OVERREGULATION OF HEALTH CARE: MUSINGS ON DISRUPTIVE INNOVATION THEORY

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I

INTRODUCTION

Health care costs in the United States are rising at an extraordinary rate.[1] The escalation has been attributed to a variety of factors, including the managed-care backlash,[2] consumer choice,[3] consumerism in an aging society,[4] and insufficient competition in the health care industry.[5] In addition, anecdotal evidence suggests that regulatory control may be a significant driver of health care costs.[6] In this paper, we hope to expand on the discussion of

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This article is also available at http://law.duke.edu/journals/lcp.

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The authors thank Damon Seils for editorial assistance and manuscript preparation.

1. *See* Sarah Lueck, *Health-Care Spending Rises 8.7%, Fastest Expansion in 10 Years*, WALL ST. J., Jan. 8, 2003, at D2; Robert Pear, *Spending on Health Care Increased Sharply in 2001*, N.Y. TIMES, Jan. 8, 2003, at A12.

2. *See* James C. Robinson, *The End of Managed Care*, 285 JAMA 2622, 2622–28 (2001) (detailing the departure from an economically successful but politically unpopular model of managed care); Carol Gentry, *UnitedHealth Move on Reviews is Seen as Industry Watershed*, WALL ST. J., Nov. 10, 1999, at B6; Jonathan Oberlander, *The U.S. Health Care System: On a Road to Nowhere?*, 167 CAN. MED. ASS'N J. 163, 166–68 (2002).

3. *See* Robinson, *supra* note 2.

4. *See* Marilyn Moon, *Medicare*, 344 NEW ENG. J. MED. 928, 928 (2001) (detailing the growth in life expectancy, especially among those who have already reached a mature age).

5. *See* Thomas Bodenheimer, *High and Rising Health Care Costs, Part 1: Seeking an Explanation*, 142 ANNALS OF INTERNAL MEDICINE 847, 850 (2005).

6. *See* PRICEWATERHOUSECOOPERS, THE FACTORS FUELING RISING HEALTHCARE COSTS 3 (2002), *available at* http://www.aahp.org/InternalLinks/PwCFinalReport.pdf (claiming that fifteen percent of the total increase in health care premiums is a result of government mandates and regulation); GEN. ACCOUNTING OFFICE, HEALTH INSURANCE REGULATION: VARYING STATE REQUIREMENTS AFFECT COST OF INSURANCE 2 (1996) (concluding that state health insurance regulations add costs to insured health plans); *See also* SECRETARY'S ADVISORY COMM. ON REGULATORY REFORM, BRINGING COMMON SENSE TO HEALTH CARE REGULATIONS 10 (2002), *available at* http://www.rwhc.com/papers/DHHS.RRAC.11.21.02.Report.pdf.

"overregulation" by Havighurst and Richman[7] by considering in particular some of the effects that regulatory controls may have on innovation in the health sector.

For the purpose of this discussion, we adopt a definition of regulatory controls ("regulations") offered by Berenson[8] and extend it to private and public entities performing the same function. Regulatory-control activities involve applying external rules in a consistent, uniform, and mechanistic way to patients and providers. For example, strictly enforcing a defined benefit package and paying physicians according to a fixed-fee schedule are regulatory tools.[9] Regulations, whether aimed at improving quality or controlling prices, may exert upward pressure on costs in a variety of ways.[10] First, documentation of compliance with regulations often requires substantial paperwork. A recent survey by the American Medical Association suggests that physicians may spend one hour completing Medicare paperwork for every four hours of patient care.[11] Second, regulations in one area may conflict with regulatory requirements in another, resulting in confusion and duplication of effort.[12] For example, a Medicare beneficiary may have the same information collected by as many as five care providers (for example, hospitals, physicians, home health, nursing home, and durable medical equipment). Third, directives that micromanage processes of care become obsolete as health care technology and the health care delivery system evolve. According to one estimate, more than 132,000 pages of governmental rules, requirements, guidelines, and directives currently govern the delivery of health care.[13]

In addition, regulations may profoundly affect costs by stifling innovation in service delivery and quality improvement.[14] Rules designed to protect consumers may have the unintended consequence of preventing good-quality, lower-cost alternatives from reaching the marketplace. In this article, we draw on the theory of disruptive innovation to explore this unintended consequence of regulation—specifically, how regulation of the primary-care delivery system may increase costs without providing improvements in quality. First, we present the theory of disruptive innovation and apply it to the heavily regulated health care market. Second, we discuss disruptive innovation in the primary-

7. Clark C. Havighurst & Barak D. Richman, *Distributive Injustice(s) in American Health Care*, 69 LAW & CONTEMP. PROBS. 7, 50–71 (Autumn 2006).

