleans has lost approximately $43 million on operations. *Id.* at 27. East Jefferson Hospital has lost about $41 million, and continues to lose about $3 million per month. *Id.* East Jefferson Hospital has seen its percentage of uninsured cases rise from three percent before Katrina to about eight percent in August 2006. *Id.*

48. Press Release, U.S. Dep't of Health and Human Servs., HHS Announces $1.3 Billion in Funding to States for Bioterrorism Preparedness (May 13, 2005), *available at* http://www.hhs.gov/news/press/2005pres/20050513.html.

49. Medicare and Medicaid, the largest health care funding programs sponsored by the federal government, are both designated as payors of last resort by law. *See* 42 U.S.C. § 1395y(b) (2000) (Medicare); 42 U.S.C. § 1396k (2000) (Medicaid).

victims. Hospitals may engage in tactics designed to ensure they will not be designated as "ground zero" for a pandemic. These tactics may include removing pandemic victims from their emergency rooms early in a pandemic, appropriately transferring pandemic victims, or placing the hospital on diversion status so that ambulances cannot bring pandemic victims to the emergency room.[50] Hospitals may also funnel funding away from pandemic preparedness in the hope that public health officials will not choose the institution as an isolation or quarantine center.[51]

Generally, hospitals are not paid for their actual costs, nor are they paid their actual charges for a particular service. Most payors pay hospitals based on a formula used to set a rate for an entire course of treatment for a particular diagnosis, commonly called the Diagnosis-Related Group (DRG) for inpatient care, and the outpatient prospective payment system (PPS) for outpatient care.[52] In theory, the DRG or outpatient PPS payment represents an efficient hospital's cost of caring for an average case presenting with a particular principal diagnosis, as determined upon admission to the hospital or presentation for outpatient care.[53] Uncomplicated cases within a particular DRG or PPS category are likely to be more lucrative than complicated cases that use more hospital resources.[54] Likewise, the DRGs for many elective surgeries also tend to result in better payment levels for hospitals than complicated medical cases.[55] Therefore,

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50. Although the Emergency Medical Treatment and Labor Act ("EMTALA"), 42 U.S.C. § 1395dd (2000), is designed to prevent hospitals from refusing emergency treatment to patients, and authorizes punishments for hospitals that engage in such practices, the penalties these laws carry pale in comparison to the likely effects on a hospital designated as an isolation or quarantine center. *See* FURROW ET AL., *supra* note 34, at 167 (noting that administrative enforcement actions under EMTALA are very few and the monetary penalties imposed very small). EMTALA does authorize an injured individual or a medical facility that suffers financial loss due to a hospital's EMTALA violation to bring a private right of action against the violating hospital. 42 U.S.C. § 1395dd(d)(2). Nevertheless, a hospital faced with incurring potentially massive financial losses if it is designated an isolation or quarantine center may be willing to risk EMTALA lawsuits rather than the certain ruin of the designation. *See also* Gravely & Whaley, *supra* note 16, at 5.

51. *See* discussion *infra* Section III.A.

52. FURROW ET AL., *supra* note 34, at 373-74. Although the term "DRG" is used by the Medicare program, virtually all payors use a similar form of prospective payment.

53. *Id.*

54. Stuart Guterman, *Specialty Hospitals: A Problem or a Symptom?*, 25 HEALTH AFF. 95, 97 (2006).

55. *See id.* at 97-98. The DRG is only the starting point for determining a hospital's reimbursement. DRG payments are adjusted to compensate teaching hospitals for the costs of operating an educational program, for extraordinarily expensive or "outlier" cases, and for the particular circumstances of the hospital (e.g. rural versus urban, hospitals that treat a disproportionate share of low-income patients). FURROW ET AL., *supra* note 34, at 374.

hospitals often compete to attract the type of cases for which DRG compensation is comparatively generous in order to offset the costs of providing services for which the DRG does not accurately reflect total costs of care.[56]

In a normal flu year, influenza results in 114,000 hospitalizations, and between 5 and 10 million outpatient visits.[57] If we experience an influenza pandemic, the federal government estimates a three to seven-fold increase in hospitalizations, and a four-fold increase in outpatient visits.[58] The Centers for Disease Control and Prevention has estimated the direct and indirect medical costs of an influenza pandemic as follows.[59]

56. Guterman, *supra* note 54, at 95.

57. U.S. DEP'T OF HEALTH AND HUMAN SERVS., DRAFT PANDEMIC INFLUENZA PREPAREDNESS AND RESPONSE PLAN 15 (2004).

58. U.S. DEP'T OF HEALTH AND HUMAN SERVS., PANDEMIC INFLUENZA PLAN 18 (2005), *available at* http://www.hhs.gov/pandemicflu/plan/.

59. Meltzer et al., *supra* note 13, at 666.

Table 1: Direct and Indirect Costs of Influenza Pandemic Per Gross Attack Rate by Deaths, Hospitalizations, Outpatients Illnesses and Total Costs (1995 U.S. $)

	Cost per gross attack rate[a] ($ millions)				
	15%	20%	25%	30%	35%
Deaths					
Mean	59,288	79,051	98,814	118,577	138,340
5th percentile	23,800	31,733	39,666	47,599	55,532
95th percentile	94,907	126,543	158,179	189,815	221,451
Hospitalizations					
Mean	1,928	2,571	3,214	3,856	4,499
5th percentile	1,250	1,667	2,084	2,501	2,917
95th percentile	2,683	3,579	4,472	5,367	6,261
Outpatients					
Mean	5,708	7,611	9,513	11,416	13,318
5th percentile	4,871	6,495	8,119	9,742	11,366
95th percentile	6,557	8,742	10,928	13,113	15,299
Ill, no medical care sought[b]					
Mean	4,422	5,896	7,370	8,844	10,317
5th percentile	3,270	4,360	5,450	6,540	7,629
95th percentile	5,557	7,409	9,262	11,114	12,967
Grand totals					
Mean	71,346	95,128	118,910	142,692	166,474
5th percentile	35,405	47,206	59,008	70,810	82,611
95th percentile	106,988	142,650	178,313	213,975	249,638

[a] Gross attack rate = percentage of clinical influenza illness per population.

[b] Persons who become clinically ill due to influenza but do not seek medical care; still illness has an economic impact (e.g., half day off work).

Hospitals report that, on average, they can provide only twenty-eight to twenty-nine additional staffed beds twelve hours after a disaster.[60] In order to deal with the anticipated three- to seven-fold increase in hospitalizations during an influenza pandemic, hospitals will have to voluntarily or involuntarily turn away the business whose DRG payments keeps them financially sound during normal times—uncomplicated cases and elective surgical procedures.[61] The bulk

60. AM. HOSP. ASS'N, TAKING THE PULSE: THE STATE OF AMERICA'S HOSPITALS (2005), *available at* http://www.aha.org/aha/content/2005/pdf/TakingthePulse.pdf.

61. Consultants estimated that during the SARS outbreak of 2003 in Canada, approximately

of the costs in Table One are attributable to the costs incurred in caring for victims who ultimately die,[62] who will consume an intensive amount of hospital services, staff time, and financial resources with little or no increased DRG payment. A hospital that cannot offset the under-compensated costs of caring for complicated, expensive cases with more lucrative elective surgeries or simple cases will experience an exacerbation of the financial effects of a pandemic. A hospital designated as an isolation hospital during an infectious disease outbreak for an extended period of time is likely to face bankruptcy.[63]

Hospitals may also be used as quarantine centers for healthy individuals, such as health care workers who were exposed to the disease but are not sick themselves.[64] The DRG and outpatient PPS systems rely on the concept of payment for specific diagnoses of illnesses.[65] Typically, payors make no payment for custodial care of people who are not ill. A hospital that is designated as a quarantine center is likely to be at even greater financial risk than a hospital functioning as an isolation center, because there is no DRG payment for holding healthy persons. Thus, hospitals are extremely likely to resist designation as quarantine facilities. Failure to quarantine people who have come into contact with pandemic victims at the place where they first come into contact with them, very possibly a hospital, as was the case during the 2003 outbreak of Severe Acute Respiratory Syndrome (SARS), will cause an increased outbreak of the pandemic disease in the general population.[66]

Even with the ability to cost-shift and compete for highly reimbursed business, American hospitals are losing money.[67] Hospitals reported they lost money on taking care of patients at the rate of 2.8% in 2004.[68] Approximately

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6600 inpatient elective surgeries and 18,000 ambulatory surgeries were deferred from hospitals. NAT'L ADVISORY COMM. ON SARS & PUB. HEALTH, LEARNING FROM SARS: RENEWAL OF PUBLIC HEALTH IN CANADA 10 (2003), *available at* http://www.phac-aspc.gc.ca/publicat/sars-sras/pdf/sars-e.pdf.

62. Meltzer et al., *supra* note 13.

63. *See, e.g.*, Mark A. Rothstein, *Are Traditional Public Health Strategies Consistent with Contemporary American Values?*, 77 TEMP. L. REV. 175, 179 (2004). *See also* Santora, *supra* note 5 (quoting Susan C. Waltman, a senior vice president at the Greater New York Hospital Association, confirming that in a pandemic, "elective operations would probably be postponed and only seriously ill patients would be admitted to the hospital.").

64. *See, e.g.*, ROTHSTEIN ET AL., *supra* note 15, at 24.

65. *See supra* text accompanying note 55.

66. *See, e.g.*, U.S. DEP'T OF HEALTH AND HUMAN SERVS., *supra* note 58, at 8 (discussing the likelihood that HHS will implement quarantine as a means of slowing the spread of a pandemic influenza).

67. AM. HOSP. ASS'N, *supra* note 60.

68. *Id.* at 1. This is a decrease of 1.1% since 1997, when hospitals reported patient care

one-third of hospitals lose money on their overall operations.[69] Most hospitals make up for these shortfalls by using investment income to subsidize operations.[70] The likely sharp decline in the nation's GDP and downturn in the stock market during and immediately after a pandemic will negatively affect hospitals' investment income, at least for the short term.[71] With hospitals having few cash reserves on hand and little operating revenue, the downturn in the economy during and immediately following a pandemic will have a major impact on the viability of ongoing hospital operations.

C. Increases in Personnel Costs

Often, much of the CDC's recent estimates of medical costs associated with a pandemic are attributed to the increased number of health care workers that would be needed to handle a pandemic.[72] Nevertheless, it is likely that health care workers will be hard-hit by a pandemic,[73] and will have a rate of absenteeism that is even higher than the rates of absenteeism among the general public.[74] Furthermore, history tells us that many health care workers, from physicians to orderlies, refuse to treat patients with new and emerging infectious diseases.[75]

In 1918, the existing supply of health care workers was no match for the numbers of patients with Spanish Flu. Many health care workers came down with the flu themselves, further exacerbating the shortage of medical personnel available to care for the sick.[76] The American Red Cross and the United States Public Health Service were inundated with wire messages begging for help.[77] Unable to meet the demand and despite heroic efforts to track down any and all available health care workers,[78] they called upon civic-minded housewives, retired nurses and doctors, medical and dental students, and all able-bodied citizens who were not in the military to tend to the thousands of sick patients in the emergency hospitals, and to provide supplies and essential services, such as

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margins of negative 1.7%.

69. *Id.*

70. *Id.*

71. *See supra* notes 40-44 and accompanying text.

72. Meltzer et al., *supra* note 13.

73. Rothstein, *supra* note 63, at 185.

74. *Id.*

75. *Id.* at 186.

76. *See* CROSBY, *supra* note 1.

77. BARRY, *supra* note 4, at 351.

78. Barry relates one episode of a nurse named Josey Brown watching a movie in a St. Louis theater. During the movie, the lights went on, the screen went blank, and a man announced that anyone named Josey Brown should go to the ticket booth. *Id.*

sanitation, that were disrupted because of the large amount of workers out with the flu.[79] Although many people responded to the call for help, the number of volunteers was not sufficient to meet the need.[80] In San Francisco, during the height of its Spanish Flu epidemic, the Red Cross offered practical nurses twenty dollars per week if they would report for work.[81] This was a considerable sum in 1918,[82] but even with this incentive, the Red Cross could not fill the nursing needs of the city.[83] Most other American cities experienced similar shortages. The situation became so dire that some nurses were forcibly held in patients' homes to care for the sick.[84]

During the more recent SARS outbreak, many doctors and nurses chose to resign rather than be forced to treat patients with SARS.[85] Hospitals in Taiwan were forced to offer danger pay to those working with SARS patients.[86] In Vietnam, personnel treating SARS patients received a government allowance of five times the amount normally given to health care workers.[87] These stipends were paid initially by each medical institution treating SARS patients, and were ultimately reimbursed to the hospital by the government.[88]

Even substantial financial incentives may be insufficient to recruit and retain needed medical personnel. During the SARS outbreak in Taiwan, 160 health care workers resigned rather than work with SARS patients.[89] In Toronto, Lucy Smith, a nurse with seventeen years of experience, refused to work with SARS patients despite an order from the hospital where she worked and an offer of increased pay.[90] When discussing her reasons for refusing to work with SARS

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79. CROSBY, *supra* note 1, at 81, 96-97.

80. *Id.* at 82-83, 96-97.

81. *Id.* at 97.

82. Twenty dollars in 1918 is the equivalent of $267.28 in 2006. *See* U.S. Bureau of Labor Statistics Inflation Calculator, http://www.bls.gov/cpi/ (last visited Dec. 8, 2006). This was a considerable sum in the early part of the twentieth century. For example, in 1916, in Morris County, New Jersey, bread cost between $0.04 and $0.98 per loaf, a six-room rental house near a park cost $12 per month, and a new Ford sedan cost $740. Morris County Library, Morris County New Jersey Historical Price Survey 1906-2006, http://www.gti.net/mocolib1/prices/1916.html (last visited Nov. 8, 2006).

83. CROSBY, *supra* note 1, at 97.

84. Rothstein, *supra* note 63, at 191.

85. ROTHSTEIN ET AL., *supra* note 15, at 103.

86. *Id.* at 133.

87. *Id.* at 114.

88. *Id.*

89. *Id.* at 103.

90. Barbara Sibbald, *Right To Refuse Work Becomes Another SARS Issue*, 169 CAN. MED. ASS'N J. 141 (2003).

patients, Ms. Smith cited the fact that she had three children and an immunocompromised mother, and cited her responsibility to them as well as her responsibility to her patients.[91] Dr. Peter Singer, director of the University of Toronto Joint Centre for Bioethics explained in response to questions regarding Ms. Smith's position, there is a "threshold beyond which health care workers are not obliged to take personal risks. We do not expect firefighters to jump into a burning pit, or police officers to throw themselves in front of a bullet."[92]

It is unlikely that Americans will behave more selflessly than their Canadian, Vietnamese, or Taiwanese counterparts when faced with an infectious disease outbreak. Differences between American culture and the cultures of the countries that experienced the SARS outbreak suggest that Americans may even behave more self-protectively. Many of the Asian countries that experienced SARS outbreaks are known for their communitarian cultures.[93] Canada is known for a commitment to social solidarity, especially in the area of health care and its health care system.[94] These cultures contrast with American culture, which has a "strong tradition of individualism and skepticism about government."[95] In particular, Americans have a tradition of governmental non-interference in health care decision-making. [96]

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91. *Id.* Ms. Smith's concerns for her and her family's safety were well-founded. SARS was transmitted largely through hospital-based exposures, and health care workers were disproportionately affected. Forty percent of Toronto's SARS patients were health-care workers. Nineteen percent of China's SARS cases involved health-care workers, as were fifty-seven percent of Vietnam's. Rothstein, *supra* note 63, at 185. In Hong Kong, twenty-two percent of SARS deaths were among physicians and nurses. *Id.*

92. Sibbald, *supra* note 90. Although the heroic actions of firefighters and police responding to the 9/11 attacks on the World Trade Center in New York belie this statement, first-responder reaction to a highly visible, spectacular terrorist attack is likely to be more heroic than the medical community's reaction to a comparatively slower-moving, much more invidious emergency like a naturally occurring infectious disease pandemic.

93. ROTHSTEIN ET AL., *supra* note 15, at 26. *See also* Rothstein, *supra* note 63, at 189-90 (discussing the traditional Chinese view of unity of household and the necessity of individuals performing their assigned roles to assure family survival, and that Chinese children are taught that "different is dangerous." (*citing* RICHARD GUNDE, CULTURES AND CUSTOMS OF CHINA 167, 171 (2002)) and Lucian W. Pye, *"Asian Values": From Dynamos to Dominoes?*, *in* CULTURE MATTERS: HOW VALUES SHAPE HUMAN PROGRESS 250 (Lawrence E. Harrison & Samuel P. Huntington eds. 2000)).

94. ROTHSTEIN ET AL., *supra* note 15, at 26.

95. *Id.*

96. Rothstein, *supra* note 63, at 190. Although EMTALA is a government incursion into health care decision-making, it applies only in the most dire of circumstances—where a patient is in an emergency condition and is likely to be unable to make decisions on her own. Furthermore, it requires that hospitals do the bare minimum—screen and stabilize the patient. 42 U.S.C. §1395dd

Historical evidence suggests that even during a health care emergency, Americans acted in accordance with their tradition of personal liberty when formulating their reactions to the crisis. During the Spanish flu epidemic, many people fled even from their own loved ones who came down with the flu.[97] The sheer inability of hospitals to deal with a sudden surge in patient demand was compounded by the failure of trained medical personnel to show up for work, not only because they themselves were ill, but also because of fear of contact with the sick.[98] Towns that were not hit during the Spanish flu pandemic's first wave, but had notice of the coming pandemic, enforced complete isolation from their surroundings at gunpoint.[99] Although this method of enforced quarantine was apparently effective,[100] it does not evidence American self-sacrifice in the face of epidemic disease. After all, "[t]he Lone Ranger is more than a fictional character; his name describes a cultural *modus operandi*, although doing so overlooks the role of Tonto; thus, we respect and admire the Lone Ranger, while overlooking Tonto," the symbol of self-sacrifice.[101]

The attitude of American health care workers toward self-sacrifice in the face of epidemic disease does not appear to have improved since 1918. In fact, it may be even worse now than it was then. The American Medical Association's Code of Ethics in 1847 stated that "when pestilence prevails, it is [physicians'] duty to face the danger . . . . even at the jeopardy of their own lives."[102] This statement has since been replaced with a much weaker directive that physicians should use their knowledge and skills even when doing so may put them at risk.[103] A study from the fall of 2003 found that only fifty-five percent of doctors surveyed agreed that physicians have an obligation to care for patients even if it might endanger their own health.[104] Another example comes from the 1980s:

(2000). After that, hospitals have no obligation to continue treatment under EMTALA.

97. BARRY, *supra* note 4, at 342-43.

98. Santora, *supra* note 5.

99. BARRY, *supra* note 4, at 345.

100. Gunnison, Colorado, which enforced a total isolation of the town by closing it and banning public gatherings, escaped without a single death, while the nearby town of Sargents suffered six deaths in a single day, out of a total population of 130. *Id.* at 345-46.

101. Rothstein, *supra* note 63, at 190.

102. *Id.* at 187 (quoting AMER. MED. ASS'N, CODE OF MEDICAL ETHICS 105 (1847)).

103. *See* Chalmers C. Clark, *In Harm's Way: Service in the Face of SARS*, HASTINGS CTR. REP., July-Aug. 2003, at inside back cover.

104. G. Caleb Alexander & Matthew K. Wynia, *Ready and Willing? Physicians' Sense of Preparedness for Bioterrorism*, 22 HEALTH AFF. 189, 195 (2003). Again, this attitude among health care providers distinguishes them from persons who we traditionally consider first responders, such as firefighters and police officers, who exhibited their willingness to risk their own lives during a public emergency after the 9/11 attacks on the World Trade Center.

when it became known that the Human Immunodeficiency Virus (HIV) could be transmitted through bodily fluids, doctors and other health care providers turned away AIDS patients.[105] In June 2003, a physician in Rockford, Illinois who volunteered to treat a girl with monkeypox[106] incurred the wrath of his physician partners, who felt that his contact with the girl would put them all at risk.[107]

Fears of bioterrorism can also fuel health care workers' reluctance to treat. One physician with small children who treated a monkeypox patient explained that prior to a definitive diagnosis of a patient presenting with smallpox-like symptoms, he feared a bioterror attack: "My attitude was, I'm going to stay as far away from this guy as possible . . . ."[108] This physician's experience with monkeypox has convinced him that he would not volunteer for anything dangerous in the future, and that he would not be "turned into" a first responder in a public health emergency.[109] A recent study found that sixty-seven percent would not treat smallpox without having been vaccinated.[110]

Medical professionals' attitudes of individual choice with regard to whom they treat may have become even more entrenched than it was in the past because of structural changes in health care delivery. The advent of managed care and greater compartmentalization of health care are also cited as reasons for the erosion of a sense of community in American health care.[111] Many physicians believe that managed care has undermined the physician-patient relationship because it diminishes the physician's ability to serve as an advocate for patients' interests.[112] Physicians advocating for their patients' interests often find their advocacy conflicting with their own financial interests.[113] Physicians are also much less likely to be social colleagues of their patients than they were in the

105. *See, e.g.*, Bragdon v. Abbott, 524 U.S. 624 (1998) (concerning a dentist who refused to treat an HIV-positive patient in his office).

106. Monkeypox is an orthopox virus similar to smallpox. There was a monkeypox outbreak in the American Midwest in 2003, which was traced to Gambian giant pouched rats imported from Ghana to the United States as exotic pets. The Gambian rats infected prairie dogs at area pet shops, which in turn infected at least thirty-seven people in the Midwest. Gretchen Reynolds, *Why Were Doctors Afraid to Treat Rebecca McLester?*, N.Y. TIMES MAG., Apr. 18, 2004, at 32.

107. *Id.*

108. *Id.*

109. *Id.*

110. Alexander & Wynia, *supra* note 104, at 192.

111. Rothstein, *supra* note 63, at 186-87.

112. *Id.* (quoting Debra S. Feldman et al., *Effects of Managed Care on Physician-Patient Relations, Quality of Care, and the Ethical Practice of Medicine*, 158 ARCHIVES INTERNAL MED. 1626, 1630 (1998)).

113. *Id.*

past.[114] In fact, they are much less likely to even know their patients' names.[115]

Although financial incentives alone are unlikely to avoid or alleviate a shortage in medical personnel during a pandemic, it is unreasonable to expect physicians and other health care professionals to risk their lives for total strangers without substantial financial incentives.[116] The need for such incentives will further increase hospitals' costs in coping with a pandemic.

D. The Lingering Economic Effects of a Pandemic on Hospitals

Any effective plan to alleviate the economic burden of a pandemic on the nation's hospitals and to ensure that they promptly comply with the orders of public health officials must offset the potentially great long-term economic effects that a hospital would face upon being designated as a modern-day "pesthouse." Throughout American history, the places used to quarantine and/or isolate persons with infectious diseases such as smallpox or leprosy have been considered undesirable and unmarketable.[117] During the Spanish flu pandemic of 1918, at least one set of property owners protested local public health officials taking their property for use as quarantine or isolation centers because they feared that a lingering stigma would hurt their businesses. They found no sympathy from local health officers. In response to a complaint filed by a hotel owner protesting the commandeering of his property for an emergency flu hospital, a health official in Spokane, Washington reportedly said: "We don't care a rap what the owners of the building think about it or about us . . . . This is a very serious emergency and if the owners of the Lion Hotel think they can put a dollar on one side of the scale and a human life on the other and get away with it they are very, very badly mistaken."[118] The disease-based stigma is not limited to

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114. *Id.* at 187.

115. *Id.*

116. *See id.*

117. *See, e.g.*, Kirk v. Wyman, 65 S.E. 387 (S.C. 1909) (describing a house formerly used to isolate persons with smallpox as a "pesthouse," and describing the efforts of an elderly citizen of the city with leprosy to avoid being sent to live there); Brown v. Pierce County, 68 P. 872 (Wash. 1902) (claiming a right to compensation from the city of Tacoma for the full value of property used by the city as a "pesthouse" for the isolation and quarantine of persons with smallpox because by such use the marketable value of the property was destroyed).

118. Heather Lalley, *Flu Outbreak of 1918 Proved Devastating to Spokane, World*, SPOKANE SPOKESMAN-REV., Nov. 18, 2004, at D1. Of course, we live in a different world today. Through the ascendancy of private health insurance as the primary method of payment for hospital care in the years since 1918, the efforts to control rising health care costs since the 1970s, and the most recent appearance of consumer-driven health care spending, Americans are used to a health care system that weighs expenses against human life. The recent debate in California and other states about mandating nurse staffing ratios in hospitals is a good example of the prevalence of weighing cost

places where victims actually lived. Landowners all over the country have protested government attempts to locate "pesthouses" near their property, fearing not only the disease itself, but that the location of the "pesthouse" would lower their property values.[119]

Hospitals are also susceptible to the stigma of being designated a "pesthouse." The Scarborough Hospital in Toronto, Canada was the first hospital in Toronto to isolate SARS patients.[120] Scarborough's first SARS patient waited in the hospital emergency department with other patients for eighteen to twenty hours before SARS was suspected.[121] Persons who entered the hospital after the first patient, but before the hospital implemented adequate infection control measures, were asked to adhere to a ten day home quarantine.[122] Subsequently, during the second outbreak of SARS in Toronto, four hospitals were designated as SARS facilities.[123] Despite the cessation of the SARS outbreak by the summer of 2003, The Scarborough Hospital continued to experience a loss in patients and severe stigma for a significant period after the outbreak ended.[124] At the onset of the SARS outbreak, an American running a business in China reports having her staff call approximately one dozen hospitals in Shanghai to ask them which hospital would be best for someone exhibiting the symptoms of SARS. With only

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against life in our health care delivery system. A recent study shows that trimming a nurse's workload by a single patient can save lives, but costs between $24,000 and $136,000. Michael B. Rothberg et al., *Improving Nurse-to-Patient Staffing Ratios as a Cost-Effective Safety Intervention*, 43 MED. CARE 8 (2005). Hospitals and legislators are using the study to debate the wisdom of mandating a nurse-to-patient ratio in Massachusetts. Melanie Evans, *Putting a Price On Care*, MOD. HEALTHCARE, August 8, 2005, at 14.

119. *See, e.g.*, Birchard v. Bd. of Health, 169 N.W. 901 (Mich. 1918); Hessin v. City of Manhattan, 105 P. 44 (Kan. 1909); Mayor of Baltimore v. Fairfield Improvement Co., 39 A. 1081 (Md. App. 1898); Haag v. Bd. of Comm'rs of Vanderburgh Co., 60 Ind. 511 (1878).

120. ROTHSTEIN ET AL., *supra* note 15, at 54.

121. *Id.* Ultimately, two other patients who shared the emergency room with the patient became ill with SARS. NAT'L ADVISORY COMM. ON SARS & PUB. HEALTH, *supra* note 61, at 25. Sharp criticism was leveled several months after the SARS outbreak at the public health decision-makers in Toronto who did not close Scarborough Hospital to new patients early in the outbreak. The Ontario Health Minister acknowledged that closing a hospital because of a disease outbreak carries a serious social stigma for the hospital and the region and has tremendous consequences. Pamela Varley, *Emergency Response System Under Duress: The Public Health Fight to Contain SARS in Toronto (A)*, at 13, (Kennedy Sch. of Gov't Case Program No. C16-05-1792.0, 2005).

122. NAT'L ADVISORY COMM. ON SARS AND PUBLIC HEALTH, *supra* note 61, at 26.

123. ROTHSTEIN ET AL., *supra* note 15, at 56.

124. Telephone Interview with David Baird, Counsel, Fasken Martineu DuMoulin, in Ont., Can. (Oct. 20, 2006); David Baird, Remarks at Seattle University School of Law, Breaking Down the Divide: Contemporary Corporate Theory Applied to the Health Care Industry (Feb. 27, 2004); Varley, *supra* note 121, at 13.

one exception, the hospitals told her staff persons that they did not know which hospital was best, but that the sick person should definitely not come to that hospital.[125]

If a patient boycott occurred in an American hospital, privately insured patients' refusal to go to the hospital would seriously challenge a hospital's financial viability.[126] The stigmatized hospitals would be left caring only for those patients who had no choice of providers—generally, the publicly funded patients whose care is paid for at less than cost, patients who come to the emergency room (the most expensive place to render care), or uninsured patients who cannot pay at all.[127] This would exacerbate the already-precarious financial position of the hospital after a pandemic.

Privately owned hospitals are particularly sensitive to social stigma. Not-for-profit privately owned hospitals rely on their ability to issue and sell bonds to the public to finance their capital needs.[128] For-profit privately owned hospitals are dependent upon the capital markets for their needs.[129] If the public fears going to a particular hospital because of its prior designation as an isolation or quarantine facility, the hospital will have great difficulty attracting investment in either the bond or stock markets. The aftermath of Hurricane Katrina on hospitals in the New Orleans area illustrates the effect that a major disruption in the hospital's normal business activities due to a natural disaster can have on the hospital's ability to resume its normal activities.[130] Because hospitals have been deregulated at both the state and federal levels during the past several decades, the marketplace, rather than the actual health care needs of a population or government planning, determines the viability of hospitals.[131] In New Orleans, many hospitals that were not physically damaged by the hurricane have remained closed since the disaster, due to lack of funds to reopen and uncertainty about the

125. E-mail from Linda Currey, Director, Tiny Tots International Pre-School and Kindergarten, to Vickie J. Williams, Assistant Professor of Law, Gonzaga University School of Law (Sept. 8, 2006, 21:09 PDT) (on file with the author).

126. *See* Varley, *supra* note 121, at 13 (discussing how a hospital's loss of revenue due to its inability to continue its normal lines of business during a disease outbreak is extremely expensive, carrying tremendous consequences).

127. As hospitals that do not carry the stigma of the "pesthouse" fill up with privately insured patients, they will be able to legally divert patients away from their emergency rooms. *See* 42 C.F.R. § 489.24(b) (2005).

128. *See* Reed Abelson, *Can Hospitals Reopen? It's a Matter of Money*, N.Y. TIMES, Sept. 14, 2005, at C1.

129. *Id.*

130. *See supra* note 47 and accompanying text.

131. Abelson, *supra* note 128.

recovery of the city.[132] Whether these hospitals reopen or not is entirely dependent on the capital markets, and investors' perceptions of whether these hospitals will be profitable, not on the health care needs of the returning residents.[133]

Ensuring hospital survival of an infectious disease pandemic will require assuring hospitals that they will be reimbursed for the costs of caring for pandemic victims, for their loss of ability to cost-shift during the pandemic, and for the probable loss of business they will experience after the pandemic ends. Any remedial compensation scheme or financial incentive program for hospitals that fails to take into account likely ongoing business losses due to social stigma after the pandemic is over is inadequate from its inception.

II. THE INADEQUACY OF EXISTING LAW TO PROTECT OUR HOSPITALS FROM THE EFFECTS OF A PANDEMIC

A financially sound hospital system before, during, and after a public health emergency is critical to the public's health and the economic and social recovery of a region.[134] For example, since Hurricane Katrina, the hospitals of New Orleans have been unable to attract enough private financing through the capital markets to ensure adequate hospital resources for the city's residents.[135] Because the capital markets are unlikely to be responsive to the immediate needs of the victims of a public health emergency, the law is our primary mechanism for ensuring that our hospital system remains sound after a pandemic.[136] Nevertheless, although public health systems and hospitals are heavily regulated at the federal, state, and local government levels, current law does not ensure the financial health and continued viability of the nation's hospitals during and after a pandemic. Although government officials and the private sector have been paying increased attention to legal preparedness for a public health emergency in recent years, these efforts fail to address the economic hardships that hospitals will face during and after a pandemic.[137] Without considering the economic issues, government planning efforts will fail to ensure that hospitals and other first-responders are ready and available to respond to a pandemic. The

132. *Id.*

133. *Id. See also* Zigmond, *supra* note 47 (stating that for-profit hospital owners have backed away from investing in New Orleans hospitals since Katrina).

134. *Id.*

135. *Id.*

136. *See generally* LAWRENCE O. GOSTIN, PUBLIC HEALTH LAW: POWER, DUTY, RESTRAINT 4 (2000); Barry S. Levy, *Twenty-First Century Challenges for Law and Public Health*, 32 IND. L. REV. 1149 (1999).

137. *See, e.g.*, HOMELAND SEC. COUNCIL, *supra* note 11.

government also will fail to ensure that hospitals can resume their vital function in our health care delivery system after the pandemic subsides. The following Sections discuss current federal and state laws that provide economic protections in the event of a pandemic, and they also highlight the ways in which the existing law fails to deal with the realities of hospital finance.

On the federal level, there are a number of constitutional provisions,[138] statutes, regulations, and administrative pronouncements that could be interpreted to address the economic interests of health care providers responding to a pandemic. Nevertheless, they are inadequate to assure complete compensation for health care providers in the event of a pandemic. They also fail to provide incentives to hospitals and their medical staffs to put their duties as first responders during a pandemic above their interests in preserving the economic status quo.

A. The Takings Clause

Although legal scholars disagree about whether protection of wealth and property was the primary motivating force behind the Constitution, there is no doubt that the framers sought to protect economic and private property rights.[139] The Takings Clause decrees that private property may not be taken for public use without just compensation.[140] When a hospital receives an order from a public health official adversely affecting its economic interests, such as an order for

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138. In addition to the Takings Clause, at various times in our history the courts have interpreted the Contracts Clause and the Due Process Clause to protect private economic interests from encroachment by state or federal government. *See* U.S. CONST. art. I, § 10, cl. 1 (Contracts Clause); U.S. CONST. amend. XIV, § 1 (Due Process Clause); ERWIN CHEMERINSKY, CONSTITUTIONAL LAW 222-24, 559 (2d ed. 2005). Nevertheless, the Contracts Clause cannot be used to override the power of the state to regulate as necessary to ensure the health, safety, and general welfare of the community. *See, e.g.*, Atl. Coast Line R.R. Co. v. City of Goldsboro, 232 U.S. 548, 548 (1914). And the use of the Due Process Clause to protect private contractual relationships from government interference has given way to extreme deference to the legislature's determination that there is a rational basis for a law that allegedly interferes with the economic liberty of private persons. *See* Williamson v. Lee Optical, 348 U.S. 483, 483-91 (1955). Therefore these constitutional provisions are likely to be of little use to hospitals seeking compensation from the government for damages caused by compliance with orders of isolation and quarantine during a pandemic.

139. CHEMERINSKY, *supra* note 138, at 519-20.

140. U.S. CONST. amend. V. The Takings Clause has been deemed to apply to state governments and political subdivisions of states through the Fourteenth Amendment's due process guarantee. *See* Chicago, B. & Q. R.R. Co. v. Chicago, 166 U.S. 226, 226 (1897). Furthermore, all state constitutions either expressly or impliedly prohibit takings without just compensation. Steven P. Calandrillo, *Eminent Domain Economics: Should "Just Compensation" Be Abolished, and Would "Takings Insurance" Work Instead?*, 64 OHIO ST. L.J. 451, 471 (2003).

isolating sick patients or quarantining exposed persons, it is likely that the facility will call upon the courts to decide whether a compensable taking has occurred.[141] Such a case is likely to raise a host of vexing questions about what types of government actions constitute compensable takings.

The Takings Clause authorizes the government to take private property for "public use."[142] The United States Supreme Court has interpreted "public use" to be coterminous with a legitimate exercise of the state's police powers.[143] With regard to the protection of the public's health, the Court recognizes the authority of a state to enact "health laws of every description" to be well within the state's police powers.[144] Under this test, government orders designating the use of private property for isolation and quarantine would almost certainly constitute a public use.[145] Indeed, the Takings Clause presupposes that the government's actions are for a valid public purpose.[146] The burden of proving otherwise is on the private property owner seeking compensation. This presents a significant hurdle to a property owner seeking compensation for a government taking.

Nevertheless, according to the Supreme Court, not all appropriations or regulations of private property require just compensation.[147] Takings Clause

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141. Because we have not had an outbreak of infectious disease requiring public health authorities to take such actions against hospitals since our modern Takings Clause jurisprudence has developed, there are no illustrative cases. Nevertheless, the behavior of property owners whose revenue-producing property has been regulated to their economic detriment in order to protect the public's health in other contexts indicates litigation will ensue. *See, e.g., In re* Property Located at 14255 53rd Ave S. v. Dep't of Agric., 86 P.3d 222 (Wash. Ct. App. 2004) (adjudicating property owners' claims that the state Department of Agriculture owed compensation under the Takings Clause for destruction of trees in order to prevent infestation by dangerous pest); City of New York v. New St. Mark's Baths, 497 N.Y.S.2d 979 (App. Div. 1986) (concerning Takings Clause compensation for owners of bathhouses shut down by order of New York City to prevent the spread of AIDS); Cougar Bus. Owners Ass'n v. State, 647 P.2d 481 (Wash. 1982) (concerning business owners in a town that was adversely affected by the governor's declaration of a state of emergency due to the volcanic eruption of Mt. St. Helens who challenged the governor's actions as an uncompensated taking).

142. U.S. CONST. amend. V.

143. Hawaii Hous. Auth. v. Midkiff, 467 U.S. 229, 240 (1984).

144. Jacobson v. Massachusetts, 197 U.S. 11, 25 (1905).

145. *Id. See also* Birchard v. Bd. of Health, 169 N.W. 901 (Mich. 1918) (recognizing a municipality's right to erect and maintain pesthouses and other facilities for the protection of the public's health as long as they do not constitute a public nuisance).

146. Lingle v. Chevron U.S.A. Inc., 544 U.S. 528 (2005).

147. *See, e.g.*, United States v. Caltex (Phil.), Inc., 344 U.S. 149 (1952) (holding that destruction of a company's oil facilities during World War II to keep them out of the hands of the enemy was not a compensable taking). In cases of large-scale national emergencies such as war, the Court appears to be very concerned with the possibility that the United States could be held responsible to

jurisprudence reflects the tension between the Court's desire to prevent the government from forcing some people to bear public burdens on their own and ensuring that government will be able to function without having to compensate individuals for every action that has economic consequences.[148] In order to resolve these tensions in the context of individual cases, the Court has held that whether a compensable taking has occurred depends on the type of government action taken, the relative strength of the interests of the public versus the interests of the affected property owner, the extent of the property owner's economic loss, and the reasonable expectations of the property owner.[149]

How the courts would resolve this tension in the context of government interference with hospitals during a pandemic is *terra incognita*. Contemporary Takings Clause jurisprudence developed simultaneously with great advances in the fields of medicine and public health. Advances in public health have accounted for about twenty-five of the thirty years of increased life expectancy in the United States since the beginning of the twentieth century.[150] Because of these medical advances, large-scale epidemics requiring isolation and quarantine of sick persons in modern hospitals have been virtually unknown in this country since the Spanish flu in 1918. Yet, it was not until 1922 that the Court began to interpret the Takings Clause to require just compensation for government regulatory actions, both permanent and temporary, which had previously been considered non-compensable.[151] Therefore, the Takings Clause jurisprudence that existed the last time the United States had to contemplate the consequences of large-scale isolation and quarantine of infectious disease victims has limited utility for analyzing what the courts would do today if faced with hospital claims for compensation based on their compliance with isolation and quarantine orders.

Although an order establishing an isolation or quarantine center on private property is undoubtedly a "public use" within the meaning of the Takings Clause, it is less certain whether such an order involves a taking of "property." Physical occupation of the hospital by the government would clearly involve interference with "property," since even a *de minimus* physical occupation of real property constitutes a compensable taking.[152] An order establishing an isolation or

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everyone who suffers from the ravages and burdens of the emergency. *Id.* at 155-56.

148. *See Lingle*, 544 U.S. at 537-39.

149. *See* Loretto v. Teleprompter Manhattan CATV Corp., 458 U.S. 419, 434-35 (1982); Penn Cent. Transp. Co. v. New York City, 438 U.S. 104 (1978).

150. Levy, *supra* note 136, at 1150.

151. *See Lingle*, 544 U.S. at 537; Penn. Coal Co. v. Mahon, 260 U.S. 393 (1922) (establishing that government regulation of private property may be considered a constitutional taking, requiring just compensation, even if the government does not directly appropriate the property).

152. *See, e.g., Loretto*, 458 U.S. 419 (1982) (holding that installation of cables on an apartment building was a physical occupation requiring just compensation).

quarantine center at a hospital could involve a physical occupation of the hospital by the government. Nevertheless, it is far more likely to constitute a regulatory action directing the hospital to use its premises in a certain manner, thus disrupting the facility's day-to-day business. It is far from clear whether the hospital's contracts with insurers and other business associates, and day-to-day revenue-producing operations, are "property" within the meaning of the Takings Clause. Protecting these intangible interests would be of paramount importance to a hospital when considering whether to comply with an order designating it an isolation or quarantine center. The Supreme Court has found compensable takings when government action adversely affects intangible interests such as loss of repose,[153] intellectual property,[154] and monetary interest on pooled funds.[155] Yet, hospital managers could not be certain whether the Takings Clause would protect the hospital's intangible business interests.[156] Intangible business-related interests have been characterized as compensable "property" in some types of takings, but have been characterized as non-compensable losses in others.[157]

Most commentators and court decisions distinguish between two types of takings: possessory and regulatory.[158] A possessory taking occurs when the government confiscates or physically occupies private property.[159] A permanent physical occupation of property, no matter how minor, is a compensable taking no matter how strong the public interest that the government's action serves.[160] If

153. United States v. Causby, 328 U.S. 256 (1946).

154. Ruckelshaus v. Monsanto Co., 467 U.S. 986 (1984).

155. Phillips v. Wash. Legal Found., 524 U.S. 156 (1998).

156. *See* United States v. Caltex (Phil.), Inc. 344 U.S. 149, 156 (1952) ("No rigid rules can be laid down to distinguish compensable losses from noncompensable losses. Each case must be judged on its own facts.").

157. *See* David B. Sweet, Annotation, *Supreme Court's Views As to What Constitutes "Private Property" Within Meaning of Prohibition, Under Federal Constitution's Fifth Amendment, Against Taking of Private Property for Public Use Without Just Compensation*, 91 L. Ed. 2d. 582, § 6 (2006). State law governs whether intangibles are characterized as property protected by the Takings Clause. *See generally* JOHN E. NOWAK & RONALD D. ROTUNDA, CONSTITUTIONAL LAW § 11 (7th ed. 2004).

158. Some scholars argue that there are actually three types of takings: possessory, regulatory, and derivative. They define a derivative taking as occurring when government action affecting specific property diminishes the value of surrounding property. Abraham Bell & Gideon Parchomovsky, *Takings Reassessed*, 87 VA. L. REV. 277, 280 (2001). If the courts were to adopt Bell and Parhomovsky's theory of compensatory derivative takings, the number of possible compensatory takings due to government actions to combat a pandemic would likely increase beyond what is likely to occur under current jurisprudence.

159. CHEMERINSKY, *supra* note 138, at 575.

160. Loretto v. Teleprompter Manhattan CATV Corp., 458 U.S. 419, 441 (1982). The Court has

the government physically occupied a hospital permanently and ran it as an isolation or quarantine facility, the former owners of the hospital would clearly be entitled to compensation.[161] Nevertheless, there would still be a question remaining about the proper measure of damages.

The value compensable in the case of a permanent physical occupation of property by the government is the value that is capable of transfer from owner to owner, i.e., the fair market value of the property at the time of the government's action, from the perspective of the owner.[162] Nevertheless, the loss to the owner of nontransferable value deriving from a unique need for the property, or a sentimental or illogical attachment to it, is treated as a loss for the common good and is not compensable.[163] Sentimental value or inordinate attachment to a piece of property is not something that is transferable to the government. Likewise, eminent domain law generally does not recognize a right to compensation for destruction of business goodwill, provided the former owner is free to pick up and continue her business elsewhere.[164] The government must only pay for what it gets, not for what the owner loses.[165] The government does not receive the goodwill interests, because it does not continue to operate the property seized as a business. These types of losses are treated as the price of citizenship—a sacrifice for the greater good of the community.[166]

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found compensation for a possessory taking necessary even during wartime. *See* United States v. Pewee Coal Co., 341 U.S. 114 (1951).

161. For an example of statutory authority for a public health authority to commandeer and operate a hospital during a public health emergency, see LAWRENCE O. GOSTIN, CTR. FOR LAW & THE PUB.'S HEALTH, GEORGETOWN & JOHNS HOPKINS UNIV., MODEL STATE EMERGENCY HEALTH POWERS ACT 21 (2001) [hereinafter MSEHPA], *available at* http://www.publichealthlaw.net/MSEHPA/MSEHPA2.pdf. As of Feb. 1, 2006, § 502 of the MSEHPA had been adopted by twelve states. *See* Ctr. For Law & the Pub.'s Health, Model State Emergency Health Powers Act Legislative Surveillance Table, *available at* http://www.publichealthlaw.net/MSEHPA/MSEHPA%20Surveillance.pdf (last visited Nov. 8, 2006).

162. Kimball Laundry Co. v. United States, 338 U.S. 1, 5 (1949).

163. *Id.*

164. *See, e.g.*, WMX Tech. v. Miller, 197 F.3d 367 (9th Cir. 1999); Comm. Redevelopment Agency v. Abrams, 543 P.2d 905 (Cal. 1975); Mich. State Highway Comm'n v. Gaffield, 310 N.W.2d 281 (Mich. Ct. App. 1981); Port of N.Y. Auth. v. Howell, 157 A.2d 731 (N.J. Super. 1960), *aff'd* 173 A.2d 310 (N.J. 1960); Sandra L. K. Davidson, Annotation, *Good Will as Element of Damages for Condemnation of Property on Which Private Business is Conducted*, 81 A.L.R.3d 198 (1977). *But c.f.* United States v. 0.88 Acres of Land, 670 F. Supp. 210 (W.D. Mich. 1987); Dep't of Transp. v. Arnold, 530 S.E.2d 767, 771-72 (Ga. Ct. App. 2000) (holding that where the business owner is unable to relocate because of the unique nature of the condemned property, the government must pay compensation for lost goodwill).

165. *See generally WMX Tech.*, 197 F.3d at 367.

166. *Kimball Laundry Co.*, 338 U.S. at 5.

Thus, if the government seizes a hospital and subsequently shuts it down, courts might consider compensation constitutionally adequate if it is based on the fair market value of the property seized (e.g., the land, equipment, and fixtures). After all, the former hospital owners would not have a hospital with a significantly diminished value in the future returned to them. If the hospital owners wished to engage in the business of operating a general acute care hospital again, they could take the fair market value payment they received from the government for the hospital's tangible assets, find a new location, and start over, pointing to their record as owners of a successful acute care hospital prior to the government's actions as support for their new business.[167] No lingering stigma of a hospital's former designation as a "pesthouse" would follow them to their new business venture. They would not have to entice paying patients back to the hospital after it is no longer an isolation or quarantine center. They would not need to assure potential patients or insurers that a feared infectious disease was completely gone from the hospital, or that the hospital was once again capable of delivering the same type of quality care patients had come to expect from it before it was appropriated by the government. Theoretically, hospital owners can re-establish their relationships with insurers, suppliers, and employees on the same or similar terms to those that were previously negotiated, with no ill effects.[168]

Although the government has the legal authority to physically occupy a hospital and run it as an isolation or quarantine facility, if the government does so, it is highly unlikely that such an occupation would be permanent. When the immediate public health crisis subsides, and the government no longer needs the hospital, it will most likely return the hospital to the owners. The owners of a business that was temporarily occupied by the government and run as an ongoing business enterprise, then returned to the owners after the government's need for the business ends, are in a much different position than the owners of a business that is permanently appropriated by the government. Unlike owners whose businesses are gone forever, it is not financially feasible for business owners who know that they will ultimately get their business back to open a new version of that business while the government still occupies their old one. If they do, ultimately those owners are likely to find themselves with two identical

167. This presumes that the government has not regulated itself a monopoly on the provision of acute care hospital services, leaving the hospital with no means of continuing its business elsewhere. *See generally* Huntleigh USA v. United States, 63 Fed. Cl. 440 (2005) (holding that the complete federalization of the airline security business may require the government to compensate a private airline security business for loss of its ongoing business opportunity).

168. Generally, the courts award no compensation for loss of customers due to loss of location, because the customer base depends on additional factors such as the initiative and industry of the proprietors. *See, e.g.*, Hendrickson v. State, 127 N.W.2d 165, 167 (Minn. 1964).

businesses, neither of which can be operated at a profit because of the existence of the other business.[169] This temporary interruption of the owner's business narrows the range of alternatives open to the owner so much that it increases the government's obligation.[170] Although the usual measure of damages for a temporary possessory taking is the fair rental value of the property for the time period it is used by the government,[171] when the government's actions have so narrowed the range of alternatives available to the property owner, the government may be required to pay for the loss of going-concern value experienced by the owner.[172] In this situation, the government is receiving and using the going-concern value and goodwill of the business, and these interests are considered compensable property.

Although the government has the power to occupy and operate a hospital during a public health emergency, it is far more likely that public health authorities will rely on their statutory or regulatory power to designate hospitals as isolation and quarantine facilities, and require the hospital to comply with those orders, while the owners remain in possession and continue to operate the hospital.[173] If this type of government action qualifies as a taking at all, it would constitute a regulatory taking. There is no set formula for determining when government regulation has gone too far in encroaching on the rights of private property owners, constituting a regulatory taking.[174] If government action permanently deprives a property owner of *all* economically beneficial use of her property, the government must pay the owner just compensation.[175] In such a

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169. *Kimball Laundry Co.*, 338 U.S. at 14.

170. *Id.* at 15.

171. *See* J.E. Keefe, Jr., Annotation, *Elements and Measure of Compensation in Eminent Domain for Temporary Use and Occupancy*, 7 A.L.R.2d 1297 (1949).

172. *Kimball Laundry Co.*, 338 U.S. at 15-16. This principle has recently been held to apply to a regulatory taking that creates a government monopoly in the former business owner's line of work. *See* Huntleigh USA v. United States, 63 Fed. Cl. 440, 443 (2005) (holding that the proper measure of damages to a former airline security business for the federal government's takeover of the airline security industry should include payment for lost goodwill and going-concern value).

173. *See, e.g.*, MSEHPA, *supra* note 161, § 502(b) (describing the government's powers under these circumstances). Federal, state and local governments do not have the personnel necessary to physically occupy the number of hospitals that are likely to be needed in the event of a large-scale public health emergency. The United States Public Health Service has only roughly 1300 commissioned medical officers, roughly 1000 nurse officers, and roughly 730 pharmacy officers. *See* U.S. Pub. Health Commissioned Corps, Professions, *available at* http://www.usphs.gov/html/professions.html (last visited Nov. 8, 2006).

174. Pa. Coal Co. v. Mahon, 260 U.S. 393, 415 (1922).

175. Lingle v. Chevron U.S.A. Inc., 544 U.S. 528, (2005) (quoting Lucas v. S.C. Coastal Council, 505 U.S. 1003, 1019 (1992)).

case, business goodwill and going concern value may be compensable property, as they are compensable when the government actually possesses the property temporarily.[176] This is especially true if the government has made it impossible, through regulation or otherwise, for the former business owners to engage in their former business elsewhere.[177]

Nevertheless, this *per se* rule of compensation does not appear to apply to a *temporary* regulatory taking, even if the regulation does deprive the property owner of all beneficial use of her property while it is in effect.[178] For temporary regulatory actions, whether a compensable taking has occurred is an unqualified maybe.[179] Furthermore, the Court has cautioned against applying precedents from possessory takings cases to regulatory takings cases, making analysis of temporary regulatory takings cases even more unpredictable and fact-specific.[180]

For the vast majority of regulatory takings cases, both permanent and temporary, the Court has applied a three-factor test to determine if compensation is due to the property owners. This test is known as the *Penn Central* test.[181] The primary *Penn Central* factors are: the economic impact of the regulation on the property owner; the extent to which the regulation interferes with investment-backed expectations; and the character of the governmental action.[182] The inquiry is specific to the facts of each case, making it virtually impossible to predict in advance whether or not a particular government action will result in a compensable taking.

The unsatisfactory state of the law of compensation for goodwill and going concern value if the government designates a hospital as an isolation or quarantine facility during a pandemic is summarized in Table Two.

176. *See Kimball Laundry Co.*, 338 U.S. at 2.

177. *See* Huntleigh USA, 63 Fed. Cl. at 440.

178. *See, e.g.*, Tahoe-Sierra Pres. Council v. Tahoe Reg'l Planning Agency, 535 U.S. 302 (2002) (holding that a building moratorium lasting thirty-two months did not necessarily constitute a *per se* compensable taking).

179. *Id.* at 321.

180. *Id.* at 323. This caution has not troubled the United States Court of Federal Claims. The Court of Federal Claims recently extended the holding in *Kimball Laundry*, 338 U.S. 1, a temporary possessory takings case requiring compensation for lost good will and going concern value, to a permanent regulatory taking. *Huntleigh USA*, 63 Fed. Cl. at 440.

181. *See Tahoe-Sierra Pres. Council*, 535 U.S. at 323.

182. Penn Cent. Transp. Co. v. New York City, 438 U.S. 104, 124 (1978).

Table 2: Availability of Compensation for Loss of Goodwill and Going Concern Value When a Hospital is Designated an Isolation or Quarantine Center

	Government Physically Occupies and Runs the Hospital	*Government Designates the Hospital as an Isolation or Quarantine Center*
Temporary Taking	Probably compensable	Unknown
Permanent Taking	Not compensable unless the government uses the hospital's goodwill to conduct its business.	Not compensable unless government deprives owner of all economically beneficial use.

In the context of an order designating a hospital as a temporary isolation or quarantine center, one could imagine myriad fact-specific inquiries that would plague the courts applying the *Penn Central* test. For example, with regard to the economic impact of the regulation on the property owner, should loss to the hospital be offset by any payment made to the hospital by the public health authorities for caring for isolated or quarantined people? What are the hospital's damages, given the cost-shifting phenomenon and the convoluted nature of hospital payments structures? What kind of investment-backed expectations exist for private non-profit hospitals, and how does a charitable mission factor into these expectations? With regard to the character of the government action, shouldn't hospitals, which are heavily regulated by the state, expect to be subject to orders of this nature, and therefore be devoid of the type of vested property right that would warrant compensation?[183]

The most likely government action is a temporary regulatory designation as an isolation or quarantine facility. Under current Takings Clause jurisprudence, the only certainty in this scenario is that a hospital can argue about whether it is entitled to receive any compensation from the government. And even if the hospital convinces a court that the *Penn Central* factors favor compensation, it must then argue that the Court's possessory Takings Clause jurisprudence allowing compensation for goodwill and going-concern value in certain circumstances should apply to a temporary regulatory taking, an analogy that the Court has discouraged.[184] And even if the hospital convinces the court that goodwill and going-concern value are compensable property in the case of a

183. *See generally Huntleigh USA*, 63 Fed. Cl. 440, 446-48 (2005) (discussing the highly regulated nature of the airline security business and rejecting that as a reason to refrain from ordering compensation for government taking).

184. *Tahoe-Sierra*, 535 U.S. at 323-24.

temporary regulatory taking, such damages are notoriously hard to quantify.[185]

Because the availability, type, or amount of compensation under the Takings Clause is uncertain, the Clause is not an incentive for hospitals to comply with the orders of public health authorities during a pandemic. In the case of a wide-scale public health emergency requiring multiple isolation and quarantine centers capable of using sophisticated medical technology, the threat of massive amounts of litigation regarding the compensation due to hospitals is likely to cool the eagerness of hospitals to comply with the orders of public health authorities. It could also make the government think twice about designating hospitals as isolation and quarantine centers. This fear may dilute the response to the emergency, cause delay, and adversely affect the public's health. The undeveloped state of our Takings Clause jurisprudence in the context of public health emergencies encourages hospitals to protect themselves by resisting such orders in the first place. Resistance becomes far more attractive than taking the chance of complying and engaging in protracted litigation about the amount of compensation due afterward.

"Demoralization costs" are a less apparent danger to the viability and quality of our health care system from the uncertainty surrounding compensation for takings in public health emergencies.[186] A "demoralization cost" is the loss in utility that can be attributed to the likelihood that a property owner, knowing that the compensation she receives will be inadequate if her property is taken, will fail to maintain the property or use it properly.[187] A hospital that knows that it is unlikely to receive adequate compensation for its losses if it is designated as an isolation or quarantine facility has little economic incentive to build additional capacity or invest in additional equipment in anticipation of a pandemic.[188] In this context, demoralization costs may take the form of hospitals choosing to make themselves less attractive isolation or quarantine centers by channeling funds away from pandemic preparedness. Hence, hospitals that might have been well-prepared for a pandemic may consciously choose to under-prepare so that they can reap the financial benefits related to treating the more lucrative patients that

185. Even a scholar of law and economics as respected as Justice Felix Frankfurter was apparently stumped when trying to quantify damages for a temporary regulatory taking. In *Kimball Laundry Co.*, 338 U.S. at 1, Justice Frankfurter's majority opinion did not dictate a methodology for the trial court to use in valuing good will or going-concern value. *Id.* at 16. Instead, it set forth various examples of how to calculate the value of these intangibles from economic texts of the time, and remanded the matter to the trial court to sort out. *Id.* The dissenters noted with disdain that the majority opinion includes an "academic dissertation on valuation." *Id.* at 23.

186. *See, e.g.*, Frank I. Michelman, *Property, Utility and Fairness: Comments on the Ethical Foundations of "Just Compensation" Law*, 80 HARV. L. REV. 1165 (1967).

187. *Id.* at 1214.

188. *Id. See also* Calandrillo, *supra* note 140, at 525.

isolation and quarantine centers will have to turn away. A perverse incentive to under-prepare such as this works to the severe detriment of the public's health by decreasing overall pandemic preparedness.

B. Federal Statutory and Regulatory Financial Safeguards

A small number of diseases, including pandemic flu, are subject to federal quarantine authority.[189] Expenses for the care and treatment of persons quarantined pursuant to federal quarantine authority, including victims of pandemic flu, may be paid by the United States Public Health Service.[190] However, the legislation does not specify a payment amount or rate.[191] Therefore, it does little to provide assurance or incentives to hospitals to quarantine victims of diseases subject to federal quarantine.

For all other diseases, state and local governments have primary responsibility for isolation and quarantine within their borders.[192] Federal authorities do not have jurisdiction until the Director of the CDC determines that measures taken by state or local authorities are inadequate to prevent the spread of a communicable disease outside of a state.[193]

However, there are provisions for federal financial assistance to hospitals in the event of a pandemic. Federal statutes such as the Stafford Act[194] and the Public Health Service Act[195] specify certain conditions under which the federal government will contribute resources, personnel, and financial aid in the event of a public health emergency. Nevertheless, these statutes provide no assurance that federal financial resources will be adequate to meet the hospitals' short-term needs, nor are they directed toward alleviating the long-term financial effects of a

189. Exec. Order No. 13,375, 70 Fed. Reg. 17299 (Apr. 1, 2005); Exec. Order No. 13,295, 68 Fed. Reg. 17,255 (Apr. 4, 2003). These diseases are cholera, diphtheria, infectious tuberculosis, plague, smallpox, yellow fever, viral hemorrhagic fevers (Lassa, Marburg, Ebola, Crimean-Congo, South American, and others not yet isolated or named), SARS, and influenza caused by novel or reemergent influenza viruses that are causing, or have the potential to cause, a pandemic.

190. 42 U.S.C. § 249 (2000). Although persons not otherwise entitled to treatment by the Public Health Service may be treated in cases of emergency, they will be charged for treatment. 42 C.F.R. § 32.111 (2005). This will leave the hospital holding the bag with regard to payment for any treatment they render under orders of the Public Health Service that are not for one of the diseases subject to federal quarantine.

191. 42 U.S.C. § 249.

192. CDC, Severe Acute Respiratory Syndrome (SARS): Fact Sheet on Isolation and Quarantine 1 (2004), *available at* http://www.cdc.gov/ncidod/sars/pdf/isolationquarantine.pdf.

193. 42 C.F.R. § 70.2 (2005).

194. 42 U.S.C. § 5121 (2000).

195. 42 U.S.C. § 241 (2000).

pandemic on hospitals. Rather, the vast majority of federal expenditures authorized under these statutes are allocated to state and local governments to prepare and plan for immediate needs during a public health emergency, such as enhanced communications between first responders, and pre-emergency development of hospital surge capacity.[196] Virtually no funds have been earmarked for alleviating the long-term financial effects of a public health emergency on the nation's health care delivery system. Although it is laudable and necessary to spend funds to develop better disease surveillance systems and hospital surge capacity, these planning efforts do not provide an economic incentive for hospitals and other first responders to cooperate with the orders of public health authorities during the critical early stages of a pandemic.

1. The Stafford Act

The Stafford Act is the federal government's primary legislation designed to alleviate the consequences of major disasters and emergencies in the United States.[197] Occurrences that trigger the Stafford Act's provisions are divided into "emergencies" and "major disasters."[198] The Stafford Act defines "major disasters" as natural catastrophes, generally involving weather-related phenomena, geological occurrences, fires, floods, or explosions.[199] The Stafford Act's definition of "emergency" is more nebulous.[200] Under the Stafford Act, an "emergency" means any occasion or instance for which the President determines that "federal assistance is needed to supplement State and local efforts and capabilities to save lives and to protect property and public health and safety, or to lessen or avert the threat of a catastrophe in any part of the United States."[201] Thus, the President could trigger the Stafford Act by declaring a pandemic an "emergency."[202]

However, the President can only declare a state of emergency exists in response to a request of the Governor of an affected state.[203] The Governor must base his or her request "on a finding that the disaster is of such severity and magnitude that effective response is beyond the capabilities of the State and the affected local governments and that Federal assistance is necessary."[204] In the

196. *See, e.g.*, U.S. Dep't of Health & Human Servs., *supra* note 48.
197. 42 U.S.C. § 5121 (2000).
198. 42 U.S.C. § 5122(1)-(2) (2000).
199. 42 U.S.C. § 5122(2) (2000).
200. 42 U.S.C. § 5122(1) (2000).
201. *Id.*
202. *See id.*
203. 42 U.S.C. § 5170 (2000)
204. *Id.*

context of a pandemic, public officials have serious disincentives to admitting that the situation is beyond their capabilities. There is a serious stigma and accompanying loss of revenue that surrounds a geographic area, industry, or even building that becomes associated in the public's mind with an infectious disease.[205] The disruptions have political consequences as well. During the outbreak of an influenza virus in 1976 at Fort Dix, New Jersey that became known as the "swine flu," pig farmers complained that the name "swine flu" might frighten people away from eating pork.[206] They suggested renaming the flu the "New Jersey flu."[207] State officials, concerned about the effect the name "New Jersey flu" would have on the state's image, vigorously resisted this moniker.[208]

More recently, China delayed release of information on the SARS outbreak because of its fear that news of SARS would impact negatively its local economies, particularly before the upcoming Chinese New Year.[209] During the SARS outbreak in Taiwan, the Taiwanese Health Department fined three physicians the equivalent of $2600, and three hospitals the equivalent of $43,000 each for covering up or delaying the reporting of possible SARS cases.[210] The City of Toronto and the Province of Ontario are currently defending several lawsuits alleging that they failed to take appropriate measures to control the outbreak of SARS.[211] The plaintiffs allege that the government's failures were driven by their desire to preserve the public image of Toronto and not alarm the international community.[212]

It is likely that state and local officials will be reluctant to stigmatize their communities by requesting federal assistance at an early stage of a pandemic. Therefore, federal assistance may well be delayed until the situation is dire enough to override these concerns and force a Governor to request assistance under the Stafford Act. By that time, it may be too late to contain a fast-moving pandemic.

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205. *See* Varley, *supra* note 121.

206. KOLATA, *supra* note 4, at 155. The virus was called "swine flu" because the type of influenza virus was identified as a pig virus.

207. *Id.*

208. *Id.*

209. David Bishop, Note, *Lessons from SARS: Why the WHO Must Provide Greater Economic Incentives for Countries to Comply with International Health Regulations*, 36 GEO. J. INT'L L. 1173, 1184 (2005).

210. ROTHSTEIN ET AL., *supra* note 15, at 103.

211. *See, e.g.*, Reasons for Decision at 2-4, Between Andrea Williams and The Attorney-General of Canada *et al.*, No. 03-CV-259366 CP, Ont. Super. Ct. of J., Aug. 22, 2005) (on file with the author).

212. *Id.*

Nevertheless, once the President declares a federal emergency, Stafford Act assistance designed to support local efforts to "save lives, protect property and public health and safety, and lessen or avert the threat of a catastrophe" becomes available.[213] Total assistance for a single emergency cannot exceed $5 million, unless the President determines that continued emergency assistance is immediately required because of a continuing and immediate risk to lives, property, public health or safety, and that necessary assistance will not otherwise be provided on a timely basis.[214] Under the Stafford Act, the federal government is the payor of last resort; an applicant for aid under the Act must exhaust all other sources of aid first, including private insurance.[215] The United States may recoup federal assistance if it duplicates benefits available to the person from another source.[216]

When the President declares an emergency under the Stafford Act that involves public health needs or a developing potential medical situation, the Department of Health and Human Services Emergency Support Function #8 (ESF 8) describes the structure within which the federal government delivers assistance.[217] ESF 8 specifies the types of supplemental federal assistance available to state and local governments to meet the health and medical needs of victims of emergencies.[218] The federal assistance authorized under ESF 8 takes the form of administration and coordination of supplemental federal resource distribution.[219] ESF 8 specifically states that "[A]rrangements for definitive medical care are primarily a local function. Requests for additional assistance should first be referred to State authorities."[220] ESF 8 does not provide for any federal involvement in the after-effects of a public health emergency, economic or otherwise, on the nation's hospitals.

2. The Public Health Service Act

The Stafford Act is not the only federal legislation applicable to a public health emergency situation. In addition to establishing the Public Health Service, the Public Health Service Act[221] (PHSA) specifically addresses the powers and

213. 42 U.S.C. § 5192(a)(2) (2000).

214. 42 U.S.C. § 5193(b) (2000).

215. 42 U.S.C. § 5155(a) (2000).

216. 42 U.S.C. § 5155(c).

217. U.S. DEP'T HOMELAND SEC., NATIONAL RESPONSE PLAN § ESF 8-1 (2004), *available at* http://www.dhs.gov/xlibrary/assets/NRP_FullText.pdf.

218. *Id.*

219. *Id.*

220. U.S. DEP'T HOMELAND SEC., NATIONAL RESPONSE PLAN § ESF 8-14 (2003).

221. Public Health Service Act, 42 U.S.C. §§ 201-300hh (2000).

role of the federal government during public health and medical emergencies.[222] The PHSA supplements, but does not supplant, the Stafford Act, and it is specifically directed toward public health emergencies.[223] Both authorities can be invoked in the event of a public health emergency that meets the respective definitions of "emergency" under the two statutes.[224] Under the PHSA, the Secretary of the Department of Health and Human Services can declare a public health emergency and may make grants and provide awards for expenses to entities involved in responding to such an emergency.[225] The Secretary's declaration of a public health emergency automatically expires after ninety days, subject to renewal.[226] The PHSA establishes a "Public Health Emergency Fund" available to the Secretary in the event she declares a public health emergency.[227] Although the fund was previously required to have a balance of $30 million at the beginning of each fiscal year, current legislation does not establish any specific funding level for the fund.[228] Expenditures from the fund are designed to meet short-term public health emergency needs; they can only be made while a declaration of a public health emergency is in effect.[229] The fund is not meant to assist in the long-term economic recovery of hospitals and other health care providers.

The PHSA was amended in June 2002 by the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (Response Act), specifically for the purpose of enhancing the United States' preparedness for a large-scale public health emergency.[230] To supplement the Public Health Emergency Fund, the Response Act earmarks federal funds for preparation for a public health emergency.[231] There are funds set aside for assessing national needs to combat threats to the public health, for grants to states or local authorities to assess public health threats, for grants to improve state and local public health agency preparedness, for grants to improve state, local, and hospital preparedness

222. U.S. Dep't Health and Human Servs., Planning & Response 4 (2004) [hereinafter Planning], http://www.pandemicflu.gov/plan/ (last visited Dec. 8, 2006).

223. 42 U.S.C. § 247d(c) (2000).

224. 42 U.S.C. § 247d. The PHSA does not contain a definition of a "public health emergency," but leaves it to the determination of the Secretary of the Department of Health and Human Services in consultation with "such public health officials as may be necessary." 42 U.S.C. § 247d(a).

225. 42 U.S.C. § 247d(a).

226. *Id.*

227. 42 U.S.C.A. § 247d(b).

228. *Id.*

229. *Id.*

230. Public Health Security and Bioterrorism Preparedness and Response Act of 2002, Pub. L. No. 107-188, 116 Stat. 594 (2002).