8. Robert A. Berenson, *A Physician's View of Managed Care*, HEALTH AFF., Winter 1991, at 106, 110.

9. *Id.*

10. Christopher J. Conover, *Health Care Regulation: A $169 Billion Hidden Tax*, 527 POL'Y ANALYSIS 1, 1 (2004).

11. *Medicare Reform: Bringing Regulatory Relief to Beneficiaries: Hearing Before the Subcomm. on Health of the H. Comm. on Ways and Means*, 107th Cong. 12 (2001) [hereinafter *Hearings*] (statement of Richard F. Corlin, President-elect, American Medical Association).

12. *See* SECRETARY'S ADVISORY COMM., *supra* note 6, at 13.

13. *Hearings*, *supra* note 11, at 134–35 (letter and attachment of Bruce M. Kelly, director of government relations, Mayo Foundation).

14. SECRETARY'S ADVISORY COMM., *supra* note 6, at 48.

care delivery system, using diabetes care as an example. Finally, we discuss the challenges of making the regulatory environment more hospitable to innovation in a way that improves the quality and reduces the costs of health care.

II

DISRUPTIVE INNOVATION THEORY

Disruptive innovation—proposed by Christensen[15] and further explicated in an important paper by Macher and Richman[16]—attempts to explain why some companies fail to stay atop their industries when faced with certain types of market and technological change. The theory assumes that consumer preferences for individual technologies are widely distributed.[17] Early innovators enter markets with basic products that meet the needs of a segment of the market.[18] Over time, innovators improve the product's capabilities ("sustaining innovation") to meet the demands of high-end consumers who offer potentially higher margins and more profitable markets.[19] Business models (and products within an individual firm) typically evolve by continuing to meet the needs of those customers through high-end innovation. The resulting higher-quality products serve the needs of the most lucrative segments of the market.[20]

Christensen argues, however, that "sustaining innovation" leads firms to develop products that possess capabilities far beyond what the average consumer desires or can absorb (Figure 1).[21] The overdeveloped product creates an opportunity for a new product, process, or business model—one initially offering the most basic features—to enter the market. "Disruptive innovation" occurs when this new product, entering the market at a lower level of sophistication, rapidly progresses to meet the needs of the majority of consumers in the marketplace and, as a result, captures market share from well-established firms.[22]

III

DISRUPTIVE INNOVATION IN THE HEALTH CARE SECTOR

Does the theory of disruptive innovation apply to a highly regulated market like health care? A key tenet of Christensen's theory is that a firm introduces into the market a new business model offering products with basic features, thus securing a substantial portion of the consumer base, and then enhances the

15. CLAYTON M. CHRISTENSEN, THE INNOVATOR'S DILEMMA (1997).

16. Jeffrey T. Macher & Barak D. Richman, *Organisational Responses to Discontinuous Innovation: A Case Study Approach*, 8 INT'L J. INNOVATION MGMT. 87 (2004).

17. *See* CHRISTENSEN, *supra* note 15, at xv–xxiv.