231. 42 U.S.C. § 247d-1 to -3 (2000).

for a public health emergency, and for grants for community-hospital partnerships to prepare for a public health emergency.[232] For fiscal year 2003, 1.6 billion dollars in federal funds were allocated for these purposes.[233] The funds can be expended for a variety of planning and preparedness functions, including response training for health care professionals, enhancing worker safety in the event of a bioterror attack, and simulations and exercises to test the capability and timeliness of public health emergency responses.[234]

The Response Act also enhanced the National Disaster Medical System (NDMS).[235] The NDMS is specifically designed to augment the country's emergency medical response capability during a public health emergency. The Secretary may activate the NDMS to provide medical services to the victims of a public health emergency, even if a public health emergency has not been declared under the PHSA.[236] Private hospitals may voluntarily join the NDMS by entering into an agreement with NDMS.[237] Hospitals agreeing to join NDMS agree to commit a number of their available acute-care beds for NDMS patients.[238] The number of beds committed may be adjusted at will by the hospital, even after the NDMS is activated.[239] As of March 2006, approximately 1818 hospitals have committed approximately 110,605 acute-care beds to the NDMS program.[240] Although at first glance, this sounds promising, even in a normal year flu patients occupy over 114,000 hospital beds.[241] Given the needs for beds in even a normal flu year, it is apparent that hospitals are not eagerly lining up to contribute beds to the NDMS in sufficient numbers to make a dent in the bed capacity that will be needed in the event of even a moderate influenza pandemic.[242] Further incentives are necessary to enlist sufficient numbers of hospitals for the NDMS to have any real effect during a public health emergency.

One reason for the lackluster hospital response to the NDMS might be financial. Although hospitals that admit NDMS patients are assured that they will be reimbursed by the federal government, the legislation only contemplates

232. 42 U.S.C.. § 247d-3b (2000).

233. 42 U.S.C. § 247d-3a (2000).

234. *Id.*

235. 42 U.S.C.A. § 300hh-11 (West 2006).

236. 42 U.S.C.A. § 300hh-11(b)(3)(A)(i) (West 2006).

237. *See* U.S. Dept. of Homeland Sec., Frequently Asked Questions About NDMS, http://mediccom.org/public/tadmat/ndms/NDMSFAQ.html (last visited Nov. 8, 2006).

238. *Id.*

239. *Id.*

240. U.S. Dept. of Homeland Sec., NDMS Statistics, http://mediccom.org/public/tadmat/ndms/ndmsstat.html (last visited Nov. 8, 2006).

241. *See* Meltzer et al., *supra* note 13.

242. *See supra* fig. 1.

reimbursement for the actual expenditures incurred in furtherance of the program.[243] The legislation authorizing appropriations to pay for the program does not specify a method for calculating the amounts hospitals will receive for each bed occupied by an NDMS patient. It is left to the Secretary to provide the resources necessary to reimburse expenditures carried out in furtherance of the program.[244] A hospital might easily decide that the reimbursement contemplated is too uncertain for it to take the risks associated with designating beds as NDMS beds. Without any understanding of what payment will be made for beds committed to the NDMS, hospitals are likely to decline to join the NDMS, or quickly withdraw their beds from the program at the start of an emergency, if the beds are filled with more lucrative privately insured patients at that time. Even if its beds are not filled, hospitals are unlikely to run the risk of losing whatever more lucrative business they do have at the beginning of a pandemic by designating empty beds to the NDMS and running the risk that they will become isolation or quarantine centers and that they will lose their lucrative privately insured patients to other hospitals.

C. Federal Administrative Preparations for Public Health Emergencies

An enormous amount of money has been earmarked for public health emergency preparedness through these legislative schemes. Nevertheless, there is confusion about the amount and character of funds earmarked for actual direct payment to health care providers responding to a public health emergency. Additionally, none of these legislative schemes allocates money to hospitals for the purpose of dealing with the economic aftermath of a pandemic. In November 2005, the President released the National Strategy for Pandemic Influenza, along with a request to Congress for $7.1 billion in funding.[245] The funding request asked for $251 million to detect and contain outbreaks before they spread around the world; $2.8 billion to accelerate development of cell-culture technology; $800 million for development of new treatments and vaccines; $1.519 billion for the Department of Health and Human Services and Defense to purchase influenza vaccines; $1.029 billion to stockpile antiviral medications; and $644 million to ensure that all levels of government are prepared to respond to a pandemic outbreak.[246] Along with the National Strategy, the Department of Health and Human Services released its more detailed Pandemic Influenza

243. 42 U.S.C.A. § 300hh-11(b)(3)(A) (West 2006).

244. 42 U.S.C.A. § 300hh-11(h) (West 2006).

245. HOMELAND SEC. COUNCIL, NATIONAL STRATEGY FOR PANDEMIC INFLUENZA AND FUNDING REQUEST (2005), *available at* http://www.whitehouse.gov/homeland/pandemic-influenza.html (last visited Nov. 8, 2006).

246. *Id.*

Plan.[247] Health and Human Services's Pandemic Influenza Plan provides further details of how it will expend the bounty of federal preparedness funds authorized in response to the President's request.[248] The Plan sets forth a detailed operational framework for prevention, preparedness, evaluation, response, containment and recovery from an influenza pandemic.[249] It specifically describes who is responsible for what activities among the various federal agencies with overlapping responsibilities in the area of public health.

Yet, despite this level of specificity, the Plan is vague about whose obligation it is to pay for care once a public health emergency is declared, and through what agency the money will flow. This vagueness is echoed in the more general Concept of Operations Plan (CONOPS) for Public Health and Medical Emergencies that was previously promulgated by the Department of Health and Human Services.[250] CONOPS merely states that funding for the activities described in the Plan will be provided through direct and supplemental appropriations and reimbursements.[251] CONOPS also notes that the states could be made to reimburse the federal government for certain activities carried out during a public health emergency under the PHSA, setting the stage for widespread and numerous arguments about payment responsibilities.[252] Not only will private insurers and the government argue about payment for pandemic victims, but so too will hospitals and local authorities, local authorities and state agencies, and the federal government and the states. Knowing that the states and the federal government have not agreed on who will pay for care during a public health emergency hardly provides an incentive for swift hospital compliance with local public health authority orders.

As far as the economic aftermath of a public health emergency is concerned, the discussion of recovery in CONOPS is limited to a brief statement regarding demobilizing the Secretary's Emergency Response Team, and an assurance that there are medical and mental health services available to agency workers after deployment.[253] Consistent with the federal assumption that a public health emergency is a short-lived, limited scope phenomenon and that direct provision of medical care is a primarily local concern, CONOPS does little to address the after-effects of a public health emergency on the nation's health care delivery system, economic or otherwise.

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247. *Id.*
248. Planning, *supra* note 222.
249. *Id.* at 9.
250. *Id.*
251. *Id.* at 8.
252. *Id.* at 9.
253. *Id.* at 14.

D. State and Local Authorities

Authority to isolate or quarantine in the event of a public health emergency varies widely from state to state.[254] This Section examines what type of compensation hospitals subject to isolation or quarantine orders can expect if they comply under three different pandemic planning efforts: the Model State Emergency Health Powers Act (MSEHPA); the planning efforts of our most densely populated state, New Jersey; and the planning efforts of an extremely populous state, California.[255] Both states consider themselves prime candidates to be the starting point of a pandemic in the United States.[256]

The MSEHPA reflects an attempt by public health law scholars to bring some uniformity to state public health powers and authorities.[257] Parts of the MSEHPA, or provisions modeled on parts of the MSEHPA, have been adopted by thirty-eight states as of July 15, 2006.[258] The MSEHPA specifies that compensation for property taken by a public health authority during a public health emergency shall be calculated in accordance with the applicable laws of eminent domain in a non-emergency situation.[259] Unless a state's constitution has been interpreted to provide compensation beyond that contemplated under the federal Constitution in a temporary regulatory taking situation, a hospital that has been used as an isolation or quarantine facility and is located in a state that follows the MSEHPA would find itself in the Takings Clause compensatory netherworld described in Section III.A.

States that have not enacted this provision of the MSEHPA do not necessarily have plans in effect that are more likely to assure hospital compliance with orders of public health authorities. For example, New Jersey, the most densely populated state, considers itself to be particularly vulnerable to the importation and spread of infectious disease.[260] Over half a million people commute between New York and New Jersey every day. This high volume of traffic makes the region particularly susceptible to the interstate spread of disease

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254. CDC, *supra* note 192.

255. *See* CAL. DEP'T OF HEALTH SERVS., PANDEMIC INFLUENZA PREPAREDNESS AND RESPONSE PLAN 6 (2006), *available at* http://www.dhs.ca.gov/ps/dcdc/izgroup/pdf/pandemic.pdf; N.J. DEP'T OF HEALTH & SENIOR SERVS., INFLUENZA PANDEMIC PLAN 12 (2006), *available at* http://www.cste.org/specialprojects/Influenzaplans/StateMap.asp.

256. See *infra* Section III.C.

257. MSEHPA, *supra* note 161.

258. *See* Ctr. for Law & the Pub.'s Health, *supra* note 161.

259. MSEHPA, *supra* note 161, at §§ 506, 805(c). As of July 15, 2006 8 states (Ala., Del., Iowa, La. Mo., N.H.) had adopted § 506 of the MSEHPA. *See* Ctr. for Law & the Pub.'s Health, *supra* note 161.

260. N.J. DEP'T OF HEALTH & SENIOR SERVS., *supra* note 255.

during a pandemic.[261] Recognizing its potential vulnerability to an influenza pandemic, New Jersey has a lengthy and detailed draft Influenza Pandemic Plan.[262] The Plan was developed in close collaboration with partner organizations throughout the state, and reviewed by both public and private sector stakeholders.[263] The Plan recognizes that because of the likely scope and duration of an influenza pandemic, it will be difficult to shift resources between states, and New Jersey must plan to be self-reliant.[264] The Plan acknowledges that influenza prophylaxis and treatment during a pandemic will predominantly be the responsibility of individuals and organizations in the private sector, and that the private sector will need to voluntarily comply with guidelines and directives from governmental agencies.[265] New Jersey also acknowledges that the pre-pandemic period is the critical period for determining the impact of the pandemic on health care resources.[266]

Despite the apparent awareness of New Jersey public health authorities that cooperation from the private health care sector will be critical in a public health emergency, the Plan contains no provisions for alleviating the immediate or long-term economic impact the private health care sector is likely to experience from treating victims of an influenza pandemic.[267] In fact, the plan acknowledges that the economic impact of an influenza pandemic will be significant, but then states that the economic impact is not within the purview of the public health response plan.[268] The closest the Plan comes to addressing the problem is a promise that the New Jersey Department of Health and Senior Services Office of the State Epidemiologist will coordinate a state-wide effort to assess the impact of the pandemic on health care resources and prepare a report with recommendations

261. *Id.*

262. *Id.*

263. *Id.* at 2.

264. *Id.*

265. *Id.* To facilitate private sector cooperation, New Jersey has provided an "Influenza Pandemic Plan Guide for Health Care Facilities." N.J. Dept. of Health & Human Servs., Influenza Pandemic Plan Guide for Health Care Facilities (Aug. 31, 2005), *available at* http://nj.gov/health/flu/pandemic.shtml.

266. *Id.*

267. The New Jersey Department of Health and Senior Services estimates that an eight week wave of pandemic influenza with an attack rate of thirty-five percent will result in 40,904 hospital admissions, 9553 patients in ICU, 4775 flu patients on ventilators, and 8141 deaths (of which 5700 will occur in hospitals). *Id.* at 13. New Jersey acknowledges that these numbers are most likely underestimates of what would occur during such a pandemic. *Id.*

268. *Id.* at 14. The New Jersey plan cites the effect of the SARS outbreak on Toronto as evidence of the likely economic impact of a pandemic on the state.

for the future when the pandemic is over.[269]

It is doubtful that the assurance that the authorities will prepare a report with recommendations will be sufficient to persuade hospitals to comply with the orders of public health authorities designating them as isolation or quarantine centers. Nor does the state constitution provide any comfort to hospitals facing financial ruin. The New Jersey Constitution's Takings Clause has been construed to be coextensive with the United States Constitution's Takings Clause.[270] Given the uncertainty that hospitals will be compensated under traditional Takings Clause analysis, this seems a recipe for hospital defiance rather than cooperation in the event of a pandemic.

California, a populous state in close proximity to Asia and a large immigrant population, acknowledges that a pandemic is likely to affect everyone in California, and that no amount of planning will allow response to a major pandemic to be "business as usual."[271] The California Department of Health, in its Pandemic Influenza Preparedness and Response Plan, estimates that twenty-five to thirty-five percent of the population could become ill with influenza in the event of a pandemic, and that there could be 200,000 deaths.[272] The Department of Health acknowledges that a pandemic could continue for months, or even years, and will require a sustained health facility response.[273] The Plan's objectives for health care planning are to maintain, to the greatest extent possible, the provision of health care services sufficient to meet the needs of all Californians during an influenza pandemic, as well as respond to the health care needs of pandemic victims and coordinate that response among providers.[274] In order to accomplish this, the public health authorities are exploring their legal authority to require hospitals to cancel elective surgeries or otherwise develop capacity in anticipation of a pandemic.[275] Yet the Plan says nothing about assuring hospitals that they will be compensated for the economic damage they will experience if public health authorities do cancel such surgeries or designate the hospitals as isolation or quarantine centers.

Once again, the state constitution does not hold any comfort for hospitals facing potential financial ruin. The California Supreme Court has characterized a "somewhat broader" range of valuation for property taken by the government under the California Constitution, but otherwise, the state and federal Takings

269. *Id.* at 78.

270. *See* Rohaly v. State, 732 A.2d 524, 526 (N.J. Super. Ct. App. Div. 1999).

271. CAL. DEP'T OF HEALTH SERVS., *supra* note 255.

272. *Id.* at 3.

273. *Id.* at 6; *id.* app. 3 § 3.1.

274. *Id.* app. 3 § 3.3.

275. *Id.* app. 3 § 3.6.1.

Clauses are construed identically.[276] Without any financial assurances beyond the vagaries of litigation under the Takings Clause, privately owned hospitals are likely to succumb to the "not in my backyard" syndrome and do whatever they can to avoid being associated with the pandemic, at least during its critical early stages.

III. ENSURING THAT HOSPITALS ACT IN THE INTERESTS OF PUBLIC HEALTH DURING A PANDEMIC

Current law does little to ensure that hospitals will be adequately compensated if they comply with the orders of public health authorities during the critical early stages of an infectious disease pandemic. It does not encourage hospitals to comply with such orders in the face of countervailing economic self-interest. In order to be reassured that they will not be forced out of business if they comply with such orders, hospitals must be convinced of three things: that they will be paid for the actual costs of caring for victims of a pandemic; that they will be paid for lost revenue from disruption of their routine business and their inability to cost-shift while caring for pandemic victims; and that they will receive adequate compensation after the pandemic is over to make up for stigma of having cared for pandemic victims. If we can ensure that hospitals will be compensated adequately for these losses, we can ensure that our hospitals will act in the interest of the public's health in the face of a pandemic, rather than acting in a manner contrary to the public interest for economic self-preservation. The remainder of this Article suggests that an efficient way to provide adequate compensation to hospitals and ensure the public's health is through changing the laws to clarify the responsibilities of various government actors to pay hospitals for caring for pandemic victims, and to assure hospitals levels of compensation that reflect the realities of our health care financing system. Necessary changes to the laws include adopting legislation mandating that the public and the private sectors collaborate in ways that take advantage of their respective areas of expertise.

A. Amending Current Disaster and Emergency Laws To Assure Prompt Payment for the Direct Costs of Care

During the thick of a public health emergency, quick economic relief to hospitals is of paramount importance. Our existing emergency and disaster relief laws should clearly provide for direct payments to hospitals in the throes of dealing with pandemic disease, regardless of whether the hospitals are acting pursuant to a federal emergency declaration or in response to the orders of local

276. *See* San Remo Hotel v. City of San Fransisco, 41 P.3d 87, 88 (Cal. 2002).

public health officials. After the crisis passes, the law should allow the government to recoup the amounts it expended in caring for sick patients from the patients' private health insurers. This will prevent private health insurers from receiving a windfall at the expense of the public, postpone the inevitable arguing about who is responsible to pay for the treatment of pandemic victims until the pandemic subsides and the immediate public health crisis is over, and shift the onus of that argument from the hospitals to the federal or local governments.

Where will these initial payments come from? Although federal and state laws are full of preparedness initiatives, and substantial funding from all levels of government has been directed toward preparedness, confusion reigns about who will pay for what when pandemic victims are actually hospitalized.[277] Although some hospitals have accumulated large reserves in recent years and may be able to handle the disruption in their revenue streams that will occur when they are responding to a pandemic, many hospitals operate at the edge of solvency.[278] In order to ensure that hospitals have funds readily available to survive the interruption of their normal revenue streams, Congress should earmark some of the dollars allocated for influenza and pandemic preparedness for a reserve fund designed to pay for the care of pandemic victims as care is rendered. In keeping with the philosophy expressed in ESF 8 that arranging for medical care is primarily a local function, and to ensure that the federal government does not encroach on police powers that are reserved to the states, the reserves could be held at the state and local level in secure, interest-bearing accounts, with access limited to the chief public health official of each political subdivision. With the knowledge that funds to compensate them are actually available and under the control of the local chief public health official, it is far more likely that hospitals will comply with the orders of that official and perform their duties without resistance.[279]

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277. *See* Gravely & Whaley, *supra* note 16, at 1.

278. *See* Monty Veazey, *A Growing Crisis*, MOD. HEALTHCARE, Aug. 22, 2005, at 32. Veazey notes that in Georgia, on average, the non-profit hospitals lose more than $1 million per year in operating income, and three of the five largest hospitals in the state are running at negative operating margins. *See also* AM. HOSP. ASS'N, *supra* note 60 (reporting that one-third of hospitals lose money on their patient care operations).

279. The United States Homeland Security Council has stated that it is likely that all sources of external aid may be compromised during a pandemic, and that state, local, and tribal entities must be prepared to function self-sufficiently. HOMELAND SEC. COUNCIL, *supra* note 11, at 109. In addition, hospitals are likely to be very familiar with the local chief public health official of their jurisdiction, and are likely to have worked with that official on pandemic planning and response. Likewise, the local chief public health official of a jurisdiction is in the best position to know the capabilities and capacities of hospitals within her jurisdiction. *Cf.* U.S. Dep't of Health & Human Servs., State and Local Pandemic Influenza Planning Checklist, *available at*

In order to be effective, the payment made to a hospital for each pandemic victim treated must be sufficient to at least cover the hospital's costs of care. State Medicaid payment levels, for instance, would be insufficient to ensure compliance.[280] The payment must include compensation for any "combat pay" the hospital must offer its staff to get them to care for pandemic victims. Federal legislation establishing reserve accounts should specify that the payment rates established by local public health authorities must compensate for the actual costs of providing care for patients with symptoms similar to pandemic victims (to the extent comparisons are possible), as well as additional costs that are likely to be incurred by the hospital in providing medical personnel to care for such patients, such as incentive bonuses to staff. Setting the rates will require careful study of the rates paid by various insurers to hospitals caring for their beneficiaries with specific conditions or illnesses, the costs of providing this care, and the prevailing wages paid to medical personnel in the area. Much of this data is currently gathered by the Department of Health and Human Services Centers for Medicare and Medicaid Services, for use in setting hospital Medicare reimbursement.[281] Additional research in the area should be funded by the federal government as part of emergency preparedness activities.

B. Insuring Against Loss During a Pandemic

The government should encourage hospitals to view the risks of loss associated with pandemics as they view other risks of loss from natural disasters, such as fire and flood, and purchase insurance against such losses. Many businesses purchase private "business interruption insurance" to protect themselves from the risks of interruptions to their revenue streams due to natural or man-made disasters. Private business interruption insurance is designed to

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http://www.pandemicflu.gov/plan/statelocalchecklist.html (Jan. 9, 2006). Local control of a pandemic compensation fund also is attractive because it will minimize any conflict between state and local authority if a pandemic occurs in a home rule city. Home rule cities are authorized by state law to legislate matters of local concern without specific state authority, without a delegation of specific state authority, or if the state has not regulated the matter. DANIEL R. MANDELKER, LAND USE LAW § 4.24 (5th ed. 2003). Because in their earliest phases, infectious disease outbreaks are purely local concerns, placing the funds in the hands of the chief public health officer of a home-rule city will ensure that early action taken to contain a pandemic, including designating isolation and quarantine facilities, will not be hampered by wangling between state and local authorities regarding payment of funds.

280. Veazey, *supra* note 278 (noting that Georgia hospitals lose thirteen percent on every Medicaid patient they treat).

281. *See, e.g.*, 42 U.S.C. § 1395ww (2000) (describing methodology for calculating payments to hospitals for inpatient services, including calculation of the wage index and cost report amounts).

indemnify the insured against losses arising from an inability to operate a commercial establishment in a normal manner due to a natural or man-made disaster.[282] Currently, the majority of such policies limit coverage to interruptions from events for which an insurer has significant actuarial experience such as fire, flood, tornado, or hurricane.[283] Even then, the insurance is only triggered by physical damage to the policyholder's property and only covers the insured for the time period necessary to rebuild, replace, or repair physical damage.[284] Standard business interruption insurance is therefore useless to a hospital faced with the loss of its revenue stream from its most lucrative lines of patient care business, such as elective surgeries, because it was designated as an isolation or quarantine center.

Therefore, in order for the compensation scheme to work, state insurance regulators would have to mandate that business interruption insurance offered to hospitals cannot exclude coverage for business losses due to pandemics.[285] Regulators would also have to mandate that any insurer who offered business interruption insurance within the state must offer it to hospitals. This would create "public health emergency business interruption insurance" (PHEBII) available to hospitals.

Although state mandating the terms and availability of PHEBII is a necessary first step, it is highly unlikely that it will suffice to create a private market in PHEBII on its own. The private insurance market has already demonstrated its unwillingness to insure against risks associated with public health emergencies and threats of infectious disease pandemics; risks that have historically been perceived as a government problem.[286] For example, in 1976, believing that a potentially deadly influenza pandemic of swine flu was imminent, the federal government undertook a national swine flu vaccine

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282. *See* Robert T. Horst & Mark Rosenberg, *Successful Use of the Examination Under Oath Policy Provision and the Evaluation of the Time Element Claim*, 1 MEALEY'S BUS. INTERRUPTION INS., Sept. 2002, at 23.

283. *Id.*

284. *Id.*

285. For the most part, the regulation of insurance is left to the states under the McCarran-Ferguson Act. *See* 15 U.S.C. § 1012(b) (2000). Under this authority, state insurance regulators are generally free to mandate insurance contract terms in their states. *See* Ky. Ass'n of Health Plans v. Miller, 538 U.S. 329 (2003).

286. The propensity to classify natural risks as a government problem is not limited to the arena of public health. Shortly after Hurricane Katrina hit the Gulf Coast, a spokesman for Allstate Insurance (one of the largest homeowners insurance providers in Mississippi) said: "Flood insurance is the province of the federal government." CNN Money, Mississippi Slaps Insurers with Suit, Sept. 15, 2005, *available at* http://money.cnn.com/2005/09/15/news/economy/flooding_lawsuit/index.htm (last visited Sept. 15, 2005) (original copy on file with author).

program.[287] Almost immediately, the vaccine manufacturers' liability insurers refused to provide liability insurance to their clients against adverse effects associated with the vaccine.[288] Concerned about the potentially enormous numbers of claims, and uncertain of the amounts associated with the claims due to lack of prior claims experience, private insurers took the position that if the public was endangered, then the government should take the risk.[289] Congress, however, was unconvinced that it should do so. Ultimately, the impasse was broken by the emergence of Legionnaire's disease, another public health scare, during the standoff. Congress, believing that people were becoming ill with swine flu while Congress delayed a vaccine by refusing to indemnify the manufacturers, recognized the political nightmare that was likely to ensue and gave in to the manufacturers' demands.[290]

Private insurers will likely react to being told by state regulators to cover a business interruption due to a public health emergency just as they reacted during the swine flu public health emergency—with a firm "no." And after a public health emergency occurs, insurance for its effects will likely be virtually impossible to obtain at any price, just as terrorism insurance was virtually unavailable at any price in the days following 9/11.[291] Faced with state insurance regulations forcing them to take on what they consider to be unknowable and unquantifiable risks, business interruption insurers are likely to pull out of the market in a particular state rather than comply, leaving the hospitals in the state no better off than they were before state coverage mandates were instituted.

To combat this, federal legislation will be necessary. After 9/11, in response to the private market's refusal to provide terrorism insurance, Congress passed the Terrorism Risk Insurance Act of 2002 (TRIA).[292] Under the TRIA, any person who offers property or casualty insurance in the United States must offer terrorism insurance as well.[293] To address concerns that the government was mandating the insurance industry to take an unknowable, unquantifiable amount of risk, and in response to threats that insurers would pull out of the market completely, the TRIA provides federal reinsurance for losses incurred by the

287. KOLATA, *supra* note 4, at 151.

288. *Id.* at 158-59.

289. *Id.* at 159.

290. *Id.* at 163-64.

291. Michelle E. Boardman, *Known Unknowns: The Illusion of Terrorism Insurance,* 93 GEO. L.J. 783, 799 (2005).

292. Terrorism Risk Insurance Act of 2002, Pub. L. No. 107-297, 116 Stat 2322 (2002) (codified at 15 U.S.C.A. § 6701 note (West 2006)). The TRIA was extended for an additional two years by the Terrorism Risk Insurance Extension Act of 2005, Pub. L. No. 109-144, 119 Stat 2660 (2005) (amending 15 U.S.C.A. § 6701 note (West 2006)).

293. Terrorism Risk Insurance Act of 2002.

insurers due to terrorism after the insurers pay a significant deductible amount.[294] The insurers must also pay a ten percent coinsurance above the deductible for 2006 (rising to fifteen percent in 2007) before government funding is available.[295] Total public and private liability for losses due to terrorism is capped at $100 billion.[296] Federal compensation is only available when the Secretaries of the Treasury and State certify that an "act of terrorism" has occurred, and only if industry insured losses nationwide exceed $50 million in 2006 and $100 million in 2007.[297] The government will recoup a significant amount of any payments it makes for terrorism losses through a surcharge on property and casualty policyholders, regardless of whether or not the policyholders have purchased terrorism insurance.[298] The TRIA has been embraced by the insurance industry, which lobbied for its extension for an additional two years.[299]

Legislation similar to the TRIA could be used to ensure that hospitals are insured against losses of revenue due to pandemics. Such legislation would require all purveyors of business interruption insurance to offer PHEBII, yet take much of the sting out of the requirement by having the federal government reinsure the insurers against excessive and unknowable risk. Unlike the TRIA, which does not require a policyholder to purchase terrorism insurance, states could and should require hospitals to purchase PHEBII as part of their licensure requirements. This would be a proper exercise of state police power to safeguard their citizens' health. Pandemics, unlike mass terrorist events, have a long history of occurrences. Although each pandemic differs with regard to its penetration and mortality rates among the general public, we have sufficient experience with infectious disease and projections of costs for actuaries to use for initial premium calculations. Therefore, it is reasonable to require hospitals to purchase PHEBII, and many of the criticisms that have been levied against the TRIA because of the unquantifiable nature of risks associated with terrorism are less applicable to losses associated with a more predictable pandemic.

This public-reinsurer/private-insurer collaboration minimizes many of the problems inherent in a private insurance scheme. Requiring hospitals to purchase

294. *Id.*

295. Terrorism Risk Insurance Extension Act of 2005 § 4.

296. Terrorism Risk Insurance Act of 2002.

297. Terrorism Risk Insurance Extension Act of 2005 § 6.

298. Terrorism Risk Insurance Extension Act of 2005 § 103(e)(8).

299. *See* Nat'l Ass'n of Prof. Ins. Agents, Quick FAQ on the TRIA Extension, *available at* http://www.pianet.com/IssuesOfFocus/HotIssues/tria/12-20-05-6.htm (last visited Nov. 8, 2006). There has been thoughtful criticism of the TRIA by legal scholars. One such criticism is based on its failure to perform the primary function of insurance, which is to spread risk, because of the unknown nature of the risk. *See* Boardman, *supra* note 291, at 810. One could view the TRIA as a windfall for insurers.

PHEBII eliminates any possibility of adverse selection. Adverse selection refers to the tendency of only high-risk customers to purchase available insurance.[300] Without a mandatory purchase requirement, it is highly likely that only hospitals that are most likely to become isolation or quarantine centers would decide to purchase PHEBII.[301] This would artificially inflate the premiums charged for the insurance, and prevent insurers from spreading the risk among a balanced cross-section of the nation's hospitals. In the absence of a requirement of universal purchase of PHEBII by hospitals, a pandemic would cause the insurers to be liable for an enormous amount of claims and likely put them out of business.[302] Requiring hospitals to purchase PHEBII as a condition of licensure protects the hospitals, the insurers, and the public, and will keep the rates affordable by allowing the insurers to properly spread risk.

Nonetheless, the problem of adverse selection may be minimal in the context of PHEBII because of the inherently random nature of a pandemic. Typically, adverse selection in insurance occurs because the policyholder has information, which the insurer does not have, suggesting that an insurable event is likely to occur.[303] The insurer cannot adjust the premium rates to reflect the appropriate level of risk without this information and thus winds up paying out far more than anticipated. In contrast, although hospitals can make an educated guess based on population density and travel patterns regarding where and when a pandemic could occur, so can the insurers. Because the policyholders and the insurers are on a level playing field as far as knowing the where, when, and magnitude of a potential pandemic, there would probably be less adverse selection in the context of this type of insurance than in other types of insurance, even if hospitals were not required to purchase PHEBII.

Another commonly discussed problem in private insurance is moral hazard.[304] Moral hazard occurs in the insurance marketplace when the insured can take actions that affect either the probability that the event that triggers an insurance payment occurs or the magnitude of the compensable damage such an event causes.[305] A classic example is a landowner with a fire insurance policy who becomes less diligent in clearing combustibles away from his house, knowing that if the house burns, she will be compensated.[306] In the context of

300. Daniel A. Farber, *Public Choice and Just Compensation*, 9 CONST. COMMENT. 279, 284 (1992).

301. *See* Calandrillo, *supra* note 140, at 526-27.

302. *Id.* at 526.

303. Jeffrey Manns, Note, *Insuring Against Terror?*, 112 YALE L.J. 2509, 2538 (2003).

304. Lawrence Blume & Daniel L. Rubinfeld, *Compensation for Takings: An Economic Analysis*, 72 CAL. L. REV. 569, 593 (1984).

305. *Id.*

306. Malcolm Gladwell, *The Moral Hazard Myth*, NEW YORKER, Aug. 29, 2005 at 44, 46.

PHEBII, an insurer might be concerned that a hospital suffering financially would do something to make it more likely that the insurer will have to pay under the insurance policy, such as failing to resist designation as an isolation or quarantine center.[307] Unlike the typical moral hazard situation, in the context of pandemic preparedness, a hospital preparing to become an isolation or quarantine center is a desirable outcome from a public health perspective. It is a benefit to the public's health if hospitals do not resist being designated an isolation or quarantine center in the event of a pandemic, and instead, do everything in their power to prepare.

The public-private collaborative nature of this model also eliminates many of the problems inherent in a purely public compensation scheme. One of the major problems that appears when the government institutes a scheme of publicly funded compensation for some perceived social ill is the phenomenon of rent-seeking.[308] Rent-seeking occurs when a constituent who may be entitled to a payout under a public compensation scheme uses political or other means to try to fit all adverse events that affect the constituent within the category of adverse events for which the scheme is designed to compensate.[309] In the context of PHEBII, the danger is that insurers will attempt to fit all outbreaks of infectious disease into the category of a pandemic, so that the reinsurance provisions of the legislation would be triggered. This propensity toward rent-seeking, however, can be tempered by the requirement that the insurer pays a substantial deductible and coinsurance out-of-pocket before any federal assistance becomes available.[310] Such a requirement would make it so that it is only in a truly dangerous and costly pandemic situation, where the economic losses are high enough to dwarf the payout that the private insurers will make via their deductibles, that it would it be worth the insurers' while to attempt to collect the reinsurance. In such a situation, the government will likely have already declared a state of public health emergency, triggering the legislation.

C. Interpreting the Takings Clause To Require Compensation for Lost Goodwill and Going Concern Value

In addition to ensuring that hospitals comply with public health dictates during a pandemic, it is in the public's interest to ensure that we have a functioning health care delivery system after the pandemic ends. Congress and state legislatures should pass legislation requiring compensation for provable loss

307. Obviously, the hospital is highly unlikely to do anything to influence the other triggering event for a payment under the insurance policy, actually encouraging a pandemic in its community.

308. *See* Manns, *supra* note 303, at 2511-12.

309. *Id.*

310. *Id.* at 2547.

of goodwill and going concern value when the government affects a temporary regulatory taking of a going business concern in order to protect the public health.

The loss that a hospital faces when it is designated as an isolation or quarantine center is not only the loss of its ability to cost-shift during and after a pandemic, but also the lingering damage to the hospital's reputation caused by such a designation. Such a loss is not insignificant. With regard to the SARS epidemic of 2003, hospital counsel has opined that "the mere mention of SARS in the same sentence with the name of a specific health care facility can create panic among patients and families, and cause significant damage to the facility's reputation as well as its ability to continue to treat patients."[311] For the majority of hospitals, which depend on the ability to attract privately insured patients to subsidize care for publicly insured and uninsured patients, such a stigma could mean the difference between continued existence and shutting the hospital's doors.

We are unlikely to be able to change the public's attitude toward isolation and quarantine facilities through changing the law. But we can change the law to compensate hospitals and other first responders so they can survive until the public's memory of a hospital's association with a pandemic dissipates. The Takings Clause is a reflection of society's acknowledgement that if the government takes away a person's private property for the benefit of society, society as a whole should pay compensation.[312] The Supreme Court has said that the purpose of the Takings Clause is "to bar Government from forcing some people alone to bear public burdens which, in all fairness and justice, should be borne by the public as a whole."[313] No government action could yield a greater benefit to society than a taking to ensure that the public's health is protected, and that the sick are cared for. If any burden should be borne by the public as a whole, it should be the burden of protecting the public's health.

When the government takes a hospital for use as an isolation or quarantine center during a public health emergency, it is taking not only the real property, equipment, and physical improvements to the property. It is counting on the expertise of the hospital's staff and the hospital's reputation as a provider of quality health care to assure the public that the situation is under control. As such, the government is taking and using the hospital's goodwill for the duration of the emergency. Under established Takings Clause jurisprudence, the government pays for what it gets and what it can and does use. It is not much of a stretch to require compensation for goodwill in such a circumstance.

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311. Gravely & Whaley, *supra* note 16, at 5.

312. CHEMERINSKY, *supra* note 138, at 574.

313. Armstrong v. United States, 364 U.S. 40, 49 (1960).

When the pandemic is over, because of the stigma attached to a place where there has been a concentration of infectious disease, the government has used up or destroyed the hospital's goodwill.[314] This leaves hospital owners with no alternative but to start over, without the goodwill that they spent many years creating. The Model Eminent Domain Code recognizes that in situations where loss of goodwill is caused by the taking of the property, cannot reasonably be prevented by relocating the business or taking other reasonable steps, and will not be otherwise compensated, the business owner should be compensated for the loss.[315] It is consistent with the intent of the Takings Clause for Congress and state legislatures to mandate that loss of goodwill be considered compensable property when a hospital is designated by the public health authorities as an isolation or quarantine center. Legislation requiring compensation for goodwill in such a situation will remove the uncertainty inherent in leaving the courts to determine whether the government will pay any compensation for loss of goodwill. It will also act as a check on rash or unfounded action by the government that adversely affects hospitals, but does little to further the public's health, such as the premature designation of a hospital as an isolation facility.

Even with such legislation, the government and the hospital are likely to disagree about the amount of compensation due the hospital because of the government's actions. To further minimize uncertainty over the potential amount of compensation for lost goodwill, and to minimize the expenses and vagaries inherent in using the courts to determine this amount, Congress should earmark a proportion of the now expanding emergency preparedness funds to study the effects of prior epidemics on public attitudes toward hospitals in nations that suffered from epidemics in recent years and to develop projections of the effects of a pandemic on the goodwill of American hospitals. The projections could be used to develop a table for compensating hospitals for loss of goodwill based on the size, type, and location of the hospital, and the severity of the pandemic. A mediation or arbitration mechanism could be included in the legislation to resolve any claims by a particular hospital that the table does not completely compensate it for the government's actions.[316] Payment to hospitals for lost goodwill, coupled with the uninterrupted revenue stream during the public health emergency (through the emergency reserve fund and PHEBII) would be a significant step toward ensuring that hospitals do not shy away from being

314. "Goodwill" is "[a] good relationship, as of a business enterprise with its customers . . . ." THE AMERICAN HERITAGE DICTIONARY 757 (4th ed. 2000). The government's use of the hospital as a quarantine center will destroy the hospital's good reputation and relationship with its patient base.

315. MODEL EMINENT DOMAIN CODE § 1016 (1974).

316. New Jersey has established an "emergency compensation board" for each county to determine the amount of compensation due a property owner as a result of government use of private property during an emergency. *See* N.J. STAT. ANN. app. § A:9-51 (West 2006).

designated isolation or quarantine centers and that they do everything in their power to prepare for a pandemic.

CONCLUSION

We know it is not a matter of *if* but *when* a pandemic will next strike the United States. We could place our reliance on the wonders of modern medicine, and the good intentions and charitable missions of our institutional and individual health care providers to ensure that we are cared for when we are sick, and hope for the best. And chances are that there would be some form of short-term care during a future crisis. But given the state of our crumbling health care safety net, the increase in the number of for-profit hospitals in the country, and the paper-thin margins on which many of the nation's hospitals operate, chances are that many hospitals would resist taking actions that harm their bottom lines. This instinct for economic self-preservation could endanger the public's health and rob us of our best chance to minimize or avoid the most severe consequences of a pandemic. Additionally, even if hospitals comply with the public health authorities' orders, it is likely that when the immediate crisis passes, many of the hospitals that our most poor and vulnerable populations rely on to provide them with care will not survive the economic damage inflicted upon compliant hospitals.

During the past decade, our federal, state, and local governments have acknowledged the need for preparedness in the face of a public health emergency by passing legislation allocating large amounts of money to preparedness activities. Recognizing the need for public health emergency preparedness is a good thing. Nevertheless, despite this cascade of resources for planning activities, our nation's hospitals are in no better position to economically survive a public health emergency than they were before the resources appeared. As Justice Brandeis has observed, "[v]alue is a word of many meanings."[317] Rather than continuing to beef up our bureaucracies and filter dollars through layers of government in the name of "emergency preparedness," Congress and state legislatures would be better off using the existing public health bureaucracy and the expertise of private insurers to set up a system that ensures that our hospitals will actually be available during a public health emergency, will provide the care needed by the public, and will survive the emergency to continue to provide the care the public needs in the future.

317. Sw. Bell Tel. Co. v. Pub. Serv. Comm'n., 262 U.S. 276, 310 (1923).

COMMENTARY

Mortality, Equality, and Bioethics

Eric Cohen*

INTRODUCTION

Given the close connection between bioethics and biomedical technology, it is hardly surprising that bioethicists often think about the future. There is a certain prophetic pleasure that comes with predicting the problems ahead, and a strong inclination to believe that our ethical thinking needs to "keep pace" with our technology, constantly updating its moral vision of man in light of the material possibilities of the age. In some sense, of course, this is true: Our ethics does need to keep pace with our changing technological condition. New problems arise for which old thinking is inadequate. Yet, to see the future clearly, it might also help to recover what is first in bioethics – first in the sense of the discipline's origins and first in the sense of man's perennial problems and possibilities. To invite such a recovery is the aim of this Commentary.

In one sense, bioethics – at least American bioethics – began in the 1960s and 1970s, with a group of philosophers, theologians, and physicians interested in the future of human life in the budding age of biotechnology and advanced medicine. They held meetings. They wrote articles. They advised government bodies and influenced judicial decisions. They debated issues ranging from end-of-life care to organ transplantation to research with human subjects to the initiation of human life in the laboratory. Through their labors, a new discipline and myriad new institutions were born: think-tanks, journals, degrees, commissions, committees, consultants, and media stars.

Yet many of the questions these first bioethicists were asking were in fact very old, and so were many of the conflicting answers. New technological

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possibilities – such as in vitro fertilization, genetic testing of the unborn, the biochemical manipulation of psychic experience, the extended preservation of bodies between life and death, the transfer of body parts from the newly dead to the still living – were altering some of the fundamental experiences of being human. But these technical possibilities made us anxious because the image of man himself seemed to be at stake, with all the old conflicts and perennial problems about the good life and good death taking on a new, dramatic shape. Recovering this clash of images is the first step toward understanding the origins and thus the future of bioethics.

In a very modest way, I'd like to attempt such a philosophical recovery in two parts: first, by exploring certain permanent alternatives in man's quest to live well with death, which is the problem that stands at the heart of many modern bioethical quandaries; and second, by looking at the founding framework for addressing such moral questions in America, namely the Declaration of Independence, with its mysterious teaching about human equality and human happiness. That mortality and equality should be considered together seems only fitting: In death, our ultimate equality is restored; in the circumstances of death, the inequities of nature and chance are sharply revealed; in seeking to conquer or ameliorate the sting of death, we are tempted to set the democratic ideal of equality aside. Only by recovering a deeper wisdom about mortality and equality can we consider wisely the future of bioethics – and, in particular, how new technologies and new social conditions will re-open, yet again, in ever novel ways, those inescapable problems that are inherent to being human.

For a journal such as this one, devoted mostly to the practical analysis of practical questions, such an approach might seem odd. Why not just state a modern policy problem – e.g., stem cell research, assisted suicide, organ transplantation – and explore the best solution? The trouble is that knowing what to do requires knowing what seems best, and knowing what seems best requires reflection on why one way of life – or one "solution" – is better than another. This is obviously no easy task; many great men and women of the past disagreed about the best way of life, and many great men and women of the present carry on these disagreements. But without at least asking, "What is the loftiest image of man, to which we should aspire?" there is no way to know whether to harvest stem cells from embryos, or help a loved one to end his life, or promote the buying and selling of human organs. Without ethics – normative, philosophical ethics – law and policy have no compass.

I. WHY DEATH IS THE FIRST QUESTION

Death, of course, is not the only human problem of bioethical significance. Indeed, one might justly argue that *natality*, not mortality, is the source of today's gravest and most novel quandaries. With the manufacture of life in the laboratory, the prospect of human cloning and genetic engineering, and the return

of eugenics in the form of amniocentesis-and-abortion and pre-implantation genetic diagnosis, the dilemmas of conception and birth now loom large before us.

Yet it is also the case, interestingly, that the very technological civilization that has developed these marvelous new methods of making babies – children for the infertile, children without disorders, children for older women – is also the least interested in procreation, at least by the numbers. Modern, advanced democracies have rapidly plummeting birthrates; they are not producing enough children to replace themselves.[1] And it may be that our anti-natalism has much to do with our understanding (or misunderstanding) of our mortal condition. We readily ignore death, making procreation seem less urgent to men and women who think there will always be more time; and we desperately evade death, making procreation seem less important than sustaining the healthy self into the indefinite future. A death-denying civilization is also, it seems, a child-denying civilization.

Moreover, if one considers the most passionate bioethical debates of recent times – embryo research and Terri Schiavo – the central question seems to be how to live well with death, or how to care well for those who live on the precipice between life and death. With embryo research, we are forced to ask: Is it better to accept death than to destroy human embryos in an effort to oppose it? Is it better to submit to suffering and surrender to mortality than to use the seeds of the next generation as raw materials in the search for cures? With Terri Schiavo, we are left to ask: Is it love or is it torture to keep her alive indefinitely in such a diminished state? Is it mercy or is it betrayal to let her die of dehydration by removing her feeding tube? On both fronts, we need to ask: What is the good death, or what is the best death possible for moral beings who must die and who know it?[2]

Of course, these are hardly the only issues in public bioethics, even if they are the most prominent ones. The moral dilemmas of progress are many and varied. Modern medicine's capacity to defeat earlier, acute causes of death may also lead, for many of us, to an extended decline into debility and dementia.[3] The heart attack one averts at age sixty-five might lead to a decade of Alzheimer's disease – a gradual erosion of the self much different from the young Terri Schiavo's overnight debilitation. More generally, our heightened capacity to fend off death, for now, means that most of us will die in hospitals, hooked up to machines, with the end only coming when our tortured loved ones say "enough."[4]

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1. PHILLIP LONGMAN, THE EMPTY CRADLE 8 (2004).

2. *See generally* Eric Cohen & Leon Kass, *Cast Me Not Off in Old Age*, COMMENTARY, Jan. 2006, at 32.

3. *See id.* at 33.

4. *See id.*

In addition, those inventions – like dialysis – that were once seen as life-saving miracles are now seen as torturous burdens. Instead of appreciating the thousands of individuals saved each year by transplanting human organs – individuals once destined to die of organ failure – we see the organ waiting list as a "crisis" in need of solution.[5] We tend to think that things are getting worse rather than imperfectly better. And we wonder: Might it be better to buy organs from the poor or conscript organs from the nearly dead than to accept a death that might be averted? Should we lift our moral limits and set aside our ethical qualms to save more lives?

Whatever one thinks about any particular bioethical issue, we cannot deny that the problem of living well with death is integral to them all, even those that seem to center more on natality than mortality. And how one thinks about each particular bioethical issue depends, whether explicitly or unknowingly, on the image of death that one sees as best. In the Part that follows, I consider five paradigmatic images of the good death: the remembered death of Jacob; the tranquil death of Socrates; the redeemed death of Christ; the technological opposition to death of Benjamin Franklin; and the crisis of death described in Albert Camus's myth of Sisyphus. These images are the best prism for seeing our past, present, and future bioethical dilemmas for what they truly are. In the age of ventilators and nursing homes and regenerative medicine, we must always ask: In whose image should we die, and in whose image should we live on the way to death?

II. FIVE IMAGES OF THE GOOD DEATH

A. The Remembered Death

Jacob is the last of the three great biblical patriarchs, who dies surrounded by his many children.[6] He dies naturally, from illness. He is not killed by an enemy, or lost in a tragic accident, or sentenced to death by a just or unjust court. His death is foreseeable, but there is little reason to believe that he suffers an extended decline. He dies knowing that he is dying, not after years of dementia, when self-awareness of one's impending oblivion is impossible. He faces death frontally, manfully, without illusions. In his final moments, he performs the parting act of instructing his sons in their obligations and prospects.[7] How he

5. *See, e.g.*, Richard Epstein, *Kidney Beancounters*, WALL ST. J., May 15, 2006, at A15; Sally Satel, *Death's Waiting List*, N.Y. TIMES, May 15, 2006, at A21.

6. For my interpretation of Jacob's death, I am deeply indebted to conversations with Dr. Leon R. Kass of the University of Chicago, and I rely heavily on LEON R. KASS, THE BEGINNING OF WISDOM: READING GENESIS 616-59 (2003).

7. *See Genesis* 49:1-33 (The New JPS Translation 1988).

does this, and why, is the key to understanding Jacob's image of the good death.

The biblical text begins its account of Jacob's death as follows: "When Jacob was told, 'Your son Joseph has come to see you,' Israel summoned his strength and sat up in bed."[8] Jacob is sick, but he will not address his sons in a sickly posture. He sits *up* before them; his physical presence embodies both his mortal fragility (in bed) and his paternal majesty (sitting up). Even sitting, he remains the upright master, worthy of reverence, still in command even as his body shuts down. Though his last speech is a recognition of his own mortal limits, he is never an object of pity in his children's eyes.

But Jacob's death, in the end, is not ultimately about him, but about the way of life that may persist after he is gone. He recounts how God promised to make him "fertile and numerous, making of [him] a community of peoples."[9] He beholds his grandchildren with special amazement, as the fleshy embodiment of the promise of perpetuation. Then he addresses each one of his children – some with great hope, some with stinging disappointment – for he knows that the fate of his divine purpose rests on their shoulders, a prospect that leaves him to die without the certainty of success, but also without the certainty of failure.[10] He asks his children to remember him, awakening their ancestral piety as the ground for continuing life beyond themselves, in "teeming multitudes upon the earth."[11] He links reverence for the past with hope for the future. He dies, in other words, as the dying father and the dying son. This fidelity in death centers symbolically and ritually on burial – the return of Jacob to the land of his fathers. More importantly, it depends upon the willingness of his children to raise up children of their own, before whom they will one day stand in death, children who will in turn have children of their own, to perpetuate God's holy and hopeful way into the future.

One episode in particular captures this way of dying well. Just before his last speech to all of his sons, when he knows he is dying but before they do, Jacob orders Joseph to put Joseph's hand under his thigh and pledge to bury him in the land of his fathers. The point of the pledge is not simply to satisfy Jacob's self-regarding wishes – to fulfill his advance directive, so to speak. It is also a reminder to Joseph of where he comes from, who he is, and what he must teach his own children.[12] In demanding this oath, Jacob instructs his son never to forget. By demanding that Joseph place his hand under the thigh – in that physical place where the next generation finds its origins – Jacob instructs Joseph

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8. *Genesis* 48:2 (The New JPS Translation 1988).

9. *Genesis* 48:3-4 (The New JPS Translation 1988).

10. Jacob's recognition of his own limits in fulfilling God's covenant is notably revealed in his near-final encounter with Joseph. *See* KASS, *supra* note 6, at 638, 644.

11. *Genesis* 48:16 (The New JPS Translation 1988).

12. *See* KASS, *supra* note 6, at 636-38.

what fidelity really means. One remembers the dead by giving birth to the living; one dies well by giving one's children their final instructions.

Imagine, instead, if Jacob had put his hand on Joseph's back, on the body of his son, and requested a kidney in the desperate hope to stay alive. Or imagine if he had produced an embryonic clone of himself, nascent flesh of his own flesh, in the hope of manufacturing a life-saving cure. This is strange to imagine, and not merely because of the historical distance between our mythical ancestors and our modern medical practices. Such desperate requests or actions – violating the body of his son, slaying the seeds of the next generation – would pervert Jacob's way of dying well, in which he stands before his sons commanding their fidelity, majestic even in dying. Jacob needs his sons to continue life after he is gone much more than he needs their bodies to extend his life here and now. Yet Jacob's need for his sons – for he is impotent in death without them – never seems needy. Jacob's death makes sense because he stands aside for his children, yet stands above them even in the moment when he needs them most – to remember him, to bury him, and to carry on his sacred purpose. This is Jacob's way of dying well, of living well with death.

It is also why, throughout the story of the patriarchs – indeed, throughout the whole Hebrew Bible – barrenness, not sickness, is the real threat to the good life and the good death; opening the womb is the truest evidence of God's beneficence. Sarah's misery, Rachel's misery, Hannah's misery – all finally answered when God remembers each of them with a child – is the misery of infertility.[13] Even earlier, in his address to Noah after the flood, God tells man to "be fruitful and multiply" – first as a divine blessing, then as a divine commandment.[14] God seems to realize that the human revolt against children – willful sterility, not un-chosen barrenness – is a permanent human possibility, as men get lost in the ecstasies or the miseries of present life. God seems to know that only man among the animals can choose against the next generation – seeing children as a burden, or seeing life as too burdensome to inflict on the yet-unborn young.

Yet in our time, in the most death-defying civilizations in history, procreation is becoming an afterthought, as noted above. Modern technological societies, infatuated with embryo research and organ transplantation and life-saving cures, are having the fewest children of any societies in human history. Today's generation of potential parents are much less likely to die surrounded by their offspring, or remembered by their children, or sustained by their children's children. From Jacob's perspective, we are dying badly by dying alone, with no sons and daughters to instruct in our final days.

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13. *See Genesis* 18:9-15, 21:1-8, 30:1-6, 30:22-24; *1 Samuel* 1:1-2:11 (The New JPS Translation 1988).

14. *See Genesis* 9:1-7 (The New JPS Translation 1988).

But Jacob's way of dying is also threatened from a different angle in modern societies, also noted above. Today, we are much more likely to die only after an extended demise, after long years of physical and mental decline into dependency and dementia, unable to sit upright before our children in our final days. The very medical triumphs that make long life and prolonged vigor possible for so many can also (if unintentionally) make dying an extended misery. Our medical machinery makes Jacob's version of the good human death ever more unlikely. Even in the eyes of the most devoted children, we risk becoming an object of pity. Or, in our childlessness, we risk becoming a burden on the state. Such circumstances threaten to usher in a new age of euthanasia, both as a way of restoring the social balance between the old and the young and as a way of recovering the tranquil, timely death that most people still want but few people now get.

B. The Tranquil Death

The death of Socrates, as remembered by his student Xenophon, is a very different kind of human death – a noble euthanasia.[15] The philosopher has been convicted by the city for worshipping false gods, or no gods at all, and for corrupting the youth of Athens. Unlike Jacob and his fathers, Socrates does not see his life as the fulfillment of a divine commandment, or his wisdom as dependent on God's revelation. When the oracle of Apollo declares that he is the wisest man alive, Socrates sets out to prove the oracle wrong, only to discover that the oracle is right.[16] Everyone who claims to be wise is actually foolish, believing he knows the truth of ultimate things when in fact he knows nothing. Socrates at least knows that he knows nothing. He also knows when it is time to die, or at least how to die well. He has little interest in admitting guilt, or apologizing, or escaping into exile in order to avoid death. As Xenophon says, Socrates "had come to regard death as for himself preferable to life," and so he accepts his death sentence with a certain tranquility.[17]

Still a great giver of speeches, Socrates also knows that his bodily decline is looming. He seems to abhor the prospect of losing his mental powers, of being alive without the capacity for wisdom, of being an object of pity or contempt to all those who presently admire or fear him. He knows that he cannot be a thriving

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15. In my account of the death of Socrates, I rely largely upon XENOPHON, THE APOLOGY (H. G. Dakyns trans., 1998), http://www.gutenberg.org/etext/1171, and secondarily upon Plato, *Apology of Socrates*, *in* FOUR TEXTS ON SOCRATES: PLATO'S EUTHYPHRO, APOLOGY, AND CRITO, AND ARISTOPHANES' CLOUDS 63 (Thomas G. West & Grace Starry West trans., 1984).

16. For this interpretation of the relationship between Socrates and the oracle, I am indebted to LEO STRAUSS, *Jerusalem and Athens: Some Preliminary Reflections*, *in* LEO STRAUSS: STUDIES IN PLATONIC POLITICAL PHILOSOPHY 147, 171 (1983).

17. XENOPHON, *supra* note 15, at para. 1.

philosopher forever, and he sees his death, under these circumstances, as a kind of good fortune – one he attributes to a God, but which comes about by his own forced, if willing, human hand. As Socrates says:

> It may be . . . that God out of his great kindness is intervening in my behalf to suffer me to close my life in the ripeness of age, and by the gentlest of deaths. For if at this time sentence of death be passed upon me, it is plain I shall be allowed to meet an end which . . . is not only the easiest in itself, but one which will cause the least trouble to one's friends, while engendering the deepest longing for the departed. For of necessity he will only be thought of with regret and longing who leaves nothing behind unseemly or discomfortable to haunt the imagination of those beside him, but, sound of body, and his soul still capable of friendly repose, fades tranquilly away.[18]

Interestingly, the President's Council on Bioethics cites this passage in its 2005 report *Taking Care: Ethical Caregiving in Our Aging Society* as an image of what the good death might look like, in comparison to an extended modern decline into dementia and in contrast to the awful prospect of dying too soon. But the Council's sympathy for this Socratic death is not without caveats and questions, which it raises in a lengthy footnote:

> If we are still sound of body and mind, can we ever really accept death with tranquility? And if we are still a source of happiness to our friends, would they let us 'fade away' if they had the power to keep us going? Do human beings deserve the most tranquil death? Or is death, in some ways, the very opposite of tranquility – a nasty robbery of life, to which we can surrender gracefully but never happily? And what is the meaning of the fact that the peaceful death here described (the death of Socrates) is brought about by deliberate – or deliberately imposed – human action (that is, by the drinking of hemlock)? Nevertheless, Xenophon is clearly on to something: a peaceful death, in the right season, is for most of us the best we can humanly hope for.[19]

Unlike Jacob, Socrates dies among students and friends, not among his children. It is his friends' trouble he seeks to avoid; their fond memories ("longing for the departed") he seeks to sustain. That Socrates dies a noble death – a death with dignity – is hard to deny. He stands unflinchingly, almost playfully, before his supposedly pious accusers. He asks them questions they cannot answer, confronts them with contradictions they cannot ignore, and demonstrates for eternity that independent spirit that belongs to the philosopher alone. Where Jacob accepts a natural death he cannot escape, Socrates accepts an imposed death he might have averted, but averted only by betraying who and

18. *Id.* at para. 1.

19. PRESIDENT'S COUNCIL ON BIOETHICS, TAKING CARE: ETHICAL CAREGIVING IN OUR AGING SOCIETY 113 (2005).

what he was. Death thus becomes the vindication of philosophy, of truth opposed to opinion, wise questioning opposed to ignorant certainty, without the wisdom-wrecking decay of the mortal body. It is an upright death, a death that preserves the immortal dignity of the man who died at the summit of his powers and on the eve of his decline. It is also a pleasant death – swift, painless, "easiest in itself."[20]

Yet, for all its renown, the death of Socrates seems less fully human than the death of Jacob, which unites the private drama of father and sons with the public drama of Israel's beginnings as a nation. Jacob's speech, if less grand than the apology of Socrates, seems truer to what it means to live in time, called to a purpose, remembered through the fidelity and perpetuation of one's offspring. And ultimately, the Socratic death embodies a certain ambiguity as both the brave death and the tranquil death. Socrates dies well by accepting death rather than betraying his commitment to truth; yet he also needs death to come sooner rather than later, so that nature does not destroy his nobility as a philosopher by destroying his embodied mind, turning the wisest man into a post-philosophical body. For Socrates, the most pleasant death is, necessarily, the least natural death – the controlled exit, without nature's "unseemly or discomfortable" afflictions "to haunt the imagination of those beside him."[21] But the dignity of this pleasant, unnatural death also seems to require that such a death be unchosen. The death sentence of Socrates replaces the deathbed of Jacob. The heroic and the tranquil are united in one final sip of hemlock, a poison that the poisoned man sees simultaneously as both an injustice and a gift.

C. The Redeemed Death

The death of Jesus is also heroic, but hardly tranquil. Like Socrates, Jesus dies at a time decreed by the civil authorities, not by the entropy of nature. He spends his final hours among his disciples, not his children. Yet unlike Socrates, Jesus dies the most painful death imaginable, an extended public torture, horrifying to those who love him. Like Socrates, his death is imposed upon him by others. But whereas Socrates, at least according to Xenophon, seems to prefer death to life, Jesus dies as an act of submission. And while Jesus is destined in the story to rise again, there is also a way in which, unlike Socrates, Jesus dies before his time; he dies not in the proper season; he dies watched by his mother, not remembered (like Jacob) by children who follow in his footsteps.

Jesus' death is not finally about him, of course, but about the divine purpose he is called to fulfill. Childless, he looks to his disciples to perpetuate his holy way, to preach the gospel, to spread the good news. He dies the paradoxical

20. XENOPHON, *supra* note 15, at para. 1.

21. *Id.*

death – mocked, but dying to redeem the mockers; innocent, but dying to conquer sin; submitting to death, but only so he might conquer death through love. For Jesus, unlike Jacob or Socrates, death has to be a misery, "discomfortable" to those who love him. Even in his innocence, he embodies the fact that death is the wage of sin, a just sentence upon humanity, lifted only by God's grace; death is not the injustice it so often seems. Jesus' death is both in need of redemption (the human Jesus) and the redemptive act itself (the divine Jesus). His death is meant to change death forever, allowing even mere mortals to die wretchedly with the faith that death is not final. As Caitrin Nicol writes:

> Jesus' death is a physical display of sin, sister to death since Genesis, and it is sin itself that is most importantly being conquered – not faced, not escaped, not accepted, but actually conquered. As mortality was the consequence of the Fall, the literal undoing of death in the Resurrection of Jesus is there to show that the Fall has really been reversed.[22]

Although he begs in Gethsemane that the cup might pass from his lips,[23] he does not resist it when it comes. When one of his disciples tries to defend him by force, he charges him to put away his sword.[24] Cursed by his enemies,[25] betrayed by his friends,[26] abandoned even for a moment by his Father – "my God, my God, why has thou forsaken me?"[27] – Jesus confronts death and the "power of darkness"[28] with no force save one: the love that triumphs over all.

In Jesus, we see what it means to love in the face of misery, to believe in the face of physical horror, to conquer death by submitting to it. Jacob does not conquer death; he steps aside for the children who will remember him and perpetuate his holy mission. Socrates does not conquer death, but simply removes its sting, by treating it as a great unknown and therefore not a known evil, and by accepting the pleasant exit that is so unnaturally offered to him. But for Jesus, death is understood as a problem; it needs to be conquered, not simply accepted. It stings, yet with God's help, man can love and be loved even in the face of its sting.

One wonders what Socrates would have done if his punishment had been crucifixion, not hemlock: Would he have had Jesus' strength, or might he have sought some escape? And one wonders what Jacob's sons would have done if

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22. E-mail from Caitrin Nicol, Student, University of Chicago, to Author (Oct. 5, 2006, 07:23 EST) (on file with author).

23. *Matthew* 26:39.

24. *Matthew* 26:51.

25. *Matthew* 26:65-67; 27:26-44.

26. *Matthew* 26:47-49.

27. *Matthew* 27:46.

28. *Luke* 22:53.

their father, through nature's malignancies rather than man's, had suffered before them as Jesus did? Could they have stood to witness their father so tortured and still believed in their father's God, and would his desperate state have elicited their pity, or rage, or despair? Unlike Socrates and Jacob, Jesus confronts us with the horror of death endured in all its horribleness: not sought as an exit, yet not escaped at the cost of betraying one's given purpose. In Jesus, we learn what it means to forgo all control and retain all control simultaneously – what it means, passively and actively, to die as an act of surrender.

D. The Opposed Death

Modern man, by contrast, faces death with a different credo: Never surrender. For modern man, as for Jesus, death is a problem; mortality is an affront; it needs to be conquered. But the route to conquering death – or trying nobly – is not submission, but cleverness; not faith, but science. The aim is regeneration of the body (a self-made act), not resurrection of the body (a God-dependent act). In a wonderful letter to Rev. John Lathrop in 1788, Benjamin Franklin gives voice to this modern sensibility – the thirst to extend life with "useful utensils and instruments."[29] As Franklin writes:

> I have sometimes almost wished it had been my destiny to be born two or three centuries hence. For invention and improvement are prolific, and beget more of their kind. The present progress is rapid. Many of great importance, now unthought of, will before that period be produced; and then I might not only enjoy their advantages, but have my curiosity gratified in knowing what they are to be. I see a little absurdity in what I have just written, but it is to a friend, who will wink and let it pass, while I mention one reason more for such a wish, which is, that, if the art of physic shall be improved in proportion with other arts, we may then be able to avoid diseases, and live as long as the patriarchs in Genesis; to which I suppose we should make little objection.[30]

Franklin, like Socrates, seems to have an equanimity about life and death. He admits that his yearning for an ageless body is a kind of "absurdity," and requests from his friend an understanding "wink." He also acknowledges that such blessings will not arrive in time for him. But his optimism is not simply ironic. He believes that progress will fend off death's many causes, if not defeat death itself, and that science will (almost) restore the lost age of man's timeless innocence, or at least secure a life long enough to satisfy man's many curiosities. He believes that technology is a partial – and perhaps the best available – human answer to death.

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29. Letter from Benjamin Franklin to Rev. John Lathrop (May 31, 1788), *in* BENJAMIN FRANKLIN, WRITINGS 1166, 1167 (J.A. Leo Lemay ed., 1987).

30. *Id.*

Of course, we now live "two or three centuries hence," and we might wonder what Franklin would think about our achievements. The marvels of modern medicine surely outstrip the blunt instruments of his own day. The art of biology holds death at bay; it immunizes us from disease, rescues us from disease, and replaces diseased parts with new (or healthy used) ones. But at eighty-four years of age when he died, Franklin's life would still be long by modern standards, though his once uncommon longevity is increasingly routine. Science answers many deadly threats, making the body's longevity less a matter of genetic chance or good fortune, and more a matter of human control. But science has not – cannot – answer death itself. Surely one would be a fool not to see modern medical science as a godlike, perhaps even a God-given, blessing. But one also cannot ignore what Franklin's contemporary, Rousseau, observed about the effect of technological progress on human desire and human happiness:

> [S]ince men enjoyed very great leisure, they used it to procure many kinds of commodities unknown to their fathers; and that was the first yoke they imposed upon themselves without thinking about it, and the first source of the evils they prepared for their descendants. For, besides their continuing thus to soften body and mind, as these commodities had lost almost all their pleasantness through habit, and as they had at the same time degenerated into true needs, being deprived of them became much more cruel than possessing them was sweet; and people were unhappy to lose them without being happy to possess them.[31]

Of course, the sick still see their cures as blessings; they are still filled with gratitude toward their doctors when they leave the hospital to return again to normal life. But Rousseau is clearly on to something. His insight is borne out, for example, by the contemporary outcry over the "shortage" of organs for transplant. Once regarded as a miraculous gift for the fortunate few who were able to find a suitable organ, transplantation has, by its own successes, come to be regarded as a necessity. Waiting for an organ has become a novel kind of misery. The miracle of a new organ has become, for those in need, an expectation, such that "being deprived of them [is] much more cruel than possessing them [is] sweet."[32] Organ transplantation is just one example of a more widespread phenomenon. All too often, our modern medical technologies are transformed in our eyes from achievements to failures, precisely because they cannot fend off death itself or reverse the ravages of time that they temporarily hold at bay. The blessing of dialysis becomes a curse in just a few decades. The diseases of old age come to be seen as epidemics, turning life itself into a war against disease – a permanent, restless march for a cure.

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31. Jean-Jacques Rousseau, *Discourse on the Origin and Foundations of Inequality* (Second Discourse), *in* THE FIRST AND SECOND DISCOURSES 77, 147 (Roger D. Masters ed., 1964).

32. *See id.*

E. The Crisis of Death

Perhaps this is why Albert Camus's modern hero is the embattled doctor in plague-time, with the distance between plague-time and normal-time blurred by the omnipresence and omnipotence of death.[33] In Camus's myth of Sisyphus, Franklin's yearning for indefinite life becomes a rage against death. Death becomes a crisis, not just a problem. Perhaps the difference is that Sisyphus knows death firsthand, in all its wretched blankness. He dies and then returns; his passion for life comes from knowing the alternative of nothingness.

> But when he had seen again the face of this world, enjoyed water and sun, warm stones and the sea, he no longer wanted to go back to the infernal darkness. Recalls, signs of anger, warnings were of no avail. Many years more he lived facing the curve of the gulf, the sparkling sea, and the smiles of earth. A decree of the gods was necessary. Mercury came and seized the impudent man by the collar and, snatching him from his joys, led him forcibly back to the underworld, where his rock was ready for him.[34]

Whereas Socrates sees his tranquil death as a divine gift, Sisyphus sees death as a divine theft, to be opposed (futilely) with all his mortal might.

Camus's Sisyphus takes Franklin's desire for life to passionate extremes. The passion of Sisyphus is more like the passion of Christ, but without the redemptive victory. Instead of the long hours of crucifixion followed by the eternity of resurrection, Sisyphus faces the permanent recurrence of pushing a rock up a hill, never reaching the top, always rolling back down to the underworld, never fully rising again. For Sisyphus, opposition to death is everything, but success is impossible. There is, at most, a brief moment of existential satisfaction, when the rock lies still near the top, before beginning again its eternal slide to nothingness.

In Sisyphus, Camus believes he has found an answer to the modern crisis of death: heroic revolt, ending in knowing acceptance of futility, a knowledge that makes man superior to the absurdity of his fate. "The lucidity that was to constitute his torture at the same time crowns his victory. There is no fate that cannot be surmounted by scorn."[35] To some, perhaps, such scornful stoicism is satisfying, but for most people it is not. They prefer to look away from death until it stares them in the face; and when it does, they seek Franklin's help, hoping the cleverness of science can triumph one more time over the oblivion that terrifies them.

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33. *See* ALBERT CAMUS, THE PLAGUE (Stuart Gilbert trans., Vintage Int'l 1948).

34. ALBERT CAMUS, *The Myth of Sisyphus*, *in* THE MYTH OF SISYPHUS AND OTHER ESSAYS 88, 88-89 (Justin O'Brien trans., Vintage Int'l 1955).

35. *Id.* at 90.

Modern science thus takes up the mantle of death-as-crisis; the ethic of triage makes ordinary morality seem absurd in the face of death's permanent absurdity. This point is described beautifully by Yuval Levin, reflecting upon the deeper meaning of our current debates over embryo research:

> [I]f the fight against disease writ large – indeed the fight against natural death – is an emergency, and if . . . it is a struggle we can never expect fully to win, then we must always live in a state of emergency. We should be always in a crisis mode, always pulling out all stops, always suspending the rules for the sake of a critical goal. And that means, in effect, that there should be no stops and no rules; only crisis management and triage.
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> Under crisis conditions, we allow ourselves to do things we would never otherwise contemplate. In triage mode, we ruthlessly select among the living to help those who have the best chance at survival. For the sake of saving life, even the most observant Jew can violate the Sabbath. But if life is always at risk and we are always in crisis, then we must always do things that moral contemplation would suggest are wrong. If we are always in a mode of triage, then we must always choose the strong over the weak because they have a better chance at benefiting from our help. And if we must always be engaged in saving life, then we are always justified in breaking the Sabbath, so that in effect there is no Sabbath, no time for rest and contemplation of the truth. Indeed, there is no everyday life at all, against which times of urgency might be measured. There is only the struggle, only the crisis. . . .
>
> The sense of injustice we feel at the sight of a gravely ill child or the inexplicable loss of a loved one is both profound and understandable; it is also nothing new. It is at least as old as Job. But our response to it, the call to national mobilization, the marshalling of troops and arms, the sense of urgency and crisis, the demand to put aside all qualms at least until the battle has been won, these are relatively new. And in this arena, too, every victory makes the next fight seem more, not less, imperative and critical. There is never a lull after success, never a quiet afternoon, never a peace dividend. There is no everyday life in light of which we might define our morality. There is only the provisional morality of crisis: people are dying, this is no time for moralizing.
>
> But the tragic fact is, of course, that people are always dying, and that they always have been and always will be. If this means that there can never be a time for moralizing, then we are in trouble. And the tenor of our debates over the limits of science does suggest that to many that is indeed what the facts of disease and of death are taken to mean. Because the whole of the human experience remains imperfect, the whole is taken to be sick, and only the effort

to heal it is taken to be worth our time.[36]

The trouble is that in this war against disease and death, we risk undermining the ideals we profess to hold most dear, beginning with the ideal of human equality. We are tempted to treat the most vulnerable as tools to sustain us in the struggle against death. And when this fight must end inevitably in the defeat we cannot avert, we are tempted to violate equality yet again, by treating the old and debilitated (including the future self) as "lives unworthy of life," as unsightly evidence of our failure. Without Jacob's remembering children, without Jesus' saving faith, without Franklin's triumphant method, we are left in the condition of Sisyphus: faced with the crisis of death we cannot conquer, trapped in a mortal condition we seem ill-equipped to endure. In modern times, the hemlock of Socrates seems ever more appealing, requested in desperation rather than accepted in nobility. In an aging society, in which the elderly come to seem and come to feel like paralyzing burdens, the seduction of euthanasia may be too strong to resist.