18. *Id.*

19. *Id.*

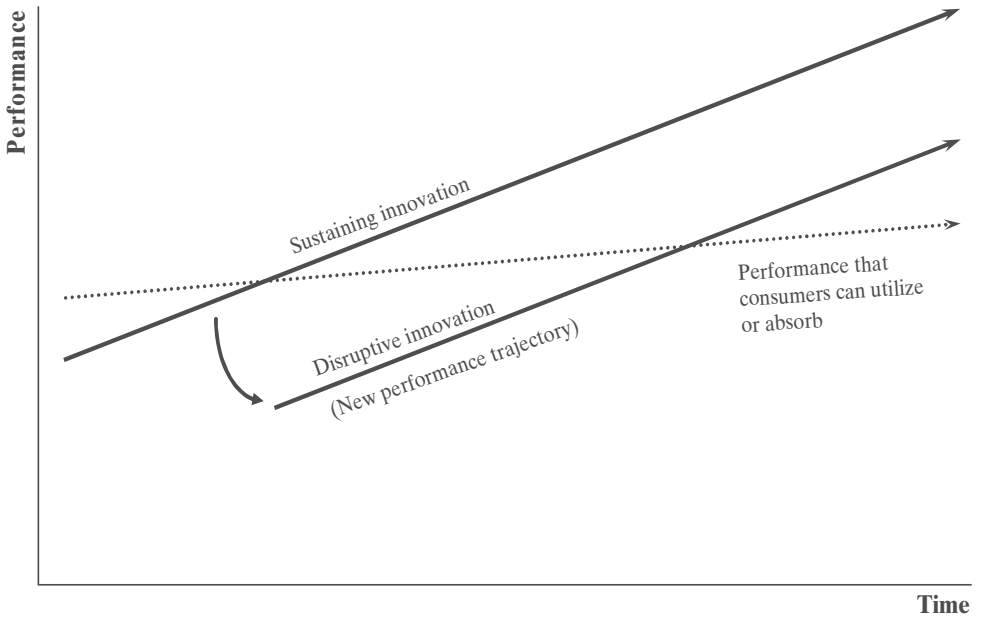
20. *Id.*

21. *Id.* at xvi.

22. *See id.* at xv.

product over time.[23] The presence of regulation, however, may effectively prevent disruptive technological improvements from occurring. In a lightly

Figure 1. Sustaining Innovation and Disruptive Innovation

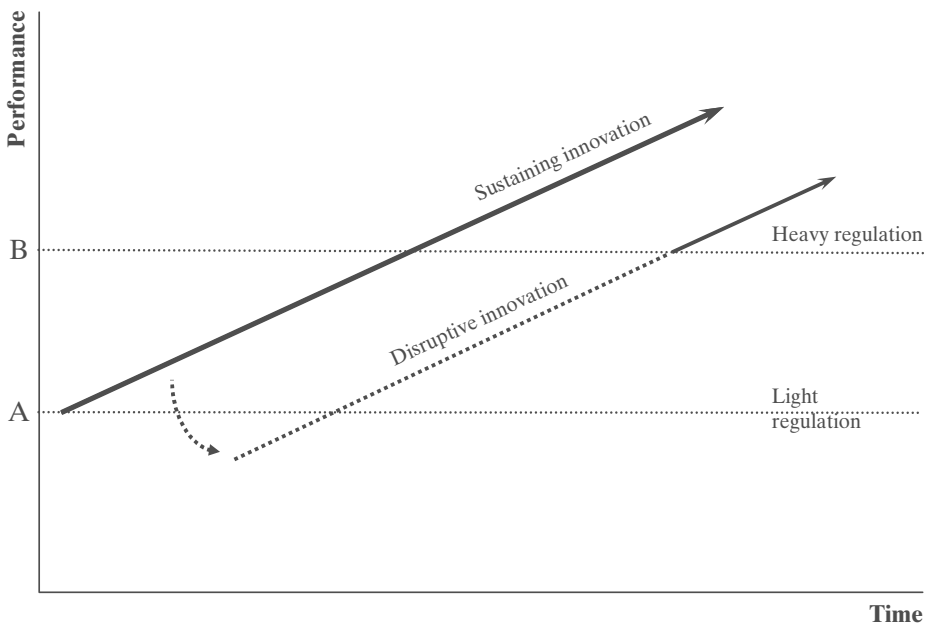


Adapted from C.M. Christensen, The Innovator's Dilemma (1997).

23. *See id.* at xxiii.

regulated market, disruptive innovation may emerge because the low threshold of mandated requirements allows the introduction of products having only basic features. (See Figure 2). In a heavily regulated market, however, the performance threshold is higher: all products must meet mandated requirements B to enter the market. Central to the theory of disruptive innovation is that disruptions occur in response to a performance oversupply.[24] The performance of the mainstream product exceeds the performance requirements of the average consumer.[25] To the extent that the requirements established by regulations exceed the requirements of the average consumer, disruptive innovation cannot occur.

Figure 2. Sustaining Innovation and Disruptive Innovation in Markets of Light and Heavy Regulation



Adapted from C.M. Christensen, The Innovator's Dilemma (1997).

24. *See id.*
25. *Id.*

In addition to the barriers to entry imposed directly by regulation, more subtle incidental barriers may also exist. Protected by regulation, health care organizations may use monopoly rents to prevent new business models from entering the market. In addition, disruptive innovators have limited access to the regulatory process. A two-person start-up is unlikely to have ready access to congressional committees or to the senior leadership of a regulatory body. Thus, rather than consider proposals for new business models that operate at the margins of existing regulations, Congress, regulatory bodies, and industry concentrate their efforts on advancing incremental changes in the status quo. Furthermore, regulatory bodies typically deal with a narrowly defined question. The overall effect of a particular decision on the evolution of the marketplace is not considered. Finally, the net impact of the rules on efficiency and quality in the marketplace is not evaluated.