III. THE CRISIS OF EQUALITY

In modern democracies, the crisis of death is experienced within a moral and political world that prizes human equality, and a reinvigoration of this egalitarian ideal is crucial if we are to resist those answers to death that might dehumanize us. Death, in one sense, is the great equalizer: Rich and poor, young and old, all return equally to the dust from which they came. But the unequal circumstances of death – especially the natural death of a child, which seems particularly unnatural – confront us with the problem of death most poignantly. As it turns out, one promising route to opposing the inequities of death – embryonic stem cell research – may require violating the principle that all human beings are equally worthy of protection, or at least equally possessed of the right not to be used simply as a means to others' ends. To find a cure for the ailing child, we would destroy the developing embryo.[37] To solve the problem of death, we introduce the crisis of equality. We are tempted to treat the not-yet-abled (i.e., human embryos) as tools to help the sick who might be abled again; and when

36. Yuval Levin, *The Crisis of Everyday Life*, THE NEW ATLANTIS, Fall 2004/Winter 2005, at 118, 120-21.

37. Of course, to the untutored human eye, an embryo does not look like much. Looking under the microscope, in our innocence, we might confuse a human embryo with a cow embryo or an ordinary skin cell. But sight and sentiment alone are not the best guides to the moral standing of embryonic human life. Even that tiny embryo is a life in-process; it is what each one of us looked like at that stage of existence. If hardly equal in life lived, memories made, and relationships formed, it is an equal member of the human species, deserving whatever rights we accord based on such membership alone.

such cure-seeking fails us, we are tempted to treat the no-longer-abled (e.g., the octogenarian with dementia) as better off dead, giving them a swift, comfortable exit from life, and in the process freeing ourselves from the excessive (unequal) burdens of their care.

In America, the ideal of human equality is grounded first and foremost in the Declaration of Independence,[38] a political document with metaphysical significance. The Declaration's claim that "all men are created equal"[39] should immediately strike us as strange. For in so many ways, human beings are *not* created equal: Some are born with remarkable natural gifts, others with debilitating natural liabilities. Every newborn is vulnerable and needy; none can survive on his or her own. But newborns are not equally vulnerable, as a brief trip to the neo-natal intensive care unit quickly reminds us, and these native differences often become more pronounced over time. While an ample share of nature's unequal gifts hardly ensures the realization of human excellence or human happiness, a disproportionate share of nature's unequal liabilities, especially malignant disease, often ensures that the pursuit of happiness will be gravely impeded or even impossible. No one who has cared for and mourned a child with a lethal cancer can easily stomach the claim that "all men are created equal." And yet those same caregivers, in their many heroic acts of devotion, are clearly moved by the belief that even a doomed child is worthy of the greatest sacrifice. Created unequal, the child's claim on them – and us – is arguably greater, not smaller.

From this existential truth about the natural fact of inequality, we might draw different ethical and social conclusions about what being "created equal" really means. In the Declaration, the teaching about equality seems designed to be limited: We are equal in rights, not necessarily in dignity or happiness. We are equally entitled not to be harmed by others, not to be treated as property, not to be used as mere things or enslaved by those who are stronger. We are equal in *negative* rights, which governments exist to protect; whether those rights have any *positive* meaning – whether we have life, or can use our liberty, or can pursue happiness with any promise of its realization – often depends on the contingencies of fate.

But for most of us, this limited teaching about political equality is existentially and morally unsatisfying. We are not content to leave the sick, or the young, or the old, to their own devices. We seek to make men equal by ameliorating the inequities of disease through regenerative medicine and by correcting the inequities of birth through redistributive politics. This belief that the afflicted deserve to be made more equal is grounded in a belief that they are already equal – that is to say, equally worthy of the care that might make an

38. THE DECLARATION OF INDEPENDENCE (U.S. 1776).

39. *Id.* at para. 2.

equal pursuit of happiness possible.

The trouble arises when making men equal is beyond our power, or when the means of doing so are morally illegitimate. At times, our two understandings of equality – equality as a moral aspiration and equality as a morally binding fact about our nature – come into direct tension. This tension is seen most clearly in the spirit and methods of modern eugenics, which aim to give every child the genetic equipment to pursue happiness as equals, without biological disadvantages. In our democratic society, the supposed quest for biological perfection is really a quest for perfect equality. So we abort the imperfect in the name of equality. We discriminate against the disabled, using prenatal genetic screening as our litmus test, in the name of producing a society where no one is disabled. We abandon the vulnerable in the name of egalitarianism. We destroy the morally binding ground of equality in our excessive hunger to make nature perfectly just.

The moral alternative to eugenics – seeing the genetically unequal as equally worthy of care, seeing the not-yet-abled and the no-longer-abled as equally worthy of protection – requires a different kind of moral imagination. It, too, is rooted in a radical egalitarianism, the proposition that all men *are* equal in the eyes of those who behold them, including those who are created unequal at birth. To see our fellow human beings in this way requires an acknowledgement of our common vulnerability: We were all once dependent on others to nurture us to self-reliance, and we may all, one day, lose our powers of self-reliance. Even more importantly, this moral disposition to treat all men equally also requires an uncommon human excellence: the resolve to stand with the no-longer-abled, not-yet-abled, or never-to-be-abled, especially when standing by them requires giving up our own hopes and plans. Living equality requires a kind of moral elevation. It is the elevation of the child who stands by a parent with Alzheimer's; the elevation of a parent who stands by a handicapped child; the elevation of a patient who accepts death rather than seeking an embryo-destructive remedy.

In the end, the most radical teaching about human equality is also a teaching about human excellence – the excellence of love, of seeing immeasurable human worth even in those who might seem worthless, of using one's superiority to elevate the weak who cannot elevate themselves. For those who believe in a redeeming God, this kind of excellence is an act of imperfect imitation. For those who believe there is no redeeming God, it is the redemptive human alternative – the activity of acting like the God that would exist, or should exist, if the world were created with love rather than set in motion with indifference.

For some, of course, even nature's most generous portion is not enough. The right to life becomes the right not to die; the right to liberty means the right to be free from all misery; the right to pursue happiness becomes the right to be happy. For those with such an insatiable hunger, the teaching that all men are created equal is a much-needed check on their ambitions. We should not extend our lives

by shortening the lives of others; we should not exercise our liberty by infringing on the rights of others; we should not pursue happiness by using others as a mere means.

Yet affirming the equal worth of every human being – the equal right not to be used – does not necessarily mean that everyone possesses equal human *dignity* in every sense of that complicated term. The truth is far more puzzling. In a limited sense, human dignity resides in the physical being of the human person – especially at its most perfected or most graceful, but even in its most deformed or still forming. In this sense, non-human animals possess a dignity of their own, as living creatures with their own distinct forms and flourishing, yearning to exist but destined to die. Yet there seems to be another dimension of human dignity for which mere physical being is not sufficient; this higher dignity depends on the lived human capacity for excellence and for shame – capacities that are uniquely human but not possessed by all humans. Only human beings can look *indignantly* upon themselves when they fall short of their own aspirations to dignity. Only human beings can be ashamed at standing before others in all their physical, or moral, or existential nakedness. And only human beings can aspire, through willful exertion, to perfect their given natures.

From this angle of vision, it seems misguided to say that a human embryo or a person with late-stage dementia possesses "equal dignity" in every sense, except in potential for the future or in memory of the past, as the being that might be or the being that once was. For the very young, the capacity for excellence and for shame does not yet exist; for the very old, it may be gone forever; for the rare, unfortunate few, it never truly arrives. Yet the fact that some human beings have lost, still await, or never achieve this higher human dignity does not make them simply sub-human things. For it would be beneath *our* dignity to dehumanize our fellow humans, whether in the name of cures, or mercy, or self-elevation.

When it comes to human embryos, our responsibility should be obvious. After all, these nascent lives might grow up to be our moral and intellectual superiors; to destroy them now is to violate the promise they uniquely embody. When it comes to those with dementia or debility, our responsibility may be less clear. Our belief in equality bids us to treat the person with Alzheimer's as a life equally worthy of living; yet something human in us also revolts against the prospect of living indefinitely and ultimately dying in such a state, against seeing our identity robbed from us, against coming to behave without dignity because we lack all control. Faced with this dire prospect, as more and more of us will be, we might wish for a death more like that of Jacob, and we can understand those aging parents who flirt with the Socratic method of dying – the unnatural exit – in order to stand before their children one last time as more than objects of pity. Perhaps the hardest life to regard as equally worthy of living is that of the future self who lacks the vigor and self-control of the person I am now.

In the end, however, a true commitment to human equality rightly tempers the belief that death is a crisis, or that only the flourishing human life is worth

living. It invites us to recognize that in the face of mortality's inevitable triumph, the best we can do is care always for those in need, even for the most debilitated and least developed human beings, and even when the aspiration to "cure now" is met with nature's recalcitrance.[40] It also invites us to submit to the care of others when the time comes, tempering the pride that tempts us to suicide. To believe in human equality ultimately requires the heroic acceptance of death, seeing it as neither a friend to be pursued in the name of mercy or nobility, nor an enemy to be opposed at all costs.[41] We are born toward death, and all those activities that elevate us above the stark fact of our mortality require living well with our unavoidable and usually un-chosen demise.

IV. THE FATE OF BIOETHICS

In the late 1960s and early 1970s, Paul Ramsey (one of the founders of modern American bioethics) wrote extensively about the ethics of end-of-life care.[42] Ramsey's central worry was the technological dehumanization of death. He feared the transformation of dying persons into objects, with a humane exit made impossible by the unyielding machinations of the modern hospital, with its modern ethic of "never surrender."[43] A decade or so later, however, Ramsey was far more worried about the opposite problem: terminating life-sustaining treatment too early; treating the debilitated as "better off dead"; defining as "futile" those who could never be restored to normal but whose lives were hardly over.[44] Ramsey did not, in that period, undergo a philosophical transformation; rather, the facts on the ground changed, and so did his bioethical concerns and priorities.[45]

The purpose of this Commentary has been to recover the permanent questions of bioethics, particularly the related problems of death and equality.

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40. Cures Now is the advocacy group that successfully led the campaign in 2004 for state funding of embryonic stem cell research in California and remains a vigorous advocate of such research. For more information, *see* Cures Now, http://www.curesnow.org (last visited Dec. 10, 2006).

41. For a discussion of the meaning of death as neither friend nor enemy, see Gilbert Meilaender, Professor of Christian Ethics, Valparaiso University, Audio recording: Death: Enemy or Friend?, Lecture Delivered at Calvin College (Jan. 20, 2000), *available at* http://www.calvin.edu/january/2000/meilae.htm.

42. *See, e.g.*, PAUL RAMSEY, THE PATIENT AS PERSON: EXPLORATIONS IN MEDICAL ETHICS 59-144, 239-77 (2d ed. 2002).

43. *See id.* at 66-112.

44. PAUL RAMSEY, ETHICS AT THE EDGES OF LIFE: MEDICAL AND LEGAL INTERSECTIONS 145-88 (1980).

45. *See* Gilbert Meilaender, *"Love's Casuistry": Paul Ramsey on Caring for the Terminally Ill*, J. RELIGIOUS ETHICS, Fall 1991, at 133.

But the development of Ramsey's work reminds us that we are all creatures of time and place, and that the bioethical concerns of the present and future require seeing man's permanent problems in light of changing technological and social conditions, and in light of those philosophical orthodoxies that reign supreme in both our bioethics institutions and the culture as a whole. If this Commentary were about the future of bioethics in Africa, its primary concern might be seeking a cure for the AIDS epidemic, against which all other bioethical problems must pale in comparison. But in the modern West, our greatest challenge is not promoting technological progress but ensuring that our technology always serves rather than impedes our quest to live and die well.

In America, in particular, Franklin's technological spirit – the will to oppose death through science – hardly needs additional support. The National Institutes of Health budget has risen dramatically in recent years, no matter how large the federal deficit or how perilous the condition of our entitlement programs for the elderly.[46] Indeed, we delude ourselves into thinking that medical progress will head off the Medicare crisis, when it is precisely that success – i.e., expensive cures and long-term care for those who have evaded earlier, swifter deaths – that makes our modern medicine so expensive in the first place. Likewise, in our society, the spirit of liberation, for both men and women, hardly needs additional moral support. We are liberated from unwanted conceptions; liberated from unwanted births; liberated from the responsibility of rearing disabled children; liberated from the responsibility of providing economically for our elders in old age; liberated to seek surgical modifications of our given bodies in the name of pursuing happiness. Too little autonomy, like too little enthusiasm for scientific progress, hardly seems like our most pressing bioethical problem.

The real challenge upon which the future of American bioethics will turn is learning how to live and die without trampling on the principle of human equality in the name of embryo research, and learning how to step aside for the next generation without treating the debilitated elderly with a fiscally responsible inhumanity. We need to recover, as best we can, Jacob's way of dying well: *naturally*, without endless machines or swift poisons; *surrounded by his children*, all assembled at the bedside and prepared to honor the dying patriarch by having children of their own; *frail but upright*, with neither the delusion of endless life nor the burdens of an extended decline into dementia.

This image of human excellence in life and in death hardly translates into a ready-made recipe for dealing with every current or foreseeable bioethical dilemma. But it might shape our moral intuitions and cultural aspirations, from which our law and our policies ultimately derive. That is, we might become more

46. For a summary of the National Institutes of Health budget, see NAT'L INSTS. OF HEALTH, SUMMARY OF THE FY 2006 PRESIDENT'S BUDGET (2005), *available at* http://www.nih.gov/news/budget/FY2006presbudget.pdf#search=%22nih%20budget%20%22.

willing to let loved ones die, within an ethical and legal framework that prohibits euthanasia and assisted suicide; more open to the responsibility to have and raise multiple children, rather than seeking the freedom that childlessness uniquely offers; more welcoming of children unconditionally, rather than subjecting them to the inegalitarian litmus tests of modern genetic screening; and more devoted to the unique human excellence required to be loving caregivers and noble patients, who forgo their plans and accept their mortality rather than mistreat the vulnerable or betray their fellow men.

Looking around, it is easy to be disheartened about bioethics and the human future: Birthrates are falling, the incidence of dementia is rising, genetic screening and abortion and embryo destruction are becoming more commonplace. But so long as we remain open to persuasion, open to the recovery of forgotten images of man, our present errors will always be amenable to future reformations. And as we look around and ahead, we should never forget that every age is twisted in its own unique way, stained by errors, getting worse even as it gets better. The only ineradicable error is believing that all the problems of human life can be solved once and for all. Short of that, we will muddle through in bioethics as we do in every realm of human life where the meaning of our humanity is on trial – with examples of excellence and depravity, but most of us stuck in that imperfect in-between, neither beasts nor gods but men with birthmarks.

NOTE

The Medical Resident Working Hours Debate: A Proposal for Private Decentralized Regulation of Graduate Medical Education

Anthony Ciolli*

INTRODUCTION

The debate over the regulation of resident working hours has been one of the most significant recent controversies in graduate medical education. A diverse array of organizations, including Congress, state governments, administrative agencies, and the Accreditation Council for Graduate Medical Education (ACGME), have had to confront this issue at some point over the past two decades. While a consensus has developed that at least some aspects of resident working conditions should be regulated in order to enhance patient safety, there remains an ongoing controversy over which organizations should implement and oversee these regulations.

This Note examines and evaluates the costs and benefits of allowing certain bodies to regulate physician residency programs. Although most scholarship has promoted regulation either by governmental entities, the ACGME, or residents themselves, none of these groups is suited to this task. This Note argues that the ideal regulatory system should involve a decentralized private sector approach, achieved by ending the ACGME monopoly over graduate medical education accreditation and allowing for multiple accrediting agencies. Switching to a private decentralized system would allow for greater experimentation, which would increase the likelihood of discovering the best way to regulate resident

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working conditions to enhance patient safety.

I. PURPOSES OF RESIDENT WORK HOUR REGULATION

Although a consensus has emerged that residents have traditionally worked an unacceptable number of hours per week,[1] the individuals and organizations that support resident work hour limitations do so for different reasons. Three of the primary reasons are patient safety, resident health and quality of life, and residency program educational quality.

A. Patient Safety

The most common, and perhaps most compelling, argument for resident work hour regulation deals with a potential externality caused by long work hours: decreased patient care quality. Multiple studies have shown that sleep loss and fatigue adversely affect resident performance. An early study, conducted in 1972, found that sleep-deprived surgical residents were more likely to make poorly planned maneuvers.[2] Later studies have reported similar findings. One 1998 study of surgical residents found that sleep-deprived residents made twenty percent more errors and took fourteen percent more time to complete tasks;[3] a 2001 study with a larger sample size found that sleep deprivation resulted in an approximately two-fold increase in errors and approximately thirty-eight percent more time to complete tasks.[4]

Researchers examining non-surgical residents found similar results. Two early studies found that residents tested after a rested night made almost half as many errors as residents who suffered sleep loss,[5] and that junior physicians' reasoning test scores reliably deteriorated with eight hours of cumulative sleep debt.[6] Various later studies have found that long hours of work in non-surgical

1. *See infra* Sections II.B-C (providing an overview of current attitudes toward resident work hour regulations).

2. Leonard I. Goldman et al., *Stresses Affecting Surgical Performance and Learning: Correlation of Heart Rate, Electrocardiogram and Operation Simultaneously Recorded on Videotapes*, 12 J. SURGICAL RES. 83, 84-85 (1972).

3. N.J. Taffinder et al., *Effect of Sleep Deprivation on Surgeons' Dexterity on Laparoscopy Simulator*, 352 LANCET 1191, 1191 (1998).

4. Teodor P. Grantcharov et al., *Laparoscopic Performance After One Night on Call in a Surgical Department: Prospective Study*, 323 BRIT. MED. J. 1222, 1222-23 (2001).

5. Richard C. Friedman et al., *The Intern and Sleep Loss*, 285 NEW ENG. J. MED. 201, 202 (1971).

6. E.C. Poulton et al., *The Performance of Junior Hospital Doctors Following Reduced Sleep and Long Hours of Work*, 21 ERGOMETRICS 279, 279 (1978).

residents results in a significant deterioration in reaction time,[7] significant impairment in cognitive function,[8] and reduction in short-term recall.[9] Another study, focusing on internal medicine residents, found that increased total sleep time resulted in twenty-five percent fewer medication errors.[10] A more recent study, which randomly assigned internal medicine interns working in intensive care units to "traditional" (including twenty-four hour or more work shifts) and "intervention" (no extended work shifts and fewer hours worked per week) schedules, found that those on the traditional schedule made nearly forty percent more serious medical errors than those on the intervention schedule and 5.6 times more serious diagnostic errors.[11] Since sleepy residents could put patients at a greater risk of injury or even death, and since many hospitals have not attempted to remedy the problem on their own, some have argued that an external entity should step in and regulate resident work hours in order to protect the safety of patients.[12]

B. Resident Health and Quality of Life

Others have argued that resident work hours should be regulated due to the detrimental impact long hours and sleep deprivation may have on residents themselves. Many studies have shown that working conditions have had negative effects on residents' health. One study found a connection between sleep and emotional health; surgical residents who experienced sleep loss were significantly more likely to feel angry, confused, and fatigued.[13] An additional study reported that residents suffered from increased stress and depression.[14] A more recent study found that seventy-six percent of residents in an internal medicine program suffered from a condition called "burnout," a condition characterized by "depersonalization, emotional exhaustion, and a sense of low

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7. D.I. Orton & J.H. Gruzelier, *Adverse Changes in Mood and Cognition Performance of House Officers After Night Duty*, 298 BRIT. MED. J. 21, 22 (1989).

8. John Robbins & Fred Gottlieb, *Sleep Deprivation and Cognitive Testing in Internal Medicine House Staff*, 12 W.J. MED. 82, 84-85 (1990).

9. Ian J. Deary & Rosemary Tait, *Effects of Sleep Disruption on Cognitive Performance and Mood in Medical House Officers*, 295 BRIT. MED. J. 1513, 1514-15 (1987).

10. Daniel J. Gottlieb et al., *Effect of a Change in Housestaff Work Schedule on Resource Utilization and Patient Care*, 151 ARCHIVES INTERNAL MED. 2065, 2068 (1991).

11. Christopher P. Landrigan et al., *Effect of Reducing Interns' Work Hours on Serious Medical Errors in Intensive Care Units*, 351 NEW ENG. J. MED. 1838, 1842-43 (2004).

12. *See infra* Section II.B.

13. Edward J. Bartle et al., *The Effects of Acute Sleep Deprivation During Residency Training*, 104 SURGERY 311, 314 (1988).

14. David B. Reuben, *Psychologic Effects of Residency*, 76 S. MED. J. 380 (1983).

personal accomplishment."[15] The authors hypothesized that burnout may also contribute to "increases in cynicism and decreases in compassion."[16]

Evidence also shows that long hours may have a negative impact on the physical health of residents. One study, for instance, found that sleep-deprived residents suffered from greater complications during pregnancy, though this difference lost significance when controlling for socio-economic status and medical sophistication.[17] In 1988,[18] 1996,[19] 1997,[20] and 1999,[21] four authors noted that residents suffering from sleep loss are at a significantly greater risk of being in a motor vehicle accident. The most recent motor vehicle study, published in 2005, reports that working extended shifts significantly increases the risk that an intern will fall asleep while driving or while stopped in traffic, and every extended work shift increases an intern's chance of being involved in a motor vehicle accident during the commute from work by over sixteen percent.[22]

Several studies have shown that residents' social health and overall quality of life is impaired due to long work hours. A 1993 study found that work hour reductions increased resident satisfaction by allowing them to spend more time with their families.[23] Another study found that work hour limitations improved the quality of residents' personal lives and relationships.[24] A 2004 study that compared a traditional system to a new (two shift) system found that residents' spouses rated residents' abilities to attend family events significantly improved

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15. Tait D. Shanafelt et al., *Burnout and Self-Reported Patient Care in an Internal Medicine Residency Program*, 136 ANNALS INTERNAL MED. 358, 358 (2002).

16. *Id.* at 366.

17. L.M. Osborn et al., *Outcomes of Pregnancies Experienced During Residency*, 31 J. FAM. PRAC. 618 (1990).

18. James Robert Wendt & Lester J. Yen, *The Resident by Moonlight: A Misguided Missile*, 259 JAMA 43 (1988).

19. Carole L. Marcus & Gerald M. Loughlin, *Effect of Sleep Deprivation on Driving Safety in Housestaff*, 19 SLEEP 763, 765 (1996).

20. R.T. Geer et al., *Incidence of Automobile Accidents Involving Anesthesia Residents After On-Call Duty Cycles*, 87 ANESTHESIOLOGY A938 (1997).

21. Mark T. Steele et al., *The Occupational Risk of Motor Vehicle Collisions for Emergency Medicine Residents*, 610 ACAD. EMERGENCY MED. 1050, 1052 (1999).

22. Laura K. Barger et al., *Extended Work Shifts and the Risk of Motor Vehicle Crashes Among Interns*, 352 NEW ENG. J. MED. 125, 125 (2005).

23. Joseph Conigliaro et al., *Internal Medicine Housestaff and Attending Physician Perceptions of the Impact of the New York State Section 405 Regulations on Working Conditions and Supervision of Residents in Two Training Programs*, 8 J. GEN. INTERNAL MED. 502, 505 (1993).

24. Amelia Kelly et al., *The Effect of New York State Restrictions on Resident Work Hours*, 78 OBSTETRICS & GYNECOLOGY 468, 468 (1991).

after the change to the two shift system.[25] Yet another recently published study reports that there is a relationship between hours worked and a resident's happiness and ability to take care of responsibilities outside of work.[26]

C. Residency Program Educational Quality

Still others have proposed that resident work hours be regulated in order to improve the educational quality of residency programs. By reducing hours, some believe that residents will benefit more from the hours they do spend at work. In one experiment, where average work hours were reduced from 110 hours a week to 75 hours a week, many residents felt that overall educational quality improved, although faculty believed that, on average, there was no change.[27] Another study found that work hour reductions allowed residents to have more time for reading as well as for preparing for conferences and cases.[28]

Some, however, have argued that the largest gains in educational quality are achieved when hours spent performing administrative or ancillary functions – often referred to as "scut work" – are reduced.[29] Several studies support this claim. In one study, where health technicians were added to surgical teams, resident work hours dropped from an average of 16.3 per weekday to 12.9 per weekday; however, resident hours spent in the operating room increased from 3.3 hours per week to 9.8 hours per week.[30]

Medical student and resident advocacy groups, such as the American Medical Student Association, support work hour limits primarily to "protect resident physicians from overwork,"[31] although such organizations believe "an

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25. The two shift system involved dividing residents into a day shift and a night shift. M.J. Goldstein et al., *A 360 Degrees Evaluation of a Night-Float System for General Surgery: A Response to Mandated Work-Hours Reduction*, 61 CURRENT SURGERY 445, 448 (2004).

26. Kara C. Kort et al., *Resident Perceptions of the Impact of Work-Hour Restrictions on Health Care Delivery and Surgical Education: Time for Transformational Change*, 136 SURGERY 861, 864-65 (2004).

27. Kelly et al., *supra* note 24, at 470.

28. Chandrasekhar Bob Basu et al., *The Effect of the Accreditation Council for Graduate Medical Education Duty Hours Policy on Plastic Surgery Resident Education and Patient Care: An Outcomes Study*, 114 PLASTIC & RECONSTRUCTIVE SURGERY 1878, 1881 (2004).

29. Some current and former residents despise "scut work" to such an extent that they participate on interactive websites in order to inform prospective applicants about the amount of "scut work" their programs require. *See, e.g.*, Scutwork.com: Residency Program Reviews, http://www.Scutwork.com.

30. Yale D. Podnos et al., *Reducing the Noneducational and Nonclinical Workload of the Surgical Resident: Defining the Role of the Health Technician*, 60 CURRENT SURGERY 529, 530 (2003).

31. Am. Med. Student Ass'n, The Resident Work Hour Issue: Your Home for the Most Up-to-

improved working environment" would also ensure patient safety.[32] However, most proponents of work hour regulations, such as patient rights organizations, legislators, and the mass media, have placed a significantly greater emphasis on the patient safety.[33] Thus, every attempt to limit resident work hours was made with that purpose in mind.[34] The following Part provides a brief overview of the history of graduate medical education and attempts to regulate it by both government entities and the ACGME.

II. GRADUATE MEDICAL EDUCATION: A BRIEF HISTORY

The U.S. Department of Health and Human Services defines graduate medical education as "the process for providing academic and clinical education to physicians after they have graduated from an accredited medical school."[35] Medical school graduates enroll in these programs in order to obtain advanced training in a specialty area, such as surgery.[36] Such education typically takes place at teaching hospitals,[37] often affiliated with medical schools,[38] which allows physician residents to provide patient care under the supervision of a teaching physician.[39] While program lengths vary by specialty, typical residencies last from three to seven years.[40]

Formal residency programs have existed for almost 120 years.[41] One can divide the regulatory history of resident work hour limits into three distinct eras: laissez-faire, New York State regulation, and ACGME self-regulation.

Date Information, http://www.amsa.org/rwh/ (last visited Dec. 9, 2006).

32. *Id.*

33. *See infra* Sections II.B-C (explaining why New York State and the ACGME ultimately chose to regulate resident work hours).

34. *See infra* Sections II.B-C.

35. NAT'L CTR. FOR HEALTH WORKFORCE INFO. & ANALYSIS, U.S. DEP'T OF HEALTH & HUMAN SERVS., GRADUATE MEDICAL EDUCATION AND PUBLIC POLICY: A PRIMER 1 (2000) [hereinafter PRIMER].

36. *Id.* at 2.

37. *Id.* at 1.

38. More than ninety percent of all graduate medical education programs are affiliated with a medical school. *Id.* at 3.

39. *Id.* at 2.

40. Stewart R. Reuter, *Professional Liability in Postgraduate Medical Education*, 15 J. LEGAL MED. 485, 485-86 (1994).

41. *See* PRIMER, *supra* note 35, at 2 ("The first formal physician residency program . . . was established at Johns Hopkins Hospital in Baltimore in 1889.").

A. The Laissez-Faire Period: "The Bad Old Days"

The laissez-faire period spanned a century, from the first residency program established at Johns Hopkins Hospital in 1889 to the creation of New York State Department of Health regulations. The first half of the twentieth century marked graduate medical education's formative years. By the early 1900s, other institutions had already begun to create their own internship programs modeled after the Johns Hopkins system.[42] Although such programs "had become an accepted part of preparation for general medical practice,"[43] specialty training beyond basic one-year internships was largely unregulated until the early 1930s, when the American Board of Medical Specialties (ABMS) began to provide quality assurance by certifying specialists.[44] Starting in the early 1970s, a similar quality assurance function was performed by the Liaison Committee on Graduate Medical Education, which then evolved into the ACGME in 1981.[45]

Although some form of external oversight was present for much of this period, one must distinguish between regulation of educational quality and regulation of working conditions. The ACGME and its predecessor, while generally encouraging hospitals to deemphasize "scut work" and maximize educational value, made little or no attempt to intervene in the relationship between a program and its residents.[46]

Residency programs, in the absence of outside regulations, were free to determine resident physician working conditions as they saw fit. During this period, a general consensus emerged that residents should work very long hours as part of their training. Researchers continue to debate whether this consensus was primarily motivated by economic or pedagogical reasons.[47] There is little doubt that hospitals receive significant economic benefits from their residency programs – residents are an "elastic source of physician labor"[48] and have been

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42. *Id.*

43. *Id.*

44. *Id.* Note that the ABMS did not accredit residency programs—it provided quality assurance by testing individuals after they completed a residency program. For more information on the certification procedure, see History of the ABMS, http://www.abms.org/About_ABMS/who_we_are.aspx (last visited Dec. 9, 2006).

45. PRIMER, *supra* note 35.

46. *See generally* Lindsay Evans, Note, *Regulatory and Legislative Attempts at Limiting Medical Resident Work Hours*, 23 J. LEGAL MED. 251, 256-58 (2002) (discussing the ACGME's stance on the resident work hour issue prior to its decision to regulate work hours itself).

47. *See, e.g.*, Jennifer F. Whetsell, *Changing the Law, Changing the Culture: Rethinking the "Sleepy Resident" Problem*, 12 ANNALS HEALTH L. 23, 43-50 (2003) (discussing why the medical establishment has established and continues to support the traditional residency system).

48. David A. Asch & Ruth M. Parker, *The Libby Zion Case: One Step Forward or Two Steps*

"regularly exploited as a source of inexpensive labor" from as early as the 1920s.[49] Even at the very best teaching hospitals, programs have been criticized for using residents to perform a significant number of ancillary or administrative functions that serve no educational purpose, such as drawing blood samples or transporting patients.[50]

While economic incentives exist for hospitals to have their residents work long hours, many have argued that such hours are also necessary for educational purposes. There has been a widespread belief that new physicians must experience a "round-the-clock trial by fire" as part of their training – an idea that is still deeply entrenched to this day.[51] Doctors have historically believed that long working hours help residents to "learn to remain focused under taxing circumstances."[52] According to these doctors, it is absolutely necessary for residents to experience sleep deprivation and other hardships, for they must learn to "subordinate their needs for sleep and food to the unpredictable and often consuming demands of patient care."[53] As one doctor put it, "Patients get sick on Christmas Day. Ditto 2 o'clock in the morning, and as a physician you need to be able to take care of them."[54] Long hours also serve a psychological function, in that they allow residents to solidify social identity and learn the humility necessary to assume a powerful social role.[55] In other words, the medical establishment believes mental and physical toughness is vital to the practice of medicine, and graduate medical education programs "go to great lengths to test these residents' and interns' mettle."[56]

However, long hours did not develop as mere fraternity-like hazing rituals.

Backward?, 318 NEW ENG. J. MED. 771, 774 (1988).

49. Kenneth M. Ludmerer & Michael M. E. Johns, *Reforming Graduate Medical Education*, 294 JAMA 1083, 1084 (2005).

50. *Id.*

51. *See* Carl T. Hall, *Doctors See Loopholes in Limits on Workweek*, S.F. CHRON., June 16, 2002, at A4.

52. Tom Pelton, *New Rules on Residents Leave Hazy Prognosis for Hospitals*, BALT. SUN., June 15, 2002, at 1.A.

53. Sandra G. Boodman, *Waking Up to the Problem of Fatigue Among Medical Interns*, L.A. TIMES, Apr. 16, 2001, at S1.

54. *See* Peter C. Beller, *Your Intern Today is Both Sleepy and Bored. Feel Better?*, N.Y. TIMES, Sept. 14, 2005, at B9 (quoting Dr. James Rohack, former chairman of the American Medical Association).

55. *See* Leanord C. Groopman, *Medical Internship as Moral Education: An Essay on the System of Training Physicians*, 11 CULTURAL MED. & PSYCHIATRY 207, 207-27 (1987) (suggesting that long hours are a rite of passage that promote group cohesion, establish social identity, and further other psychological goals).

56. Whetsell, *supra* note 47, at 46.

Unlike other educational programs, where students can study the subject matter outside of the physical educational institution, a medical resident's education cannot be duplicated outside of the hospital setting – residents attempting to specialize in surgery cannot simply go home and practice their surgical skills. In order to obtain advanced clinical training in their specialty, residents have no other option but to treat actual patients in an actual clinical setting, such as a teaching hospital; thus, residents seeking to obtain as much training as possible would often want to work longer hours to hone their skills.[57]

Work hours, while universally long, still differed from program to program during the laissez-faire period. The lack of regulation allowed different specialties and sub-specialties to develop their own work hour norms over time. Such norms were not arbitrary: They were highly correlated with the intensity of the specialization. While residents in surgery often worked as many as 130 hours a week, residents in other specialties have been known to work on average as little as 60 or 70 hours per week.[58] In other words, complicated and difficult to master specialties demanded a greater time commitment from their residents than specialties that require less technical skill on the part of the resident.[59]

B. New York State Regulation: A Failed Experiment

Although some individuals expressed their concern about medical resident working hours during the laissez-faire period, no serious attempt was made to change the status quo. This began to change in the mid-1980s, when the death of an eighteen-year-old college freshman became the first step in a process that would result in the State of New York regulating resident working hours, and eventually brought about significant changes in graduate medical education nationwide.

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57. Myrle Croasdale, *Beat the Clock: The New Challenges to Residents*, AM. MED. NEWS, Mar. 8, 2004, *available at* http://www.ama-assn.org/amednews/2004/03/08/prsa0308.htm.

58. Scott Turner, *Medical Residency: An Exercise in Sleep Deprivation*, GEORGE ST. J., Oct. 4, 2001, *available at* http://www.brown.edu/Administration/George_Street_Journal/vol26/26GSJ06h.html; *cf.* Richard W. Schwartz et al., *Controllable Lifestyle: A New Factor in Career Choice by Medical Students*, 64 ACAD. MED. 606 (1989) (discussing how some medical specialties are known to have better lifestyles than others).

59. A recent survey by MercuryMD shows that this is true even today – residents in specialties that involve the least amount of direct patient care, such as pathology and radiology, work between twenty to forty fewer hours per week on average than residents in specialties that involve greater patient care responsibilities, such as surgery and ob-gyn. MERCURYMD, IMPACT OF HOSPITAL COMPUTER SYSTEMS ON RESIDENT WORK HOURS, http://www.medrecinst.com/uploadedFiles/resources/venResearch/resident(1).pdf (last visited Dec. 9, 2006).

1. The Desire To Regulate

The desire to transition from a free market system to state regulation was based on the idea that allowing individual residency programs to set their own work hour norms resulted in a market failure, for the free market system could not properly handle the patient safety externality.[60] Residency programs sought to train "tough" doctors whom the program could condition to become less dependent on sleep and used to working long and unpredictable hours;[61] however, residents do not acquire these skills immediately, if they ever do.[62] Since the typical residency programs provide residents with a very high degree of patient care responsibility at a very early stage in the program,[63] some argued that residency programs, by requiring their residents to work very long hours, were putting patients at risk by placing their care in the hands of sleep-deprived residents.[64] The death of Libby Zion confirmed these assumptions.

2. The Libby Zion Incident

On the evening of March 4, 1984, Libby Zion was admitted to New York Hospital with an earache and a 103 degree fever.[65] Although Libby's medical team, consisting of two physically present residents and an attending physician only available by phone,[66] had been specifically told she was taking Nardil, an anti-depressant, one of the residents prescribed an injection of Demerol, a drug fatal when taken in conjunction with Nardil.[67] Libby immediately began to suffer an adverse reaction to Demerol. She thrashed about violently in bed and her fever rose, but she was not seen by any doctor for about four hours. The only attention she received was from attendants who restrained her on instructions from an

60. *See supra* Section I.A (discussing the potential impact long resident work hours may have on patient safety).

61. *See* Boodman, *supra* note 53.

62. Studies have shown that, contrary to popular belief, healthy adults cannot acclimate to sleep deprivation. *See, e.g.*, Mark Blagrove et al., *The Effects of Chronic Sleep Reduction on the Performance of Cognitive Tasks Sensitive to Sleep Deprivation*, 9 APPLIED COGNITIVE PSYCHOL. 21 (1994); Mary A. Carskadon & William C. Dement, *Cumulative Effects of Sleep Restriction on Daytime Sleepiness*, 18 PSYCHOPHYSIOLOGY 107 (1981); David F. Dinges et al., *Cumulative Sleepiness, Mood Disturbance, and Psychomotor Vigilance Performance Decrements During a Week of Sleep Restricted to 4-5 Hours Per Night*, 20 SLEEP 267 (1997).

63. PRIMER, *supra* note 35, at 2.

64. *See supra* Section I.A (discussing how sleepy residents may impair patient safety).

65. Tom Wicker, *Doctors in the Dock?*, N.Y. TIMES, Dec. 23, 1985, at A17.

66. Craig Horowitz, *The Doctor Is Out*, N.Y. MAG., Nov. 3, 2003, *available at* http://newyorkmetro.com/nymetro/health/features/n_9426/index2.html.

67. Wicker, *supra* note 65.

intern who had never examined her.[68] By morning, Libby had passed away.[69]

Sidney Zion, Libby's father and a former prosecutor and *New York Times* journalist, hired attorneys to investigate his daughter's death and was shocked to discover that both residents had been working at the hospital for eighteen hours or more by the time they saw Libby.[70] Rather than merely suing the hospital for malpractice, Sidney Zion decided to use his influence to draw attention to the poor care patients may receive due to overworked and fatigued residents;[71] he successfully lobbied for a grand jury investigation of New York Hospital's residency program.[72] Although the grand jury did not issue any criminal indictments, it did provide several recommendations to improve patient care, including placing limits on medical resident working hours.[73] In 1987, the New York State Commissioner of Health appointed a committee, chaired by Dr. Bertrand Bell, to examine the grand jury's findings.[74] This committee, dubbed the Bell Commission, recommended substantial changes to graduate medical education, most notably that the state government place limits on resident working hours.[75]

3. State Regulation: Implementation and Enforcement

New York adopted many of the Bell Commission's recommendations in 1988, making New York the first state to regulate resident working hours.[76] These regulations, which went into effect in July 1989 and are still in effect today, limit residents to an eighty-hour workweek (averaged over a four-week period).[77] In addition, residents cannot work more than twenty-four consecutive hours of scheduled work (twelve hours in emergency departments) and are required to receive at least eight hours between these work assignments.[78] Furthermore, residents must receive a minimum of twenty-four nonworking

68. *Id.*

69. *Id.*

70. Horowitz, *supra* note 66.

71. Wicker, *supra* note 65.

72. *Id.*

73. Robert Steinbrock, *The Debate Over Residents' Work Hours*, 347 NEW ENG. J. MED. 1296, 1297 (2002).

74. *Id.*

75. *Id.*

76. Don Colburn, *Young Doctor's Lack of Sleep Doesn't Affect Care*, WASH. POST, Sept. 27, 1988, at Z5.

77. Steinbrock, *supra* note 73.

78. *Id.*

hours every week.[79]

At the time these regulations were adopted, many believed that other states would soon follow New York's lead and implement their own regulations.[80] However, this never came to pass; even today, New York remains the only state to have instituted limits on resident work hours. Although four states – California, Hawaii, Massachusetts, and Pennsylvania – have contemplated similar regulations, their bills never passed.[81]

The New York regulations, once warmly embraced and originally inspiring much optimism, soon became regarded as a failure due to hospitals largely ignoring the regulations. In 1989, the year the regulations went into effect, sixty-two percent of New York hospitals failed to comply with at least one major provision; in 1991 this figure rose to seventy-one percent. By 1994 a full ninety-two percent of hospitals were in non-compliance with the regulations.[82] Three factors largely explain why non-compliance rates reached such high levels.

a. Enforcement

Perhaps the most obvious reason for lack of compliance with the New York regulations was the State's inability to effectively enforce them. First, New York's monitoring mechanisms were weak. When the regulations first went into effect in 1989, New York's Department of Health visited thirty New York City hospitals in order to assure their compliance with the new regulations.[83] However, in 1993, this number dropped to only twelve visits.[84] Insufficient funding likely caused this low level of monitoring; although the Department of Health was given the additional duty of enforcing these regulations, its budget was cut by both the New York State and New York City governments.[85] Given the Department's other responsibilities, it should come as no surprise that the Department of Health did not view enforcing resident work hour regulations as a top priority.[86]

Second, this insufficient monitoring was coupled with low penalties. Hospitals found to have violated the regulations face only a $2000 fine for the

79. *Id.*

80. Whetsell, *supra* note 47, at 55.

81. *See* Boodman, *supra* note 53; Ann Japenga, *Endless Days and Sleepless Nights: Do Long Work Schedules Help or Hinder Medical Residents?*, L.A. TIMES, Mar. 6, 1988 at 1.

82. John Ronches, *Must We Squander the Legacy of Libby Zion?*, NEWSDAY, Jan. 3, 1995, at A24.

83. *Id.*

84. *Id.*

85. *Id.*

86. *Id.*

first violation.[87] Given the very low risk of getting caught, and the very small penalty if one does get caught, it is not unexpected that hospitals would not place a high priority on compliance.

b. Financing

Although New York did not effectively enforce the regulations, this lack of enforcement alone does not explain why most New York hospitals chose not to comply. While enforcement of the regulations has been weak overall, there have been periods when New York did cite a large number of hospitals for violations. For instance, New York's Department of Health conducted a series of raids in March 1998, which uncovered numerous violations at several prestigious teaching hospitals;[88] a similar raid took place in 2002, uncovering even more violations.[89]

Rather than reacting to such raids by increasing compliance with the regulations, hospitals chose to take creative measures to avoid getting caught violating them. One hospital, for example, generated two separate schedules for residents – one for clinic duties and another for in-patient duties – that were not reconciled.[90] Another hospital sought to circumvent the regulations by officially scheduling residents for twelve-hour shifts in compliance with the regulations but making it clear that they were actually required to arrive an hour or two before the official starting time and expected to stay after the official ending time.[91] Even more hospitals would schedule "technically optional" conferences that would not be included in the official work schedule, but require residents to attend.[92]

Why would hospitals take such elaborate steps in order to avoid complying with the law? Hospitals have an obvious financial incentive not to comply with these regulations: If complying with the regulations would reduce a surgical resident's average work week from 130 hours to 80 hours, the hospital would have to hire other individuals to make up for the 50 hour deficit. The costs of hiring additional staff are substantial. Hiring just one additional physician

87. Susan Rubinowitz, *Hosp Docs No Longer the Young and the Rest-less*, N.Y. POST, Jan. 26, 2000, at 18.

88. Lucette Lagnado, *Raid of Hospitals Probes Overworked Doctors*, WALL ST. J., Mar. 11, 1998, at B1.

89. Margaret Ramirez, *City Teaching Hospitals Broke Rules on Hours for Residents*, NEWSDAY, June 27, 2002, at A49.

90. Esther B. Fein, *Flouting Law, Hospitals Overwork Novice Doctors*, N.Y. TIMES, Dec. 14, 1997, at 1.

91. *Id.*

92. *Id.*

assistant may cost a hospital anywhere from $67,000 to $77,000 per year, and an additional nurse practitioner's salary could range from $53,000 to $98,000.[93] More skilled laborers, such as specialized physicians known as "hospitalists," have salaries ranging from $100,000 to $150,000.[94] At some hospitals, the costs of hiring additional staff to compensate for lost resident labor can exceed $5 million per year.[95]

One should note that the New York regulations were not a completely unfunded mandate: New York State gave hospitals $55 million a year to help comply with them.[96] However, this money did not sufficiently cover the increased expense; the New York Department of Health estimated the initial cost of compliance at $227 million, with continued compliance costing $3.1 billion for the first ten years and $5.7 billion over the first fifteen years.[97] Not only was $55 million a year insufficient, but hospitals had no guarantee that the state would perpetually provide them with $55 million a year. Furthermore, since hospitals were not required to account for how they spent the money,[98] hospitals seeking to maximize their economic position could spend this money on other things and continue not to comply with the regulations, considering the low levels of enforcement and low penalties.

c. Culture

While financial incentives played a very large role in hospital non-compliance with the New York regulations, one cannot ignore the role of culture. As discussed earlier, doctors have historically believed that residents should work long hours for a variety of reasons, ranging from pedagogical[99] to psychological.[100] It should come as no surprise that a culture so entrenched would not change overnight.

Additional cultural factors, however, likely contributed to hospitals' unwillingness to comply. Hospitals have historically been given a significant amount of deference, and for the most part they have been allowed to set their

93. Debra F. Weinstein, *Duty Hours for Resident Physicians – Tough Choices for Teaching Hospitals*, 347 NEW ENG. J. MED. 1275, 1276 (2002).

94. Bruce Japsen, *Residents Rules Cost Hospitals Millions*, CHI. TRIB., July 10, 2005, at C1.

95. Katherine Vogt, *Hospitals Count Up Cost of Reduced Resident Hours*, AM. MED. NEWS, Aug. 11, 2003, *available at* http://www.ama-assn.org/amednews/2003/08/11/bisc0811.htm.

96. Ronches, *supra* note 82.

97. GAO, HEALTH CARE: REDUCTION IN RESIDENT PHYSICIAN WORK HOURS WILL NOT BE EASY TO ATTAIN 4 (1992) [hereinafter GAO REPORT].

98. *See* Ronches, *supra* note 82.

99. Pelton, *supra* note 52.

100. Groopman, *supra* note 55.

own standards; thus, hospitals have generally been suspicious of government interference in their affairs.[101] Since "regulations may be crafted by legislators who lack intimate knowledge of the health care system," hospitals are reluctant to blindly follow government mandates without solid evidence that such regulations are truly beneficial and necessary.[102] Hospitals did not believe that the New York state government provided solid evidence. In fact, even today many hospitals and residency program directors argue that there is no relationship between work hour limits and patient safety.[103] Doctors in other states oppose state work hour legislation for similar reasons and believed hospital administrators, and not the government, should make these decisions.[104]

C. The Current State of Affairs: ACGME Regulation

When state regulation of resident work hours failed to meet expectations, some believed that residency programs simply would not submit to any form of external regulation of resident working conditions. The early twenty-first century, however, has seen a significant change in how resident work hours are regulated. On June 11, 2002, the ACGME announced that, as of July 1, 2003, all accredited residency programs would have to comply with the ACGME's resident work hour regulations in order to keep their accreditation.[105]

While New York State resident work hour regulations stemmed from the Libby Zion incident, there was no single event that precipitated the ACGME's decision to regulate nationwide. Public outcry, in fact, played little, if any, role in the ACGME's decision. Instead, the ACGME was likely motivated by a series of events that, while receiving significantly less media attention than Libby Zion, posed a real threat to both hospital and ACGME control over residency programs.

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101. Robert Trowbridge & Robert M. Wachter, *Legislation, Accreditation, and Market-Driven and Other Approaches to Improving Patient Safety in* MAKING HEALTH CARE SAFER: A CRITICAL ANALYSIS OF PATIENT SAFETY PRACTICES 601, 602 (Amy J. Markowitz ed., 2001), *available at* http://www.ahrq.gov/clinic/ptsafety/pdf/ptsafety.pdf.

102. *Id.*

103. *See infra* Section III.C (discussing why many hospitals and residency program directors believe limiting resident work hours does not enhance patient safety).

104. *See, e.g.*, David Abel, *Bill Would Put Federal Limit on Residents' Marathon Hours*, S.F. CHRON., Dec. 31, 2001, at J3 ("'I think legislation is a dangerous way to go when we are trying to provide the best training,' said Elizabeth Stengel, director of the Conference of Boston Teaching Hospitals. 'It doesn't allow flexibility and its just much better that doctors and hospital administrators make the decisions.'").

105. Hall, *supra* note 51.

1. Resident Unionization

Hospitals have historically been identified as organizations that "are most supportive of steep hierarchies in which junior staff do not question senior staff."[106] This hierarchical nature certainly applies to residencies, for the purpose of a residency program is for a resident to acquire training in a specialty area by supervising physicians who are already skilled specialists in their fields.[107] However, a ruling by the National Labor Relations Board (NLRB) in 1999 had the potential to change fundamentally the relationship between residents and their superiors.

The controversy in *Boston Medical Center Corp.*[108] began with the merger of Boston City Hospital, a public hospital, and Boston University Medical Center Hospital, a private hospital, to create the Boston Medical Center, a private entity.[109] Due to Massachusetts's Public Employee Benefits Act, residents at Boston City Hospital had been unionized since 1969, while the Boston University Medical Center Hospital had not recognized a resident union.[110] Although the Boston Medical Center was required to recognize Boston City Hospital's union as a condition of the merger, the residents' union, the Committee of Interns and Residents, brought the case before the NLRB in order to test whether residents at private institutions are primarily students or employees.[111]

The NLRB, in a split decision, reversed more than twenty years of precedent.[112] The majority found that residents, "while they may be students learning their chosen medical craft, are also 'employees' within the meaning of Section 2(3) of the [National Labor Relations] Act."[113] Under this decision, medical residents were given all the rights given to other workers protected under the NLRA, including the ability to bargain collectively and strike.[114]

The *Boston Medical Center* ruling drew immediate criticism from several prominent medical professional organizations, which saw the decision as a threat

106. Trowbridge & Wachter, *supra* note 101.

107. PRIMER, *supra* note 35, at 2.

108. 330 N.L.R.B. 152 (1999).

109. *Id.*

110. *Id.*

111. Am. Ass'n of Med. Colls., Resident Unionization, http://www.aamc.org/advocacy/library/workforce/work0003.htm (last visited Oct. 17, 2006).

112. *See, e.g.*, St. Clare's Hosp. & Health Ctr., 229 N.L.R.B. 1000 (1977); Cedars-Sinai Med. Ctr., 223 N.L.R.B. 251 (1976) (holding that medical residents are primarily students, not employees).

113. 330 N.L.R.B. at 152.

114. *Id.*

to medical education's traditional hierarchical structure. The Association of American Medical Colleges (AAMC) issued a statement condemning the decision, stating that the decision "has far-ranging, potentially damaging implications for the future of physician training in this country."[115] The AAMC's president, Jordan J. Cohen, went on to say that labor disputes and other issues arising out of medical education programs "should be the responsibility of the faculty and teaching institution," and that "residents should not have the right to strike and that the ability to do so, which is one of the primary entitlements associated with unions, is incompatible with the medical education process."[116] The ACGME, while not condemning the NLRB's decision outright, issued a statement affirming its ability to regulate resident working environments. In this statement, which was circulated to all residents, the ACGME emphasized that "[r]esidents are first and foremost students, rather than employees, and all accreditation standards and activities reflect this distinction."[117]

2. Federal Government Regulation

Resident unionization was not the only potential threat to hospital and ACGME control over residency programs nationwide. Not long after the NLRB decided the *Boston Medical Center* case, some individuals within the U.S. government contemplated federal regulation of resident working conditions.

The early twenty-first century was not the first time the federal government considered the possibility of regulating resident work hours. In fact, the U.S. government first considered the possibility in 1991, three years after the New York State regulations were instituted. Illinois Congressman Marty Russo, contemplating federal resident work hour legislation, asked the Human Resources Division of the U.S. General Accounting Office (GAO) to investigate whether the "quality of care delivered by resident physicians could be improved" through federal legislation limiting resident work hours.[118] GAO, after a yearlong study, concluded that residents who work long hours with minimal supervision "are likely to be more at risk of making errors than are properly rested and supervised personnel."[119] However, the GAO report found that federal legislation

115. Press Release, Am. Ass'n of Med. Colls., AAMC Statement on NLRB Boston Medical Center Ruling (Dec. 8, 1999), *available at* http://www.aamc.org/newsroom/pressrel/1999/991130.htm.

116. *Id.*

117. Memorandum from David C. Leach, Executive Director, ACGME, to Member Organizations of the ACGME (Mar. 1, 2000), *available at* http://www.acgme.org/acWebsite/reviewComment/rev_residentEmployee.asp.

118. GAO REPORT, *supra* note 97, at 1.

119. *Id.* at 5.

may not succeed in resolving the problem, since many hospitals, particularly those in inner cities, would not limit work hours unless the costs of compliance were fully reimbursed.[120] After receiving this report, Congressman Russo did not introduce a bill seeking to limit resident work hours.

For the next decade, the federal government made no significant attempt to regulate work hours. In April 2001, however, the Committee of Interns and Residents, an affiliate of the Service Employees International Union,[121] joined by the American Medical Student Association and the Public Citizen Health Research Group, petitioned the Occupational Safety and Health Administration (OSHA) to "enforce a federal work hour standard for residents."[122] OSHA stated that it did not believe it had the purview to regulate resident work hours.[123] Although this petition was unsuccessful, it got the attention of Michigan Congressman John Conyers, Jr., who introduced the Patient and Physician Safety and Protection Act, H.R. 3236, in November 2001.[124] This bill would have limited residents to eighty hours of work per week and would not have permitted averaging of weeks.[125]

Shortly before H.R. 3236 was formally introduced, the AAMC, in an attempt to eliminate the need for federal legislation, changed its position on the resident work hour issue and recommended that "in no case should residents be scheduled to be on duty more than 80 hours a week."[126] While this declaration was not binding on any residency program, the AAMC cited it as evidence that government intervention was not necessary. In a letter to Congressman Conyers, AAMC President Jordan J. Cohen wrote that the AAMC "agree[d] that the issues addressed in this legislation are very important" but felt that legislation was not appropriate, since "[t]he mechanisms that are in place in the private sector to safeguard the public's interest in these matters have evolved over decades" and "the academic medical community . . . ha[d] already made substantial progress in dealing with current concerns about resident and patient well being."[127] Cohen concluded the letter by arguing that "continued reliance on these proven

120. *Id.*

121. Comm. of Interns & Residents, Who We Are, http://www.cirseiu.org/ourlocal/ (last visited Oct. 17, 2006).

122. Robert Steinbrook, *The Debate Over Residents' Work Hours*, 347 NEW ENG. J. MED. 1296, 1297 (2002).

123. Jay Greene, *Petition Asks OSHA To Limit Resident Work Hours*, AM. MED. NEWS, May 21, 2001, http://www.ama-assn.org/amednews/2001/05/21/prsa0521.htm.

124. H.R. 3236, 107th Cong. (2001).

125. *See* Steinbrook, *supra* note 122, at 1296.

126. *Id.* at 1297.

127. Letter from Jordan J. Cohen, AAMC President, to John Conyers, Jr., U.S. Representative (Jan. 4, 2002), *available at* http://www.aamc.org/advocacy/library/educ/corres/2002/010402.htm.

mechanisms offers a far greater likelihood of success in dealing with the concerns addressed by H.R. 3236 than does the introduction of legislative and regulatory strictures into the complex environment of graduate medical education."[128]

When it became clear Congressman Conyers had no intention of withdrawing the bill, and that New Jersey Senator Jon Corzine also intended to introduce the bill in the Senate (as S. 2614), the ACGME decided to place formal limits on resident work hours at ACGME-accredited residency programs.[129] On June 11, 2002, the day before Senator Corzine introduced S. 2614, the ACGME announced that, effective July 1, 2003, residents could be scheduled for no more than eighty duty hours per week, averaged over four weeks, with provisions allowing for increases in certain circumstances.[130] Neither H.R. 3236 nor S. 2614 received a vote from their respective houses of Congress, and when Representative Conyers reintroduced his bill as H.R. 1228 the following year it also failed to receive a vote.[131]

III. EVALUATING EXISTING REGULATORY SCHEMES

Academics and practitioners have generally identified three possible ways to regulate resident working hours and conditions: public decentralized regulation, public centralized regulation, and private centralized regulation. This Part discusses the costs and benefits of these regulatory systems relative to an unregulated market.

A. No Regulation: The Free Market

The laissez-faire period in graduate medical education was an era of a free market, in which residency programs themselves were able to determine resident working hours and conditions without external oversight.[132] As discussed earlier, this free market system led to inefficient outcomes due to its inability to handle externalities, such as the medical mistakes that led to the deaths of Libby Zion

128. *Id.*

129. *See* Michael Romano, *Hours of Doctors-in-Training: Who's Counting?*, MOD. HEALTHCARE, Aug. 19, 2002, at 18 (quoting Peter Lurie, deputy director of the Public Citizen advocacy group, who called the ACGME regulations "a last-gasp effort to save off federal legislation").

130. Steinbrook, *supra* note 122.

131. Am. Ass'n of Med. Colls, Washington Highlights: April 1, 2005, http://www.aamc.org/advocacy/library/washhigh/2005/040105/start.htm (last visited Dec. 8, 2006) (see subheading Conyers Reintroduces Resident Hours Legislation).

132. *See supra* Section II.A (summarizing the laissez-faire period).

and others.[133] Though some residency program directors may prefer such a system and wish to return to such an era, such a change is unlikely to occur since other stakeholders in graduate medical education are no longer willing to potentially compromise patient safety.[134]

In recent years, however, some have proposed an alternate free market approach involving a shift in bargaining power. Rather than allowing individual residency programs to unilaterally determine working hour policies, residency programs would decide these policies together with residents themselves.[135] There is little dispute that economics played at least some role in shaping working hour policies during the laissez-faire period: Since residents provided hospitals with a cheap source of labor, hospitals had an incentive to require their residents to perform ancillary tasks that were unrelated to the educational goals of a residency program.[136] Residents lacked any semblance of bargaining power and could not prevent programs from assigning them to such tasks.[137]

The NLRB's 1999 decision in *Boston Medical Center*,[138] granting medical residents at private institutions the right to unionize, could allow medical residents, through their unions, to negotiate working hours and conditions as part of a collective bargaining agreement. There are clear advantages to such a system. Since residents receive minimal benefit from "scut work" and greatly prefer tasks that further education in their specialty, it is likely that meaningful negotiation between programs and residents would result in a reduction of hours performing "scut work" without a reduction in hours spent on training. As a result, residents might work fewer hours and eliminate or lessen the externality, while simultaneously not compromising their educational training. Furthermore, hospitals and residents could implement work hour regulations that are individually tailored to specific programs within specific institutions.

Although this new spin on free market regulation seems like the ideal solution, in practice it is highly unlikely to result in any meaningful reforms. First, it is doubtful that a critical mass of medical residents will ever become unionized. Unlike steelworkers or teachers, no individuals are medical residents

133. *See supra* Section II.B (summarizing the shift from the laissez-faire system to state regulation).

134. *See supra* Sections II.B-C (explaining why the government and other stakeholders will no longer tolerate a lack of regulation).

135. *See* Jason van Steenburgh, *Under Pressure, Medicine Revisits Resident Work Hours*, ACP-ASIM OBSERVER, Mar. 2002, *available at* http://www.acponline.org/journals/news/mar02/resident.htm (stating that some organizations have attempted to work with residents to negotiate working conditions directly with hospitals).

136. Ludmerer & Johns, *supra* note 49, at 1084.

137. *Id.*

138. 330 N.L.R.B. 152 (1999).

for their entire professional lives; all medical school students applying for resident positions know that their residencies are temporary positions that will only last for a certain number of years before they can move on to more lucrative opportunities of their own choosing. As a result, there is little incentive for medical residents to organize, particularly when the residents leading the organizing effort are unlikely to reap the benefits of unionization themselves, since the union recognition and collective bargaining process can take years.[139]

While some might argue that the temporary nature of teaching assistant positions has not prevented graduate students from pursuing unionization, the situations are not analogous. Medical resident salaries are virtually identical from program to program, and other points of contention, such as work hours, do not vary much among programs within a given specialty.[140] Since medical residents at a given program or hospital are unlikely to believe they are worse off relative to their peers elsewhere,[141] there is substantially less need for a union. The fact that only a small handful of medical residents have even attempted to unionize since the 1999 NLRB decision casts further doubt on this theory.[142]

Furthermore, the free market would be unlikely to create meaningful changes even if there were widespread demand among medical residents for unionization. The very high incidence of non-compliance with New York State's medical resident regulations as late as the 1990s shows that hospitals are not above ignoring laws if the benefits of non-compliance are significantly higher than the costs of compliance. Although American labor law provides certain protections to workers who are trying to organize, the procedure and remedies for enforcing these protections under the National Labor Relations Act (NLRA) are extremely weak. The process involves first filing a complaint with an NLRB office claiming the statute was violated, waiting for that office to investigate the allegation and issue a complaint, and then bringing a case before an

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139. Guaranteeing Employee Free Choice Through Democratic "Card-Check" Procedures, http://www.wslc.org/photos/temp/EFCA-cardcheck.doc (last visited Dec. 9, 2006).

140. PRIMER, *supra* note 35, at 6, 13; Neil A. Lewis, *Medical Establishment Turns to Powerful Allies To Thwart Residents' Lawsuit*, N.Y. TIMES, Aug. 18, 2003, at A10.

141. Studies show that an individual's psychological feelings toward issues such as pay will differ based on how other individuals he or she knows about are treated. For instance, studies have found that employees who work at organizations with two-tier wage structures, where new employees are paid less than current employees even though they perform the exact same work, are highly dissatisfied and significantly more likely to quit, since the wage differentials are viewed as very unfair. *See* JERALD GREENBERG & ROBERT A. BARON, BEHAVIOR IN ORGANIZATIONS 147 (2000). Similarly, when individuals know that employees at other organizations are paid more money for the same work, they are also more likely to feel resentful and take action to end the perceived inequality. *Id.*

142. Am. Ass'n of Med. Colls., Resident Unionization, *supra* note 111.

administrative law judge who may make non-binding recommendations. If the parties disagree, the matter is heard by the five members of the NLRB, which, while having the power to make an actual decision, does not have the power to compel either party to comply it.[143] For an NLRB decision to have binding impact on the parties, it must be affirmed by a U.S. Circuit Court of Appeals. This is an extremely long process, and it is certainly not uncommon for many years, and in some cases even decades, to pass from the time the unfair labor practice took place to the time an appellate court renders a binding decision.[144] Furthermore, even if the appellate court affirms a decision against the employer, the employee can only receive back pay (or reinstatement) as compensation and never punitive damages.[145] Given that widespread medical resident unionization has the potential to cost hospitals millions, and given that few residents would have the resources or desire to commence litigation that has the potential to last longer than their entire residency program, it is highly unlikely that a meaningful number of medical resident unions would ever get certified even if most residents wanted to unionize. Barring radical changes in American labor law, free market regulation with resident union input is unlikely to happen.

It is also incorrect to assume that medical resident unions would properly handle the patient safety externality. Residents and patients do not share the same interests. A medical resident union, like other unions, would view furthering its own members' interests as its primary goal. In this case, furthering member interests would likely involve improving resident quality of life and enhancing the educational value of residency programs; if one believes these should be the primary goals of resident work hour regulation, resident unionization may be an acceptable solution. However, if increasing patient safety takes precedence over those other goals, the misalignment of patient and resident interests would make unionization an ineffective means of achieving this greater goal.

While some may argue that furthering some resident goals may also further the interests of patients, there is no guarantee that this would actually transpire. For example, rather than demanding fewer hours through the elimination of "scut work," a medical resident union might ask that total work hours remain the same, but conferences and other educational activities replace hours that were previously used to perform ancillary functions. Alternatively, residents might not ask for changes in working conditions at all, and just negotiate for large salary increases, so that residents are paid on par with physician assistants, nurse practitioners, and other hospital personnel who perform some of the same duties as residents.

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143. *See generally* ROBERT J. RABIN et al., LABOR AND EMPLOYMENT LAW at ch.2 (3d ed. 2002).

144. *Id.*

145. *Id.*

Although fewer hours will likely increase a resident's quality of life, residents may not want to work fewer hours. Residents enroll in residency programs in order to obtain training in a specialty; a decrease in total work hours, even if geared toward reducing "scut work" hours, could conceivably result in residents obtaining less training than under a system where work hours are not restricted. Residents may fear that residency programs might become extended to make up for this difference.[146] Since residents must already go through four years of college and an additional four years of medical school as well as their relatively low-paying residency before they can obtain higher paying jobs, many residents may not accept a higher quality of life during residency if it means delaying entry into lucrative jobs by one or two more years.

Even if residents did successfully negotiate fewer hours, there is no guarantee that residents would use this extra time to get more sleep. One study, for instance, found that residents given "protected time," during which they were not on call, did not use their free time to sleep, but instead to engage in other activities. In fact, they averaged the same amount of sleep as residents who did not have the extra free time.[147] Thus, while fewer hours may result in higher resident quality of life, they may not further the objective of patient safety if residents do not use their additional free time to get more rest.

B. Public Decentralized Regulation

New York State experimented with public decentralized regulation of residency programs starting in 1989, when it implemented the Bell Regulations.[148] Originally, many individuals believed other states would join New York in passing their own resident work hour regulations. Those favoring state regulation argued that, as Justice Brandeis observed in his famous dissent in *New State Ice Co. v. Liebmann*,[149] each individual state would "serve as a laboratory" and "try novel social and economic experiments without risk to the rest of the country."[150] Of course, this did not take place: Other states did not create their own version of the Bell Regulations,[151] and New York itself did a

146. *See, e.g.*, Croasdale, *supra* note 57 ("One [resident] is convinced that the [ACGME work hour] rules eventually will mean an extension in the length of training programs because studies show that the more procedures performed the better the doctor becomes at them.").

147. G.S. Richardson et al., *Objective Assessment of Sleep and Alertness in Medical House Staff and the Impact of Protected Time for Sleep*, 19 SLEEP 718 (1996).

148. Colburn, *supra* note 76.

149. 285 U.S. 262 (1932).

150. *Id.* at 311.

151. Boodman, *supra* note 53.

very poor job enforcing them.[152]

One should not interpret the failure of public decentralized regulation as a sign that it is not possible to experiment with novel approaches to resident work hour regulation. While public decentralized regulation suffers from several key flaws, these problems are not due to decentralization. Rather, the problems that prevented the success of public decentralized regulation stem from the government's involvement in both implementing and enforcing the regulations.

State governments are made up of politicians; as much as we might wish for elected officials not to consider politics when setting legislative priorities, in reality, politicians simply cannot afford not to take political considerations into account when deciding what bills they should support. Many people consider health care in general as a high priority and demand that politicians improve both state and national health care services; however, some health care issues are considered significantly more important than others. While many voters care about issues such as affordable health insurance, few voters may even be aware that long resident work hours may compromise patient safety.

Although few voters consider resident work hour regulation a major issue, doctors and medical organizations have very strong opinions on the issue, and are willing to express their opinions. For example, California's attempt at regulating resident work hours was defeated due to opposition from the California Medical Association and the California Association of Hospitals and Health Systems.[153] Given the strength of the medical profession's lobbying abilities, the traditional deference given to professional organizations, and the fact that voters generally do not see this as a high priority issue, it is not surprising that politicians have largely been unwilling to push for state regulation of resident work hours.

Some would argue that this problem is not insurmountable; for instance, resident work hour regulations were implemented in New York State. However, one must examine what caused New York to implement these regulations. Clearly, media coverage of the Libby Zion incident increased public awareness of the resident fatigue problem[154] and caused the public to demand action. But what is it about the Libby Zion incident that attracted so much media attention? Libby Zion was not the first New Yorker to die due to a mistake made by a medical resident, nor was she the last. Although Libby, as an eighteen-year-old college freshman, appears a sympathetic victim, other sympathetic individuals have died under similar circumstances in other states. For instance, Taylor McCormack, a thirteen-month-old baby, died in 2000 when residents at Boston's

152. Ronches, *supra* note 82.

153. Japenga, *supra* note 81.

154. In this Note, the terms "resident fatigue problem" and "sleepy resident problem" are used interchangeably.

Children's Hospital mistakenly placed her in a non-intensive-care room and postponed her surgery;[155] the year before, William Katcher, a twenty-two-week-old baby, almost died at the same hospital due to residents failing to provide a breathing tube.[156]

Despite these shocking incidents, there was no public outcry for Massachusetts to implement resident work hour limits as there had been in New York after Libby Zion's death.[157] One needs to consider the differences between these victims. Libby Zion's father, Sidney Zion, was a well-connected lawyer and journalist.[158] Through his connections, Sidney Zion was able to draw substantial media attention to his daughter's death that otherwise would not have existed. In contrast, the families of William Katcher and Taylor McCormack were not as well connected, and therefore they did not receive the extensive media coverage or the criminal investigations that might have generated the public outcry necessary to push a bill through the Massachusetts legislature. One must acknowledge, therefore, that the New York situation was truly unique, and that it is not likely that similar situations will manifest themselves in a significant number of other states.

However, even Sidney Zion was not able to keep resident fatigue and patient safety in the headlines forever. Just as politicians do not possess an unlimited amount of political capital, government agencies do not possess unlimited budgets, and they must make trade-offs when deciding how to spend their money. As Libby Zion faded away and resident work hours moved out of the public's consciousness, New York's Department of Health, facing substantial budget cuts, no longer viewed enforcement of its resident work hour regulations as a high priority,[159] and, with the exception of New York City Public Advocate Mark Green, elected officials saw no need to remedy the situation.[160]

Furthermore, government officials do not possess the same expertise and knowledge of the health care industry as do doctors and other medical professionals. Elected officials, even if well intentioned, are at a higher risk of

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155. Anne Barnard, *Teaching Hospitals' Dilemma: Instruction vs. Care for Harried Residents, Duties Not Clear-Cut*, BOSTON GLOBE, Aug. 10, 2001, at B1.

156. *Id.*

157. Although these incidents received some media coverage, it paled in comparison to coverage of Libby Zion's death, and this limited amount of media attention did not lead to state regulation of resident work hours in Massachusetts. Abel, *supra* note 104.

158. Horowitz, *supra* note 66.

159. *See supra* Sub-section II.B.2 (discussing New York's inability to enforce its regulations).

160. *See* Horowitz, *supra* note 66 ("However, in 1997, then-public advocate Mark Green released a report that exposed the defiance on the part of the hospitals and embarrassed the state Health Department. Since then, the state has cracked down with serious financial penalties for hospitals that don't comply.").

instituting regulations that do little or nothing to solve the underlying problem than educated professionals who have a better understanding of the industry and its operations.[161]

C. Private Centralized Regulation

Private centralized regulation involves regulation by a non-governmental entity whose regulations have a national reach. Since July 2003, resident work hours have been regulated by the ACGME, a private centralized regulating entity. Unlike New York State, the ACGME has not had difficulty enforcing its regulations. As a private organization whose sole purpose is to evaluate and accredit residency programs, the ACGME has not had to make tradeoffs between enforcing its work hour regulations and other functions. Unlike a state Department of Health or other governmental entity, the ACGME's functions are highly interrelated and enforcing work hour regulations would not take a significant amount of time or money away from its other duties;[162] thus, entrusting the ACGME with resident work hour regulation duties would naturally result in more efficient outcomes.[163]

1. Implementation and Enforcement

The ACGME work hour regulations met with significant skepticism.[164] As a private organization, the ACGME lacks many of the attributes of government entities. Most notably, the ACGME does not have access to taxpayer money. Although New York State's $55 million a year subsidy could cover only a fraction of the costs of compliance with its work hour regulations, the ACGME

161. Of course, this does not mean that private organizations are not also at risk of instituting bad regulations. *See supra* Section II.C (discussing the problems with the ACGME work hour regulations).

162. There are many parallels between the ACGME's primary role of assessing the quality of residency programs and its secondary role of enforcing work hour regulations. For example, since the ACGME already routinely conducts more than 1900 site visits every year to ensure compliance with its other regulations, it should pose no hardship for the ACGME to measure compliance to its work hour regulations during these visits. *See* Accreditation Council for Graduate Med. Educ., The Role of the ACGME, http://www.acgme.org/acWebsite/about/ab_roleACGME.asp (last visited Dec. 9, 2006) (discussing the role of the ACGME).

163. Of course, if state governments took over the ACGME's accreditation function in addition to regulating work hours, they could also benefit from this; however, all the other problems of public decentralized regulation discussed earlier would still apply.

164. *See, e.g.*, Hall, *supra* note 51 ("Out on the hospital floor, however, many physicians in training said they doubt much will change, citing a hoary tradition of absurd hours for novice doctors as well as their own shockingly low salaries.").

regulations were a true unfunded mandate. Even if it wanted to, the ACGME could not cover the full costs of hospital compliance with its regulations. Therefore, some speculated that hospitals would ignore the ACGME regulations much as they did the New York regulations.[165]

While some residency programs did initially fail to comply with the ACGME regulations, the overwhelming majority of programs did comply, even without funding to make up the differentials.[166] Unlike New York State, the ACGME was able to make the potential costs of non-compliance significantly greater than the benefits: The ACGME stated that failure to comply with the ACGME work hour regulations could result in the ACGME withdrawing or temporarily suspending a residency program's accreditation.[167]

The loss of ACGME accreditation has far greater consequences than a $2000 fine. If a residency program loses ACGME accreditation, its graduates are not eligible to take the examinations required to become certified in their specialty.[168] In addition, many federal government subsidies of residency programs are directly tied to ACGME accreditation. For example, programs that do not have ACGME accreditation are not eligible for Medicare funds that are earmarked for support of graduate medical education.[169] Such subsidies are substantial: In 1998, Medicare contributed almost $6.7 billion to teaching hospitals to help with the growing costs of training physicians.[170] Thus, while hospitals might find it burdensome to spend up to $5 million a year to comply with the ACGME's work hour restrictions, the costs of compliance are significantly lower than the costs of non-compliance, which gives hospitals a very strong incentive to comply.[171]

Furthermore, the ACGME made it clear very early in the process that the loss of accreditation was not an idle threat. The ACGME, after receiving a report in 2002 that Yale-New Haven Hospital's general surgery residency program was

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165. *See, e.g.*, Romano, *supra* note 129 (stating that the ACGME regulations are "inadequate" and do not force public disclosure for violations).

166. *Tracking Residency Work-Hour Violations*, Am. Med. News, Dec. 5, 2005, *available at* www.ama-assn.org/amednews/2005/12/05/prca1205.htm [hereinafter *Violations*].

167. Accreditation Council for Graduate Med. Educ., ACGME Duty Hours Standards Fact Sheet, http://www.acgme.org/acWebsite/newsRoom/ACGMEdutyHoursfactsheet.pdf (last visited Oct. 17, 2006).

168. *Id.*

169. *Id.*

170. PRIMER, *supra* note 35, at 14-15.

171. Dr. David Leach, Executive Director of the ACGME, has stated that "[d]uty hours are being met" because "[t]he financial incentives are too heavy to risk having your accreditation withdrawn." Myrle Croasdale, *Resident Work-Hour Limits Still a Struggle One Year into Restrictions*, AM. MED. NEWS, July 19, 2004, *available at* http://www.ama-assn.org/amednews/2004/07/19/prl10719.htm.

requiring its residents to work more than 100 hours per week, immediately stated that it would withdraw the program's accreditation if it did not comply with new ACGME requirements by July 2003.[172] One week after the work hour requirements went into effect, the ACGME stated that it intended to withdraw accreditation of Johns Hopkins Hospital's internal medicine program, effective July 2004, due to violations.[173]

The ACGME, unlike New York, has also shown no signs of reducing enforcement. During the 2004-05 academic year, the ACGME reviewed 2002 of the 8037 ACGME-accredited residency programs for violations.[174] Of these programs, it cited only 147 for duty-hour violations. In other words, 92.7% surveyed programs were in compliance with the ACGME regulations.[175]

2. Problems with Private Centralized Regulation

At first glance, one may think that ACGME regulation has been highly successful. After all, in just two years the ACGME has managed to get more than ninety-two percent of residency programs to comply with its work hour regulations, without the need for legislation or substantial government aid.[176] However, a closer examination of ACGME regulation shows several disadvantages to entrusting the ACGME with this responsibility.

Perhaps the most serious problem with the ACGME as a regulator is that it has imposed a one-size-fits-all set of regulations on all residency programs without determining whether its regulations can further the underlying goal of improving patient safety. The ACGME, by forcing residency programs nationwide to implement the ACGME regulations, has made individual residency programs unable to experiment with alternate methods of improving patient safety. Of course, the inability of residency programs to experiment with alternate methods would not be considered a major loss if there were a universal consensus that the ACGME's regulations were the best solution to the sleepy resident problem. However, such a consensus does not exist; in fact, a substantial portion of the medical community believes that the ACGME regulations may actually work against the goal of improving patient safety.

Some hospitals have responded to the ACGME work hour limits by creating

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172. Adam Mehes, *Med School Program Reaccredited*, YALE DAILY NEWS, Oct. 30, 2002, *available at* http://www.yaledailynews.com/article.asp?AID=20458.

173. Patrick Gilbert & Mary Ellen Miller, *Out of Time*, HOPKINS MED., Winter 2004, *available at* http://www.hopkinsmedicine.org/hmn/W04/top.cfm.

174. *Violations*, *supra* note 166.

175. *Id.*

176. *See Violations*, *supra* note 166 (discussing the relatively low rate of non-compliance with the ACGME regulations).

two shifts – a day shift and a night shift – and hiring additional physicians to make up the difference. Brigham and Women's Hospital in Boston, for instance, responded to the change by hiring an additional thirty doctors to cover the night shift.[177] Many doctors, however, argue that having different doctors cover different shifts will endanger patient safety by impairing continuity of care. The chief surgeon of Massachusetts General Hospital stated that having different teams is a bad idea because night shift doctors would not be as familiar with patients admitted in the day shift, and vice versa.[178] Such lack of familiarity may lead to doctors making poor decisions; the chair of Boston Medical Center's orthopedic surgery department also observed several "poor patient care decisions and outcomes resulting from the on-call doctor not giving a good handoff, which is a symptom of the 80-hour rule."[179] Another doctor found significant continuity of care problems at her hospital. In fact, she and other attending physicians have had to devote a substantial amount of additional time reviewing x-ray findings, intake and output records, and other patient information because residents are rarely able to complete these important tasks when forced to sign out.[180] Despite attempts to mitigate the problem, this doctor has still observed a significant decline in patient safety at her hospital. After all, "[h]ow can a housestaff team be expected to determine whether cellulitis is improving or worsening if the same individual does not examine the patient on consecutive days?"[181]

Such concerns from physicians are not uncommon. In fact, a national survey of neurosurgery programs conducted by the Mayo Clinic found that ninety-three percent of residency program directors and residents themselves felt that the ACGME's work hour limits hurt continuity of patient care.[182] A survey of ob-gyn residents conducted after the regulations went into effect found similar results. Most ob-gyn residents viewed the hour limits as problematic due to loss of continuity, and some were concerned that they would miss the deliveries of patients they were following due to the eighty-hour limit.[183]

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177. Anne Barnard & Liz Kowalczyk, *Medical Resident Workload Curbed Big Impact Seen on Hub Hospitals*, BOSTON GLOBE, June 13, 2002, at A1.

178. *Id.*

179. Croasdale, *supra* note 57.

180. Amy L. Friedman, *Letter to the Editor: Resident Work Hour Limits Are Compromising Patient Safety*, AM. MED. NEWS, Aug. 4, 2003, *available at* http://www.ama-assn.org/amednews/2003/12t03.htm (follow "Resident Work Hour Limits Are Compromising Patient Safety" hyperlink) (password protected).

181. *Id.*

182. Myrle Croasdale, *The 80-Hour Experience: What Happens When Residents Have To Leave*, AM. MED. NEWS, July 25, 2005, *available at* http://www.ama-assn.org/amednews/2005/07/25/prsa0725.htm.

183. Myrle Croasdale, *Medical Residents Give Thumbs-Up to 80-Hour Limit*, AM. MED. NEWS,

Poor care decisions due to lack of continuity, however, are not the only patient safety concern associated with the ACGME regulations. While the ACGME limits have reduced the number of hours worked by medical residents, these limits have caused attending physicians to work longer hours to make up part of the difference. As one doctor put it, "[t]he work has to be done, and it's falling on the older physicians."[184] This same doctor observes that it is now not uncommon for her to be on call for up to forty hours at a time.[185] In addition to spending more hours on call, attending physicians have to spend more time in educational conferences with residents, but as a result of the ACGME limits, it is not uncommon for some residents not to attend conferences about particular patients, since attending the conference would violate the ACGME regulations.[186] Furthermore, in order to minimize the risks to patient safety due to lack of continuity of care, some attending physicians must spend hours collecting, rather than just reviewing, patient records, since residents rarely perform these functions before turning over patients to another shift.[187] In fact, the work hour limits have caused the morning rounds of some attending physicians to last thirty to fifty percent longer than in the past, forcing these physicians either to work significantly longer hours or to see fewer patients.[188] If fatigue and sleep loss increase the chance of medical errors, reducing resident fatigue while increasing attending physician fatigue may not improve patient safety.

However, there remains considerable doubt within the medical community as to whether limits on resident work hours actually reduce resident fatigue. The belief that work hour limits will translate into better rested residents relies on the assumption that residents, when given additional free time, will use that free time to sleep.[189] Although the ACGME has taken this assumption for granted, studies have shown that this assumption is not as safe as one might think. One study, for example, found that decreasing work hours for one group of residents did not cause that group to sleep longer hours than another group of residents who continued to work the same schedule.[190] An additional study found that surgical

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Sept. 12, 2005, *available at* http://www.ama-assn.org/amednews/2005/09/12/prsb0912.htm.

184. Myrle Croasdale, *Resident Hour Limits May Hit Attendings*, AM. MED. NEWS, July 7, 2003, *available at* http://www.ama-assn.org/amednews/2003/07/07/prsf0707.htm (quoting neonatologist Dr. Rajam Ramamurthy).

185. *Id.*

186. *Id.*

187. Friedman, *supra* note 180.

188. *Id.*

189. *See, e.g.*, Am. Med. Student Ass'n, Principles Regarding Resident and Student Work Hours, http://www.amsa.org/about/ppp/rwh.cfm (last visited Oct. 17, 2006) (making a connection between fewer working hours and reduced fatigue and sleepiness).

190. Richardson, *supra* note 147.

residents averaged the same amount of sleep per week regardless of whether they were on an every-other-night, every-third-night, or every-fourth-night on call schedule.[191] In fact, no study has found that work reductions cause sleep increases in residents.[192]

Other studies examining the indirect relationship between hours worked and patient care have not found a positive relationship between the two. For example, a 1991 study found that while work hour restrictions improved resident perceptions of their quality of life, there was no improvement in perceived patient care or resident examination scores.[193] In fact, two studies – one conducted in 1998[194] and the other in 2002[195] – found that work hour reductions resulted in a perceived decrease in the quality of patient care, even though resident quality of life increased. Another study, which examined objective changes in patient care quality rather than perceived changes, found that work hour restrictions resulted in a greater number of complications and delayed test orderings by residents.[196]

Some may wonder why the ACGME implemented work hour regulations despite the lack of a consensus that work hour limits actually improve the quality of patient care. As discussed earlier, the threat of federal legislation played a major role in the ACGME's decision to tie work hour limits to program accreditation; rather than cede regulatory power to the federal government, the ACGME instituted its own regulations in order to lessen the need for governmental intervention and preserve its power.[197] Given these circumstances, it is not surprising that, despite some differences, the ACGME regulations largely paralleled the proposed federal legislation.[198]

What is cause for concern, however, is the ACGME's inflexibility toward its regulations even after it became fairly certain that the government would not pass federal resident work hour legislation. The ACGME has not publicly announced that it will reexamine the efficacy of its regulations. In an article discussing the

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191. R.G. Sawyer et al., *Intern Call Schedules and Their Relationship to Sleep, Operating Room Participation, Stress, and Satisfaction*, 126 SURGERY 337 (1999).

192. Sigrid Veasey et al., *Sleep Loss and Fatigue in Residency Training*, 288 JAMA 1116, 1122 (2002).

193. Kelly, *supra* note 24.

194. Conigliaro, *supra* note 23.

195. C.B. Barden et al., *Effects of Limited Work Hours on Surgical Training*, 195 J. AM. C. SURGEONS 531 (2002).

196. Laine Christine et al., *The Impact of a Regulation Restricting Medical House Staff Working Hours on the Quality of Patient Care*, 269 JAMA 374 (1993).

197. *See supra* Sub-section II.C.2 (discussing why the ACGME decided to implement its regulations).

198. *Id.*

state of graduate medical education, Kenneth Ludmerer and Michael Johns expressed their displeasure with the ACGME's handling of its work hour regulations: "[W]e find it disturbing that, without good evidence or outcome data, major regulations have been implemented that are contrary to the best judgment of many educators."[199]

Several program directors feel that such inflexibility and overall lack of concern for educator input signifies an inherent problem with the ACGME. One such director believes that "[t]he ACGME has no idea what life as a patient or resident is like today, and I am frightened by what we are now turning out."[200] While the ACGME has spent years evaluating the quality of residency programs, some feel that the ACGME has done a poor job evaluating its own performance, with the rapid implementation of its work hour limits and its unwillingness to consider other possibilities the result of a larger problem of poor internal self evaluation and little accountability to other organizations.[201] Though some have recommended that the ACGME conduct a thorough internal review and submit to a peer review by an external commission, the ACGME has not taken such steps.[202] Since the ACGME possesses a monopoly over graduate medical education accreditation, it has little or no incentive to improve itself, and individual residency programs have no choice but to submit to whatever policies the ACGME wishes to impose on them.

D. Public Centralized Regulation

Because the U.S. government has never instituted public centralized regulation of resident working conditions, it is not possible to point to examples of real world successes or failures.[203] However, one can engage in informed speculation about the results of public centralized regulation by examining the pros and cons of public control as well as centralized control, drawing from experiences with both state regulation and ACGME regulation.

As with centralized ACGME regulation, federal legislation would impose a single standard on all residency programs, and thus prevent any experimentation.[204] However, like public entities such as state governments, the federal government consists of politicians who must make tradeoffs among

199. Ludmerer & Johns, *supra* note 49, at 1086.

200. *Id.*

201. *Id.*

202. *Id.*

203. Although several European countries have passed national legislation limiting resident work hours, the inherent differences between graduate medical education in Europe and in the United States makes comparisons between the two difficult.

204. *See supra* Section III.B (discussing the benefits of experimentation).

differing political priorities, as well as administrative and regulatory agencies that have multiple mandates and limited budgets.[205] It is likely, then, that federal intervention would involve the government creating mandatory work hour limits over the objections of educators, but then not properly enforcing those limits due to a lack of political will or financial resources, as in New York; however, the legislation's national reach would have a chilling effect and prevent experimentation with other regulatory systems. Furthermore, the nature of the national political process would make amending poorly conceived regulations a longer and more difficult process. Therefore, it seems likely that public centralized regulation would bring about a "worst of both worlds" scenario. While society would suffer all the disadvantages of ACGME regulation and state government regulation, it would reap the benefits of neither.

This does not mean that the federal government has no role to play in graduate medical education. The federal government has greatly improved the quality of graduate medical education by providing billions of dollars in subsidies to teaching hospitals.[206] Furthermore, the federal government may still pass legislation that enhances the strength of regulations implemented by other regulating bodies. For instance, many have believed that both the New York State regulations and the ACGME regulations lack adequate whistleblower protections for those who report violations.[207] If such protections are non-existent or inadequate, the federal government would likely not cause substantial harm by extending federal whistleblower protection legislation to medical residents. Similarly, the federal government may require accreditors to publicly disclose the names of hospitals that have violated the accreditor's work hour regulations.[208]

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205. *See supra* Section II.B (discussing the disadvantages of entrusting governments and government agencies with regulatory responsibilities).

206. PRIMER, *supra* note 35, at 14-16.

207. The American Medical Student Association believes that the lack of whistleblower protection for residents who report suspected violations of the ACGME regulations may prevent many residents from coming forward, out of a fear that their superiors would retaliate against them by singling them out and providing poor letters of recommendation. Press Release, Am. Med. Student Ass'n, Medical Students Mark Historic Work Hours Reform with Call for Whistleblower Protection, Public Accountability (June 30, 2003), *available at* http://www.amsa.org/news/release2.cfm?id=146.

208. Currently the ACGME is not required to publicly disclose the identities of hospitals that have violated its resident work hour guidelines. The American Medical Student Association believes that federal legislation is necessary to force the ACGME to make these disclosures. Am. Med. Student Ass'n, Frequently Asked Questions About Resident Work Hour Reform, http://www.amsa.org/rwh/faq.cfm (last visited Oct. 17, 2006).

IV. THE CASE FOR PRIVATE DECENTRALIZED REGULATION

Neither the free market approach nor any of the three regulatory schemes most frequently discussed by researchers seem ideal; while most possess at least one benefit over the others, all have at least one prominent cost that the others do not share. The free market, while allowing for experimentation, fails to internalize the externality of patient safety. While private centralized regulation internalizes this, it fails to allow for experimentation. State government regulation, while also allowing for experimentation, results in significant resource and enforcement problems that have little impact on patient safety. Lastly, federal government regulation would both prohibit experimentation and have no positive impact on patient safety, thus resulting in a significant cost without a corresponding benefit.

Given that a regulatory method should be adopted even if it is not ideal, most academics and practitioners who have taken a position on this issue have advocated for a particular regulatory method not because it will solve the underlying problems, but because other regulatory methods are comparatively weaker.[209] This least-of-three-evils approach is appropriate if one considers only three choices that are known to be imperfect. However, there is no reason to limit this debate to only three regulatory choices. This Section argues that a fourth regulatory scheme exists that possesses the major benefits of the other schemes without suffering from their disadvantages: private decentralized regulation.

A. What is Private Decentralized Regulation?

Private decentralized regulation combines the private sector oversight found in private centralized (ACGME) regulation with the diversity of regulating bodies found in public decentralized (state government) regulation. Rather than permitting the ACGME monopoly over graduate medical education accreditation to continue, the U.S. government would disperse accreditation responsibilities to five or six separate private organizations operated by medical professionals. Each accreditor would maintain a monopoly over accrediting residency programs in a particular geographic region; in other words, residency programs would not have the option of "accreditor shopping."

209. *See, e.g.*, Evans, *supra* note 46; Whetsell, *supra* note 47.

B. Evaluating Private Decentralized Regulation

1. The Benefits of Private Decentralized Regulation

Private decentralized regulation would ideally combine the benefits of public decentralized regulation with the benefits of private centralized regulation without incurring the costs of either system. Each new accreditor, like the ACGME, would remain a private entity whose primary purpose would involve evaluating the educational quality of residency programs. These accreditors would enforce their resident regulations just as the ACGME has been able to successfully enforce its regulations without much difficulty.[210] Since site visits are already a part of an accreditor's responsibilities, these new accreditors would regularly visit hospitals and investigate violations just as the ACGME has been able to for the past two years. Because these accreditors serve narrow purposes and are privately funded, there is no danger that these organizations would cease enforcement because of budget cuts or a change in the political climate.

However, because accreditors would possess regional monopolies, rather than national monopolies, innovation and experimentation would take place. As discussed earlier, the medical profession has not yet reached a consensus on the resident work hour issue, with as many as ninety-three percent of neurosurgery residency program directors and residents believing that the current ACGME guidelines hurt continuity of care.[211] Furthermore, those who find fault with the ACGME guidelines are unsatisfied with the regulations for different reasons, and they disagree as to the optimal solution to the sleepy resident problem.[212] Given the extent of diversity of opinion on the issue, it is likely that medical professionals serving on the boards of five or six different graduate medical education accreditors would devise five or six different regulatory schemes. For example, one accreditor may institute a blanket eighty-hour work limit, a la the ACGME; another accreditor might not institute hour limits at all, but mandate that residents obtain a certain amount of rest before performing certain tasks, or require residents to sleep a certain number of total hours per week; still another accreditor may use a combination of work limits and mandated sleep, while yet another might acknowledge differences between specialties and have separate requirements based on specialty.

Through such experimentation, at least one regulatory system should present itself as clearly superior to the others. Once empirical evidence reveals a superior system, other accreditors will alter their regulations in order to adopt it. Doctors

210. *Violations*, *supra* note 166.

211. Croasdale, *supra* note 182.

212. *See supra* Section III.C (discussing the faults with private centralized regulation).

and hospital administrators value empirical evidence.[213] Although culture accounts for part of the opposition to work hour limits,[214] most residency program directors have opposed the ACGME work hour limits due to the lack of evidence demonstrating a causal connection between lower work hours and higher patient safety.[215] If empirical evidence were to show a strong relationship between fewer medical errors and a certain method of regulating resident work conditions – whether it be limiting hours, or mandating certain rest periods, or some other practice – program directors would likely support the change.[216] However, attitudes will not change without evidence,[217] and evidence will not manifest itself without experimentation. As long as the ACGME subjects residency programs nationwide to the same regulations, such experimentation will not take place, and neither the ACGME, program directors, nor society will know whether the current regulatory system is truly the best way to further the goal of patient safety.

2. The Costs of Private Decentralized Regulation

Some might argue that private decentralized regulation may raise concerns about equity. By subjecting residents in different geographic regions to different working conditions, with the knowledge that some working conditions are likely more conducive to patient safety than others, patients in some geographic areas may face a greater risk of being harmed by a resident's medical error than patients in other regions. This is certainly a possibility; however, one must remember that such tradeoffs always exist when making policy changes. Currently, very little evidence exists that there is a relationship between hours worked and patient safety. Not only has no study shown that residents will use their additional free time to sleep, but multiple studies have also demonstrated that work hour limits actually put patients in more danger due to impaired continuity of care and other factors.[218]

While some may find it psychologically pleasing to know that there are uniform national standards in place, the existence of such standards does not mean that the standards are ideal, nor does it mean that abandoning the standards would cause more harm either in the short term or the long term. If further experimentation through private decentralized regulation were to show that

213. Trowbridge & Wachter, *supra* note 101.

214. *See* Groopman, *supra* note 55; Pelton, *supra* note 52.

215. Ludmerer & Johns, *supra* note 49, at 1086.

216. *Id.*

217. Trowbridge & Wachter, *supra* note 101.

218. *See supra* Sub-section III.C.2 (explaining why some physicians oppose the ACGME regulations).

limiting residents to eighty hours of work per week is the ideal regulatory system, then yes, the shift to private decentralized regulation would have caused a net harm, for some people in the country would have experienced increased harm while others would have retained their current safety levels. However, if experimentation proved that an eighty-hour work limit not only is not the best solution, but also that it is actually harmful to patient care, then the switch to private decentralized regulation would have made many people better off while making no one worse off than they were under the ACGME regulations; furthermore, by discovering that the eighty-hour limit is not the best way to further the goal of patient safety, all future patients would become better off as the accreditors who had retained the eighty-hour limit regulations in their regions would change their systems. Without actually knowing the most effective way to enhance patient safety, it is not possible to measure whether switching to private decentralized regulation would incur a net cost or net benefit to society. However, given the lack of evidence showing a connection between fewer work hours and improved patient safety, it seems more likely than not that a switch to private decentralized regulation would result in a net benefit rather than a net loss.

3. Criticisms and Potential Barriers to Implementation

For a variety of reasons, some may feel that private decentralized regulation is either harmful or impractical. This Sub-section will respond to these potential criticisms.

a. Reversion to the Laissez-Faire System

One might argue that residency programs have already had decades to experiment with different systems, but chose not to, suggesting that residency program directors may not truly desire innovation. Some might believe that these directors would try to persuade the new accreditors not to enact regulations at all, and they might demand a return to the laissez-faire system, just as medical organizations have lobbied against state and federal work hour legislation.[219] Such beliefs are misguided.

While it is true that individual residency programs did not experiment with limiting resident work hours or other potential solutions to the sleepy resident problem during the laissez-faire period, one must acknowledge a fundamental difference between the role of a residency program director or hospital administrator determining policies for his or her own program or hospital and the

219. *See supra* Section III.B (explaining how medical lobbying organizations prevented California from enacting state regulations governing medical resident work hours).

same individual serving as a member of an accrediting board. Hospitals exist in a competitive environment: A single hospital or residency program has very little incentive to unilaterally deviate from the status quo when doing so would incur considerable expense and little, if any, benefit. For example, if it would cost a hospital $2 million a year to reduce the resident work week from 130 hours to 80 hours, a rational hospital administrator would not incur the expense unless enacting this change would cause the hospital to gain at least $2 million a year in other benefits, such as having to settle fewer malpractice claims due to fewer patient errors. Even if a third party, such as society as a whole, would gain benefits exceeding $2 million a year from the policy change, the hospital itself has no incentive to put itself in a worse position in order to benefit society. By implementing a policy change where the costs are greater than the benefits, the hospital would put itself in a worse position relative to its peer hospitals, who, as rational actors, would not have adopted such policies.

The same individual, however, in his or her capacity as a member of a regulatory board, would likely act differently. While an individual hospital has little or no incentive to unilaterally put itself in a worse position to benefit society, all hospitals in a given region have a greater incentive to engage in such action. If an individual hospital acts unilaterally, it loses its competitive position relative to other hospitals by incurring an expense that the others do not also bear; however, this concern disappears if all hospitals in a given region make the same change and incur similar expenses.

Although medical professional organizations have lobbied against state and federal regulations, one must remember that medical professional opposition was rooted in resistance to government regulation and not a sentiment against regulation in general.[220] Physicians, as discussed earlier, are deeply suspicious of government intervention, particularly when there is a lack of evidence that such intervention is even necessary, and they prefer that health care professionals create regulations.[221] Although physicians also generally oppose the ACGME regulations, this opposition is due to the ACGME's decision to implement major regulations nationwide, without evidence that the regulations have any efficacy and against the advice of educators and informed medical professionals, which is a reflection of the ACGME's growing detachment from practitioners.[222] If the new regional accreditors pledged to obtain a significant amount of input from residency program directors and other medical educators before deciding on a set of regulations, it is doubtful that the medical community would lobby against

220. *See supra* Sub-sections III.B-C.1 (discussing why doctors opposed attempts at state and federal regulation of resident work hours).

221. *Id.*

222. Ludmerer & Johns, *supra* note 49, at 1086.

private decentralized regulation.

Furthermore, one must consider the political environment that gave rise to the ACGME regulations. As discussed earlier, the ACGME did not truly desire to regulate medical resident working hours; rather, the emerging threats of resident unionization and federal government regulation forced the ACGME to institute regulations in order to allow the health care profession to retain some semblance of control over resident working conditions.[223] This threat of external control would remain if a shift to private decentralized regulation occurred. The medical professionals serving on accrediting boards, even if they personally would rather see a return to the laissez-faire system, would understand that such a decision might motivate the federal government to pass federal work-hour legislation over the objections of those in the medical profession. Since the medical profession has demonstrated that it wishes to retain at least some control over resident work hours,[224] it is unlikely that any accreditor would refuse to regulate resident working conditions, for such a move would likely cause the federal government to take the choice out of their hands permanently.

b. Impact of Resident Preferences

Although residency programs would not be able to pick their accreditor under a private decentralized regulation system, residency program applicants would have the ability to select their residency programs on the basis of work hour regulations imposed by their accreditors.[225] Resident program applicants might rank certain programs higher than others during the "Match" process based on how they perceive certain regulatory schemes; if the most talented residents disproportionately prefer one regulatory system while "sleepy" residents gravitate toward a different system, it might become more difficult to identify the

223. *See supra* Section II.C (discussing the ACGME's motivation to regulate resident working conditions).

224. *Id.*

225. Most prospective medical residents apply to residency programs through the National Residency Matching Program (NRMP), commonly known as "The Match." Each year, approximately 16,000 U.S. medical school students and 18,000 other applicants participate in the NRMP. *See* Nat'l Residency Matching Program, About the NRMP, http://www.nrmp.org/about_nrmp/index.html (last visited Dec. 8, 2006) (discussing the NRMP's history and the size of its user base). Prospective residents use the NRMP by ranking residency programs based on their preferences; similarly, residency programs rank applicants based on their own preferences. The NRMP then uses a computerized algorithm to compare these lists and "match" applicants to programs. *See* Nat'l Residency Matching Program, How the NRMP Process Works, http://www.nrmp.org/about_nrmp/how.html (last visited Dec. 8, 2006) (explaining how the NRMP matches applicants with programs).

ideal regulatory system.

However, it is not likely that resident self selection would pose a problem. Applicants consider a wide range of factors during the matching process.[226] A program's geographic location arguably has the greatest impact; although some applicants are willing to consider residency programs in multiple geographic areas,[227] they often begin the process with at least some geographic constraints.[228] Some applicants believe that doing one's residency in the state or region one wishes to eventually practice will enhance post-residency employment prospects,[229] while other applicants, particularly women, may strongly prefer certain geographic regions for family or other reasons.[230] Applicants also place a very high value on a program's academic reputation; in fact, one recent study found that location and academic reputation were two of the five most important factors that influenced internal medicine residents to select their particular program.[231] There is no reason to believe that a critical mass of applicants would place a greater value on regulatory system than program reputation or their geographical preferences.[232]

Furthermore, accreditors could still gather enough data to identify the ideal regulatory system even if applicant self selection took place. The typical residency program lasts between three and seven years;[233] while regulatory systems may impact applicant preferences, they would not have an impact on residents who chose their residency programs before those regulatory systems were adopted. Thus, accreditors could obtain the empirical evidence they need by observing those currently enrolled in residency programs.

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226. *See generally* KENNETH V. ISERSON, ISERSON'S GETTING INTO A RESIDENCY: A GUIDE FOR MEDICAL STUDENTS (6th ed. 2003) (discussing the residency application process, including criteria applicants should consider when evaluating programs).

227. *Id.* at 244-47.

228. *See, e.g.*, Posting of Global Disrobal to http://forums.studentdoctor.net/archive/index.php/t-98718.html (Jan. 12, 2004, 16:01 EST) (stating that picking geographical locations is the first step in considering different residency programs).

229. *See, e.g.*, Posting of GreatPumpkin to http://forums.studentdoctor.net/archive/index.php/t-30879.html (June 26, 2002, 15:49 EST) (suggesting the value of doing one's residency in the region one wishes to practice).

230. *See, e.g.*, Eva M. Aagaard et al., *Factors Affecting Medical Students' Selection of an Internal Medicine Residency Program*, 97. J. NAT'L MED. ASS'N 1264, 1264 (2005) (indicating that geographic location is ranked third of the five biggest factors all applicants consider when selecting an internal medicine residency program, and that women rank location more highly than do men).

231. *Id.* at 1266.

232. For instance, there is apparently no evidence that the New York state regulations had a meaningful impact on applications to New York residency programs.

233. Reuter, *supra* note 40, at 486.

c. Creation Not Practical

Others might argue that the creation of multiple private accreditors is not practical. Since the ACGME and its previous incarnation has been the sole graduate medical education accreditor for almost three decades, multiple private accreditors may not manifest themselves if the ACGME's monopoly is broken. Such a fear is unfounded. New accreditors would not likely find it difficult to finance their creation and continued existence. Most accreditors, including the ACGME, receive much of their funding from the accreditation fees they charge the programs they accredit. Since each accreditor would have a monopoly over graduate medical education accreditation in its region and would not have to worry about losing programs to competing accreditors, these accreditors would receive a substantial amount of guaranteed funding each year that would cover their operating costs.[234]

Perhaps the most serious barrier to private decentralized regulation would be opposition from the ACGME, which would lobby to retain its power. It is difficult to speculate as to how one could overcome this political barrier; one possibility might involve allowing the ACGME to retain a role as an umbrella organization of graduate medical education accreditors, much as the Council for Higher Education Accreditation (CHEA) serves as an umbrella organization for college and university accreditors.[235]

d. Alternate Solutions

Some may believe that solutions other than private decentralized regulation could improve the medical resident regulatory situation. For instance, one might propose that the federal government create several government-controlled and funded boards that would determine resident regulation policies within a given region. This system would not only preserve regional experimentation, but also minimize the role of state politics in the regulation process. In other words, public opinion, state medical organization lobbying, and the political considerations of state elected officials would not prevent regulations from being implemented, as they have in the past.[236] However, such a system would not

234. If funding does not exist to cover an accreditor's initial start-up costs, the federal government may provide a short term loan to cover such early expenses.

235. For more information about CHEA, see Council for Higher Educ. Accreditation, CHEA Home Page, http://www.chea.org (last visited Oct. 17, 2006) (providing a general overview of CHEA and its functions).

236. As discussed earlier, several states have failed to pass legislation limiting resident work hours due to such factors. *See* Boodman, *supra* note 53; Japenga, *supra* note 81 (discussing state regulatory attempts in New York and elsewhere).

possess any practical benefits over private decentralized regulation, while still retaining some of the disadvantages inherent to public entities. These boards, as an extension of the federal government, would still face the possibility of having their effectiveness limited due to the political process; for example, the boards would remain susceptible to budget cuts. Furthermore, unless these boards would also assume the ACGME's accreditation function, such a split would become economically inefficient, since both the ACGME and these boards would spend a substantial amount of time and money conducting separate site visits of residency programs. After all, the fact that the ACGME already conducts many site visits as part of its normal duties is one of the primary reasons it has been able to enforce its regulations so well relative to the state of New York.

Of course, this raises another alternate solution: Why not simply reform the ACGME from within? For instance, if the problem with the ACGME regulations is that they do not allow for experimentation, why not lobby the ACGME to create multiple alternative sets of regulations that hospitals can choose to implement at their own discretion? Unfortunately, this solution is easier said than done; medical professionals *have* lobbied the ACGME to change its regulations.[237] The ACGME, however, has been non-responsive to these overtures,[238] and has consistently rejected requests from residency program directors and other professionals that it revise its resident work hour regulations.[239]

Furthermore, allowing hospitals to choose between alternate regulations would not necessarily result in natural experimentation. As the past has demonstrated, hospitals, when given the choice, will implement the regulation method that will cost the hospital the least amount of money.[240] For example, if hospitals are given the choice between limiting resident work hours to eighty hours a week or requiring residents to average at least six hours of sleep per night, most hospitals would likely choose the latter regulation since the costs of complying with that regulation would be significantly lower than complying with the other regulation.[241] Thus, true experimentation would not take place, and the ACGME would not have the necessary data to determine the ideal regulatory method. For natural experimentation to occur, a regulator must require all hospitals within a given region to follow one set of regulations while hospitals in

237. *See* Ludmerer & Johns, *supra* note 49, at 1086 (discussing physician dissatisfaction with the ACGME regulations).

238. *Id.*

239. *Id.*

240. *See supra* Section II.B (explaining that monetary incentives and disincentives were why hospitals complied with ACGME regulations but not with New York State regulations).

241. *Id.*

another region must follow a different set of regulations.

C. Distance Learning: A Case Study in Private Decentralized Regulation

Since private decentralized regulation of graduate medical education does not currently exist, one cannot point to real-world evidence of success or failure. However, private decentralized regulation is common in other areas of education. Most notably, colleges and universities as a whole are subject to private decentralized regulation.[242]

Just as graduate medical education has faced significant turmoil due to the resident work hour debate, colleges and universities have had to struggle with their own major controversy. For the past two decades, accreditors of colleges and universities have debated whether distance learning programs, particularly entirely online universities, should be accredited, as well as how accreditors should evaluate these programs if they can be accredited. This Section contrasts how private decentralized regulators (the regional accrediting agencies that accredit colleges and universities) and a private centralized regulator (the American Bar Association, which accredits law school J.D. programs) resolved the distance learning controversy, and it applies lessons from the distance learning case study to the resident work hour controversy.

1. College Accreditation: A Brief Overview

Private, nongovernmental organizations accredit colleges and universities in the United States.[243] Educational institution accreditation serves four primary purposes:[244] assuring quality,[245] facilitating access to federal funds,[246] easing transfer of credits,[247] and engendering private sector confidence.[248] Accreditors

242. While colleges and universities as institutions are subject to private decentralized regulation, individual programs within those institutions, such as J.D. and M.D. programs, are also subject to other types of regulation, most commonly private centralized regulation. *See infra* Subsection IV.C.1 (providing a brief overview of the college accreditation system).

243. Council for Higher Educ. Accreditation, Accrediting Organizations in the U.S.: How Do They Operate To Assure Quality? 1 (2006), http://www.chea.org/pdf/fact_sheet_5_operation.pdf [hereinafter CHEA, Quality].

244. Council for Higher Educ. Accreditation, Profile of Accreditation 2 (2006), http://www.chea.org/pdf/fact_sheet_1_profile.pdf [hereinafter CHEA, Profile].

245. *See id.* ("Accreditation is the primary means by which colleges, universities and programs assure academic quality to students and the public.").

246. *See id.* ("Accreditation of institutions and programs is required in order for students to gain access to federal funds such as student grants and loans and other federal support.").

247. *See id.* ("Accreditation of institutions and programs is important to students for smooth transfer of courses and programs among colleges and universities.").

are certified by the U.S. Department of Education (USDE);[249] the USDE recognized fifty-six accreditors as of December 2002.[250]

One can divide accrediting agencies into two broad groups: institutional accreditors and specialty accreditors. Institutional accreditors, as the name implies, accredit entire educational institutions.[251] One can further subdivide institutional accreditors into two subgroups: regional accreditors and national accreditors.[252] Regional accreditors evaluate institutions in six specific clusters of states, or regions, with each regional accreditor having a monopoly over regional institutional accreditation within its own region; national accreditors evaluate institutions nationwide regardless of the institution's geographic region.[253]

Though the USDE makes no official distinction between regional and national institutional accreditors when it comes to eligibility for federal funds, educational institutions and employers overwhelmingly consider the regional accreditors far more prestigious and view regional accreditation as the gold standard of institutional quality.[254] These perceptions are reflected in the characteristics of institutions that seek regional and national accreditation. Virtually all institutions that have received regional accreditation – over ninety-seven percent – are both degree-granting and non-profit.[255] In contrast, sixty-four percent of nationally accredited institutions do not grant degrees, and seventy-nine percent are for-profit.[256] Furthermore, many nationally accredited institutions are single-purpose schools, e.g. bible colleges and occupational training schools.[257] Because few degree-granting colleges and universities pursue national accreditation, and since many colleges that are nationally accredited chose national accreditation because they could not become regionally accredited,[258] future mentions of institutional accreditors in this Note refers to

248. *See id.* ("Accredited status of an institution or program is important to employers when evaluating credentials of job applicants and providing financial support to current employees seeking additional education.").

249. *Id.* at 1.

250. *Id.* at 2.

251. CHEA, Quality, *supra* note 243, at 1.

252. CHEA, Profile, *supra* note 244, at 1.

253. *Id.* at 2.

254. *See* Nathan Whiteside, Are Distance Learning Degrees Legitimate?, http://www.degree info.com/article1_2.html (last visited Oct. 17, 2006) ("The 'gold standard' would be . . . a US-based school which is regionally accredited.").

255. CHEA, Profile, *supra* note 244, at 1.

256. *Id.* at 2.

257. *Id.*

258. The American Military University, for instance, sought accreditation from the Distance Education Training Council (DETC), a national accreditor, after an unsuccessful attempt to achieve

regional accreditation.

Specialty accreditors, in contrast, do not accredit entire institutions,[259] but accredit specific programs within an institution.[260] Specialty accreditors exist for dozens of specialties, ranging from law to funeral service to veterinary medicine.[261] Unlike regional accreditors, specialty accreditors have a national reach in their specialty area.[262] Thus, specialty accreditors are a form of private centralized regulation, while regional accreditors are analogous to private decentralized regulation.

2. Challenges Caused by Distance Learning

The growing popularity of distance learning programs has challenged both institutional and specialty accreditors. Distance learning, contrary to popular belief, is not a new phenomenon. In fact, distance learning predates the existence of most U.S. accrediting agencies.[263] However, for most of its history distance learning never particularly posed a challenge for any accreditor. Until recently, distance learning was primarily identified with correspondence courses, where the student and the instructor communicate through postal mail. While a very small minority of established American universities created correspondence programs,[264] the overwhelming majority of correspondence courses were run by

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regional accreditation. Another institution, the University of South Africa, obtained DETC accreditation because it was ineligible for regional accreditation due to its location in a foreign country, yet still wanted recognition from a USDE-approved accreditor so that its growing number of American students could receive financial aid from the U.S. government.

259. Some exceptions apply, such as when an institution has a singular purpose and only offers one program that is in the domain of a specialty accreditor. For instance, Brooklyn Law School is accredited by the American Bar Association, a specialty accreditor, but not by a regional or national institutional accreditor. *See* CHEA Database, http://www.chea.org/search/search.asp (last visited Dec. 8, 2006) (search for "Brooklyn Law School").

260. CHEA, Profile, *supra* note 244.

261. For a complete list of specialty accreditors, see Council for Higher Educ. Accreditation, Recognized Accrediting Organizations (2006), http://www.chea.org/pdf/CHEA_USDE_AllAccred.pdf [hereinafter CHEA, List] (providing a list of all accreditors recognized by the USDE or CHEA).

262. CHEA, Profile, *supra* note 244, at 2.

263. For example, the University of London began to offer degrees through its distance learning program in 1858. *See* Univ. of London, A Brief History, http://www.london.ac.uk/history.html (last visited Oct. 17, 2006) (discussing the university's history, including the founding of its distance learning program).

264. Penn State began offering correspondence courses in 1892, primarily in agriculture. In the 1920s the program began to offer courses over the radio, and in subsequent decades the school made courses available through public and cable television as well as video and the internet. *See*

diploma mills, which engaged in little or no real teaching and literally sold unaccredited degrees through the mail for a hefty profit.[265] Since almost no legitimate American universities even offered correspondence courses, let alone correspondence degrees,[266] and since the overwhelming majority of correspondence schools were blatantly fraudulent and did not even attempt to obtain accreditation,[267] accrediting agencies did not have to concern themselves with evaluating distance learning programs.

Technological advances in the 1980s and 90s, however, changed the face of distance learning. The popularization of the VCR during the 1980s caused a small spike in distance learning programs, with some schools, including Columbia University, offering courses and even a limited number of degrees through videotape.[268] However, distance learning programs did not become popularized until the 1990s with the dawn of the Internet. Widespread Internet use, as well as ever growing demands for higher education services geared toward working professionals,[269] resulted in a large increase in distance learning programs. The 1990s saw many regionally accredited universities offer not only online courses, but also degrees that one could complete entirely online.[270] By

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Penn State, Types of Courses, http://www.worldcampus.psu.edu/StudentServices_Typesof Courses.shtml (last visited Oct. 17, 2006) (explaining distance education and providing a history of Penn State's own distance education program). Other schools offering correspondence courses during this period include the University of Chicago and the State University of Iowa. *See* Kristin Hirst, A Distance Learning Timeline, http://www.degreeinfo.com/timeline.html (last visited Oct. 17, 2006) (providing a brief history of distance learning).

265. Diploma mills have existed in the United States since the Civil War era. *See* Christopher Bahur, Diploma Mills: Fraud in Higher Education, http://www.degreeinfo.com/article24_1.html (last visited Oct. 17, 2006) (providing a history of diploma mills).

266. Hirst, *supra* note 264.

267. Bahur, *supra* note 265.

268. Columbia University created the Columbia Video Network in 1986, offering courses and degrees in engineering fields. Columbia Video Network, About CVN, http://www.cvn.columbia.edu/About_CVN/about_cvn.html (last visited Oct. 17, 2006).

269. In 2000, more than fifty-six percent of all college students were more than twenty-two years old, with over twenty-six percent older than thirty. Nat'l Ctr. for Educ. Statistics, Total Enrollment in All Degree-Granting Institutions by Sex, Age, and Attendance Status, http://nces.ed.gov/programs/projections/tables/table_11.asp (last visited Oct. 17, 2006). More than forty-one percent of college students in 2000 were enrolled as part time students. *Id.*

270. For more information on this phenomenon, see Risa Lieberwitz, *The Corporatization of the University: Distance Learning at the Cost of Academic Freedom?*, 12 B.U. PUB. INT. L.J. 73, 104-06 (providing a list of many universities that created online distance learning programs during the 1990s, including Carnegie Mellon University, Columbia University, Cornell University, Duke University, the London School of Economics, McGill University, New York University, Purdue University, Stanford University, Temple University, the University of Baltimore, the University of

2002, there were 1708 regionally accredited colleges and universities that offered distance learning programs – more than fifty-five percent of all regionally accredited institutions![271] Perhaps even more notably, several entirely online colleges and universities were founded during this period, such as Jones International University[272] and Northcentral University.[273]

The creation of so many distance learning programs in such a very short period of time caused both regional and specialty accreditors to wrestle with many new and controversial issues. Regional accreditors had to determine whether an institution with no physical campus should be accredited, and if so, what standards should be applied relative to traditional "brick and mortar" schools.[274] Furthermore, accreditors had to decide how to evaluate online programs provided by "brick and mortar" schools that were already accredited. For example, the Middle States Association of Colleges and Schools had to determine how it should evaluate Touro College, a school founded in 1971 with more than 11,000 students on its home campus in New York,[275] after Touro launched an entirely online subsidiary school, Touro University International, in 1999, with all of its administrative offices in California and an enrollment of over 7000 students.[276] Specialty accreditors had to make similar decisions; for instance, the American Bar Association had to determine whether online law schools, such as the for-profit and entirely online Concord Law School, were eligible for ABA accreditation.[277] However, despite facing very similar issues,

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California at Los Angeles, the University of Chicago, the University of Florida, the University of Maryland, the University of Michigan, the University of Toronto, and the University of Virginia).

271. COUNCIL FOR HIGHER EDUC. ACCREDITATION, ACCREDITATION AND ASSURING QUALITY IN DISTANCE LEARNING 3 (2002) [hereinafter CHEA, DISTANCE LEARNING].

272. Jones International University was founded in 1993, and in 1999 became the first entirely online university to receive regional accreditation. Jones International Univ., History of Jones International University (2006), http://www.jiu.edu/about/history/timeline.php (last visited Oct. 17, 2006).

273. Northcentral University, a for-profit online institution with no physical campus, offers degrees ranging from bachelor to doctorate level. Northcentral Univ., NCU Fact Sheet, http://www.ncu.edu/ncu_fact_sheet.asp (last visited Oct. 17, 2006).

274. *See, e.g.*, Kelly McCollum, *Accreditation of On-Line University Draws Fire,* CHRON. HIGHER EDUC., Apr. 2, 1999, at A33 (discussing the North Central Association of Colleges and Schools's controversial decision to accredit Jones International University).

275. *Touro College: At a Glance*, U.S. NEWS & WORLD REP., http://www.usnews.com/usnews/edu/college/directory/brief/drglance_10142_brief.php (last visited Dec. 8, 2006).

276. *E-Learning: Touro University International (CA): General Information*, U.S. NEWS & WORLD REP., http://www.usnews.com/usnews/edu/elearning/directory/elearn1a_666129.htm (last visited Dec. 8, 2006).

277. Concord Law School is a part of the Stanley Kaplan Corporation, which owns a chain of forty-one undergraduate colleges in addition to Concord Law School. *See* Stephen Brier & Roy

regional accreditors and the ABA reached two largely different conclusions.

3. The Regional Accreditor Response to Distance Learning

As one might expect, the six regional accreditors[278] developed greatly differing evaluation standards of distance learning programs and institutions. While some accreditors embraced distance learning and online-only institutions and developed standards that some might consider too lenient,[279] other accreditors subjected distance learning programs and institutions to levels of scrutiny that some may deem too harsh.[280] Table One suggests some of these disparities.

Table 1: Distance Learning Disparity Across Accreditors

Regional Accreditor	*Schools w/ DL Programs*[281]
Middle States Association	59.4%
New England Association	28.6%
North Central Association	62.5%
Northwest Association	70.5%
Southern Association	58.7%
Western Association	23.8%

Rosenzweig, *The Keyboard Campus; Digital Diploma Mills: The Automation of Higher Education*, THE NATION, Apr. 22, 2002, at 30 (discussing Stanley Kaplan and Concord Law School).

278. The six regional accreditors are the Middle States Association of Colleges and Schools, the New England Association of Schools and Colleges, the North Central Association of Colleges and Schools, the Northwest Commission on Colleges and Universities, the Southern Association of Colleges and Schools, and the Western Association of Schools and Colleges. Technically there are eight regional accreditors, since the New England Association and the Western Association have each divided themselves into two separate commissions: one that accredits senior colleges and universities and a second that accredits community colleges and vocational schools. CHEA, List, *supra* note 261, at 1. However, since both commissions are a part of the larger association, and since their policies do not differ drastically from each other, this Note treats them as one for purposes of this analysis unless otherwise noted.

279. *See, e.g.*, Posting of Rich Douglas to http://forums.degreeinfo.com/showthread.php?s=ad9130677a09da7369f224a788e2a4ef&threadid=1854 (June 26, 2001, 19:36 GMT) (stating that "North Central certainly has been the most open about accrediting . . . DL schools" and "Middle States has been generally positive.").

280. *See, e.g., id.* ("WASC has always been a toughie."); Posting of John Bear to http://forums.degreeinfo.com/showthread.php?s=ad9130677a09da7369f224a788e2a4ef&threadid=2741 (Oct. 29, 2001, 03:47 GMT) (stating that "the Western Association is especially difficult on nontraditional models").

281. CHEA, DISTANCE LEARNING, *supra* note 271, at 5.

The most notable differences between the regional accreditors were in their attitudes toward institutions that offered only online programs with no physical campus. In this respect, one accreditor, the North Central Association, developed a reputation as extremely receptive to purely online schools.[282] The North Central Association became the first regional accreditor to accredit an entirely online university when it accredited Jones International University in 1999, causing a substantial amount of controversy.[283] In contrast, two other accreditors, the Southern Association and the Western Association, were perceived as hostile to the idea of accrediting online schools.[284] In fact, there are several documented instances of online or mostly online schools relocating their administrative offices after failing to receive accreditation from these associations. Walden University, while not entirely a distance learning school,[285] moved its administrative offices from Naples, Florida, to Minneapolis, Minnesota, so it would fall under the jurisdiction of the North Central Association, after an unsuccessful attempt at Southern Association accreditation.[286] Touro University International made the very unusual move of asking the Middle States Association to include its programs under Touro College's accreditation in order to avoid seeking Western Association accreditation.[287] Most recently, the American Military University, an entirely online institution, moved some of its offices across the border from Virginia to West Virginia; like Walden, it failed to achieve Southern Association accreditation and felt it would have greater success with the North Central Association.[288]

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282. Douglas, *supra* note 279.

283. McCollum, *supra* note 274.

284. Douglas, *supra* note 279.

285. For example, Walden requires its doctoral students to attend academic residencies in order to "give doctoral students the opportunity to work face-to-face with faculty, staff, and other doctoral students." Walden Univ., University Services: Residencies, http://www.waldenu.edu/c/Services/UniversityServices_389.htm (last visited Oct. 17, 2006).

286. For more information about Walden University, see Walden Univ., About Walden University, http://www.waldenu.edu/c/About/About.htm (last visited Oct. 17, 2006).

287. For more information about Touro College, see Touro Coll., About Touro College, http://www.touro.edu/general/about.asp (last visited Oct. 17, 2006). *See also* Posting of BillDayson to http://forums.degreeinfo.com/showthread.php?s=5b8ef5d2f24f0ffa0f6b6166340c02d6&threadid=19904 (June 16, 2005, 12:44 GMT) (discussing the accreditation status of Touro College and its various physical and online branch campuses, and observing that "Touro seems to enjoy living on the edge").

288. The American Military University (AMU) was founded in 1993 in Virginia, and it applied for Southern Association accreditation in 1998. In 1999, AMU was told that while it "met the requirements of the majority of the SACS conditions," it would not receive accreditation due to

Each regional accreditor continued to apply different standards to distance learning programs and institutions until 2001. In that year, the regional accreditors, realizing the need for greater uniformity in this area, convened a joint committee to examine how accreditors should evaluate distance learning programs. As a result of this meeting, a set of "best practices" were codified and adopted by all of the regional accreditors.[289] These best practices "constitute a common understanding of those elements which reflect quality distance education programming."[290] These practices were not developed in a vacuum. Rather, they were determined after all regional accreditors discussed their individual experiences evaluating distance learning programs.[291] As a result of sharing their experiences, accreditors were able to adopt the evaluation methods proven to work best and discard those that were known to be ineffective, resulting in all the regional accreditors adopting distance education evaluation policies that were not only uniform,[292] but better than any one accreditor had previously enacted individually.

4. The ABA Response to Distance Learning

The ABA, as a specialty accreditor with monopoly power over J.D. program accreditation,[293] approached the distance learning controversy differently than the regional accreditors. When faced with whether it should accredit online law

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some requirements not being met. Am. Military Univ., General Information FAQs, http://web.archive.org/web/20011218233612/http://www.amunet.edu/GeneralInformation/faqs.asp (last visited Oct. 17, 2006). In 2002, AMU created a spin-off university, the American Public University, and created the American Public University System (APUS) to serve as an umbrella organization for these two institutions. APUS established its corporate offices in West Virginia, and in February 2004 APUS became a candidate for North Central Association accreditation. Am. Pub. Univ. Sys., Accreditation and Licensure, http://www.apus.edu/APUS/Accreditation/Accreditation-and-Licensure.htm (last visited Oct. 17, 2006).

289. Best Practices for Electronically Offered Degree and Certificate Programs, https://wcet.info/services/publications/accreditation/Accrediting_BestPractices.pdf [hereinafter Best Practices].

290. *Id.*

291. *Id.*

292. *Id.*

293. Some scholars have argued that the ABA has used its monopoly power to homogenize legal education to the point where it is no longer a competitive market. *See, e.g.*, Andrew P. Morriss, *The Market for Legal Education & Freedom of Association: Why the "Solomon Amendment" Is Constitutional and Law Schools Aren't Expressive Associations*, 14 WM. & MARY BILL RTS. J. 415 (2005) ("The critical point is this: the legal education market is not a competitive market. The lack of competition should make courts skeptical of the behavior of what gives every appearance of being a cartel.").

schools such as Concord Law School,[294] the ABA's answer was very simple and straightforward: No.[295] Unlike regional accreditors, who allowed experimentation with distance learning and discovered that schools can deliver many quality degree programs through electronic media,[296] the ABA has taken a very hard-line approach and has retained accreditation guidelines that make it very difficult for online law schools to become established, such as requiring physical classrooms and libraries.[297] In fact, the ABA has gone so far as to prohibit law schools from granting credit for online or correspondence study,[298] although this rule has recently been relaxed to allow students to complete a maximum of twelve credits online.[299] The ABA has justified such draconian measures by arguing that online learning does not allow for proper training[300] – a conclusion obviously in conflict with many educational administrators,[301] as well as the regional accreditors.[302]

Such a hard-line conservative reaction is not unusual for the ABA; the organization had similar harsh restrictions against for-profit law schools, until a U.S. Department of Justice lawsuit and subsequent settlement by the ABA forced the accreditor to change its practices.[303] The ABA's stance toward Concord and other online law schools, then, is only "the latest example of how the ABA's rigid and outdated standards operate to stifle innovation."[304] As a national

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294. For more information about Concord Law School, see Concord Law Sch., Dean's Message, http://www.concordlawschool.com/info/custom/concord/schoolinfo/message.asp (last visited Oct. 17, 2006) (providing a brief description of the institution).

295. Geoffrey Gagnon, *Join 'Em,* LEGAL AFF., May-June 2004, *available at* http://www.legalaffairs.org/issues/May-June-2004/scene_gagnon_mayjun04.msp (last visited Dec. 8, 2006).

296. Best Practices, *supra* note 289.

297. Gagnon, *supra* note 295.

298. *Id.*

299. *See* Am. Bar Ass'n, Standard 306: Distance Education, http://www.abanet.org/legaled/distanceeducation/Standard306.doc (last visited Oct. 17, 2006) (explaining the ABA's position on distance education).

300. Julia Scheeres, *Virtual Degrees Virtually Tough*, WIRED NEWS, Aug. 28, 2002, http://www.wired.com/news/school/0,1383,54734,00.html.

301. For example, former Harvard University President Lawrence Summers "emphasized the importance of embracing the marriage of education and technology" in his 2005 commencement speech. *See* Paul D. Rosevear, *The Ivy League Goes Online*, AOL RES. ONLINE, Jan. 25, 2006, http://encarta.msn.com/encnet/Departments/elearning/?article=IvyLeagueOnline (providing many examples of elite colleges and universities embracing distance learning).

302. Best Practices, *supra* note 289.

303. For a concise summary of the lawsuit, see Robert J. Salzer, Note, *JurisDoctor.com: Are Full-Time Internet Law Schools the Beginning of the End for Traditional Legal Education?*, 12 COMMLAW CONSPECTUS 101, 111-12 (2004).

304. Herb D. Vest, *Felling the Giant: Breaking the ABA's Stranglehold on Legal Education in America*, 50 J. LEGAL EDUC. 494, 501 (2000).

monopoly, the ABA, unlike the regional accreditors, is under no obligation to change its policies; this same monopoly power also prevents the ABA from experimenting with distance learning and seeing its results first hand. While the ABA claims that distance learning cannot properly train lawyers,[305] at the time such regulations were made the ABA had no way of knowing whether such a belief was actually true, since it had not allowed for any lawyers to obtain training through online law schools and then attempt the bar exam or practice law.[306] Since no experimentation took place, no one can point to any evidence to find fault with the ABA's policies, thus perpetuating the status quo.

5. Parallels to the Resident Working Hours Controversy

Much of the distance learning experience applies to the resident work hour regulation debate. The ABA shares many similarities with the ACGME, most notably its monopoly status over accreditation in its field, which it uses to stifle innovation and ensure homogeneity within legal education.[307] Just as the ACGME has not responded to evidence showing that work hour limits may not promote patient safety, the ABA has ignored evidence showing that quality degree programs can take place through distance learning.[308] Furthermore, both

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305. Scheeres, *supra* note 300.

306. While it is true that Concord Law School graduates are eligible to take the California Bar Exam, the majority of Concord students enroll for personal enrichment without the intention of taking a bar exam, since they are unable to take the bar exam in their own jurisdictions. (Though Concord has more than 1800 students enrolled, only 660 have taken the First Year Law Student Examinations required for students of non-ABA accredited schools who wish to take the Bar. Concord Law School, School Information: Institutional Assessment Findings, http://www.concordlawschool.com/info/custom/concord/schoolinfo/assessment_findings.asp (last visited Dec. 8, 2006).) Furthermore, Concord's lack of ABA accreditation inherently prevents it from competing for the best students, since students who do wish to take the bar and become lawyers after graduation will naturally gravitate toward ABA-accredited schools, which will allow them to take the bar exam in any jurisdiction as well as provide them with greater employment opportunities. Since many of the students Concord currently attracts who do take the bar exam are those who would not have gotten into an ABA school, it is not really fair to use Concord's California bar passage rates as an indictment on the potential of distance learning, since many such individuals would likely have failed if they had attended a traditional law school. *See* Scheeres, *supra* note 300.

307. *See* Harry First, *Competition in the Legal Education Industry*, 53 N.Y.U. L. REV. 311, 327-28 (1978) (arguing that the ABA has used its monopoly power to force law schools to adopt the "elite-preference model" of legal education).

308. *See, e.g.*, Thomas J. Balcezak et al., *A Web-based Risk Management and Medical-Legal Curriculum for Graduate Medical Education*, 25 J. BIOCOMMUNICATION 2, 4 (1998) ("Those residents who first browsed the educational module scored significantly higher on the quiz (81%)

organizations have prevented natural or controlled experimentation from taking place by using their monopoly power to institute nationwide regulations.[309]

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than those who did not (62%)."); Tina M. Day et al., *The Effects of World Wide Web Instruction and Traditional Instruction and Learning Styles on Achievement and Changes in Student Attitude in a Technical Writing in Agricommunication Course*, 39 J. AGRIC. EDUC. 65 (1998) ("[S]tudents who completed a writing course on the web exhibited higher achievement scores than those in conventional instruction in the area of communication writings."); John Dutton et al., *Do Online Students Perform as Well as Lecture Students?*, 90 J. ENGINEERING EDUC. 131, 131 (2001) ("These results demonstrate that online students can perform at least as well as traditional students."); Scott D. Johnson et al., *Comparative Analysis of Learner Satisfaction and Learning Outcomes in Online and Face-to-Face Learning Environments*, 11 J. INTERACTIVE LEARNING RES. 29, 29 (2000) ("[T]here was no difference between the two course formats in several measures of learning outcomes."); G. Klass & L. Crothers, *An Experimental Evaluation of Web-Based Tutorial Quizzes*, 18 SOC. SCI. COMPUTER REV. 508, 508 (2000) ("We find no significant differences on post test scores between students who were assigned Web quizzes and those who were not."); L.A. Lockard, *The Impact of Technology Plans on Students' and Teachers' Learning*, 29 TECH. HORIZONS EDUC. J. 18, 24 (2001) (finding that integrating technology improved graduation rates); Krisanna Machtmes & J. William Asher, *A Meta-Analysis of the Effectiveness of Telecourses in Distance Education*, 11 AM. J. DISTANCE EDUC. 29, 43 (2000) ("There does not appear to be a difference in achievement between distance and traditional learners."); M.S. Nessler et al., *Professional Socialization of Baccalaureate Nursing Students: Can Students in Distance Nursing Programs Become Socialized?*, 40 J. NURSING EDUC. 293, 300 (2001) ("[N]ursing students near completion in distance nursing programs had significantly higher scores on two measures of socialization than did campus-based nursing students."); Alan F. Smeaton & Gary Keogh, *An Analysis of the Use of Virtual Delivery of Undergraduate Lectures*, 32 COMPUTERS & EDUC. 83, 92 (1999) ("The results in this paper have shown that when virtual lectures are used in place of traditional delivery methods there is no significant difference in attainment levels as measured by end of year examination marks."); K.E. Umble et al., *Effects of Traditional Classroom and Distance Continuing Education: A Theory-Driven Evaluation of a Vaccine-Preventable Disease Course*, 90 AM. J. PUB. HEALTH 1218, 1222 (2000) ("No significant difference was found between the increases in knowledge and self-efficacy for participants in the classroom and broadcast courses, both immediately following and 3 months after the course."); Dan Carnevale, *What Matters in Judging Distance Teaching? Not How Much It's Like a Classroom Course*, CHRON. HIGHER EDUC., Feb. 21, 2001, *available at* http://chronicle.com/free/2001/02/2001022101u.htm ("The delivery mode we know for a fact does not impact the learning."); Debbie Goldberg, *Teaching Online*, WASH. POST, Apr. 5, 1998, at R04 ("[T]he off-campus students perform just as well as their on-campus counterparts in the same courses."); James V. Koch, *How Women Actually Perform in Distance Education*, CHRON. HIGHER EDUC., Sept. 11, 1998, at A60 ("[T]wo studies of students in Indiana . . . found no statistically significant difference."); Dennis A. Trinkle, *Distance Education: A Means to an End, No More, No Less*, CHRON. HIGHER EDUC., Aug. 6, 1999, at A60 ("[T]here is clear evidence that distance education can be as successful as classroom-based instruction, if not more so.").

309. *See* Vest, *supra* note 304, at 501 ("[I]f you try to offer legal education that is outside the box, such as an affordable, convenient, online program, you are likely to end up without ABA

If the ACGME's national monopoly over graduate medical education accreditation (or the ABA's monopoly over legal education) were replaced with a private decentralized system, like regional accreditation, experimentation would take place. Private decentralized graduate medical education accreditors would approach the resident work hour controversy just as regional accreditors approached the distance learning issue: at first, each accreditor would create its own policies using its best judgment, and then after sufficient evidence accumulated, the accreditors would gather together to create a set of "best practices" for the sake of uniformity. Through obtaining a significant amount of data, as well as firsthand observations, the private decentralized accreditors would select the best of all the attempted regulatory systems in order to create an effective regulatory system that would best enhance patient safety while at the same time retaining the support of residency program directors.

CONCLUSION

The resident work hour limit controversy has spurred considerable debate, both over what limits, if any, should be instituted, as well as over which organization should determine those limits. The free market's failure to account for the patient safety externality, as illustrated by the death of Libby Zion, has shown that some form of regulation is necessary; however, observable actions by state governments and the ACGME have shown that neither can serve as an ideal regulator. Though some have lobbied for the federal government to intervene,[310] it is doubtful that the federal government's involvement would improve the situation.

Private decentralized regulation appears to be the best solution to the work hour limit debate. By eliminating the ACGME monopoly over graduate medical education and entrusting multiple regional accreditors with the ACGME's current functions, individual accreditors would experiment with different policies, with an ideal policy or combination of policies eventually manifesting itself. As demonstrated by the distance learning case study, private decentralized regulation does work in practice, and it has brought about better results than private centralized regulation. It is likely, therefore, that a private decentralized approach to the regulation of graduate medical education would best further the goal of patient safety as well as provide the best framework for solving future graduate medical education controversies.

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approval.").

310. *See, e.g.*, Am. Med. Student Ass'n, *supra* note 208.