Are there examples of disruptive innovation in health care? In its purest form, capitation[26] has the hallmarks of a disruptive innovation.[27] Capitation aims to provide basic, integrated care to less-demanding customers (that is, healthier patients) at a lower cost.[28] In theory, capitation disrupts the relationship between the patient and a highly specialized, fragmented system by offering a single point of contact at a lower price.[29] As a business model, capitation is distinct from traditional fee-for-service medicine in that it permits the transfer of resources among providers so that the cost of service improvements (for example, home care for asthma) can be offset by gains in efficiency (for example, fewer hospitalizations and emergency department visits).[30]

As implemented through managed-care programs, however, capitation has failed to achieve the gains associated with disruptive innovation. Although managed care appeared initially to control health care expenses, costs are again on the rise.[31] Compliance with evidence-based guidelines[32] is comparable in

26. Here, "capitation" refers to a specific payment mechanism by which a provider is paid a fixed amount, determined in advance, for the care of an individual or group for a prespecified period of time, regardless of the type or number of services actually provided. By contrast, "managed care" refers to a type of organizational framework for the provision of health insurance, in which capitation is one commonly used mechanism for controlling health care costs.

27. Clayton M. Christensen, Richard Bohmer & John Kenagy, *Will Disruptive Innovations Cure Health Care?*, HARV. BUS. REV., Sep.–Oct., 2000, at 102.

28. *See id.* at 104.

29. *See id.* at 104–05.

30. *See* Donald M. Berwick, *Part 5: Payment by Capitation and the Quality of Care*, 335 NEW ENG. J. MED. 1227, 1228–30 (1996).

31. *See* Oberlander, *supra* note 2; Bradley C. Strunk, Paul B. Ginsburg & Jon R. Gabel, *Tracking Health Care Costs*, 2001 HEALTH AFF. (WEB EXCLUSIVES) W39, W39; Christopher Hogan, Paul B. Ginsburg & Jon R. Gabel, *Tracking Health Care Costs: Inflation Returns*, HEALTH AFF., Nov.–Dec. 2000, at 217, 217.

32. Evidence-based guidelines are systematically developed statements that define standards of care based on sound scientific research. *See* Patrick J. O'Connor, *Adding Value to Evidence-Based*

managed-care and non-managed-care settings.[33] Consumer satisfaction is consistently lower in managed-care settings, as compared to non-managed-care settings.[34] In sum, few would argue that managed care satisfies the needs of the majority of consumers in the marketplace by offering a product of markedly higher quality at a lower cost.

Christensen argues that disruptive innovation has occurred in selected pockets of health care, citing home-based blood-glucose self-monitoring for patients with diabetes, coronary angioplasty for the treatment of coronary-artery disease, and the emergence of nurse practitioners as examples.[35] In these cases, Christensen asserts, the innovation allowed tasks that historically could be performed only by specialists in centralized locations to be performed by a larger, less-skilled group in a more convenient, less-expensive setting.[36] Moreover, by enabling less-costly providers (even patients themselves) to address specific health care needs, these innovations increased efficiency and access without compromising quality.[37]

Why has managed care failed as a disruptive innovation while home glucose monitoring, coronary angioplasty, and the nurse-practitioner model have succeeded? One might argue that none of these "successful" innovations is truly disruptive at the market level. None has fundamentally changed the system of primary care or fostered the development of new and innovative models of health care delivery. Instead, technology has added to the existing system, resulting in increased costs with uncertain consequences for quality.[38] Physicians supervise nurse practitioners and, in most markets, payment regulations restrict nurse practitioners to a primary-care role.[39] Although patients monitor their blood glucose, there is no real-time interface with the physician to integrate the resulting data into treatment strategies. Finally, angioplasty relies on the same hospital-based business model as does cardiac surgery; the procedure is simply performed by a cardiologist rather than a cardiac surgeon.

An alternative argument is that disruptive innovations that succeed in health care do so because they face fewer regulatory barriers. To some degree,

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Clinical Guidelines, 294 JAMA 741, 741–43 (2006) (describing evidence-based clinical practice guidelines and their role in quality-improvement initiatives).

33. *See* Robert H. Miller & Harold S. Luft, *HMO Plan Performance Update: An Analysis of the Literature, 1997–2001*, HEALTH AFF., July–Aug. 2002, at 63 [hereinafter *HMO Performance*]; Robert H. Miller & Harold S. Luft, *Does Managed Care Lead to Better or Worse Quality of Care?*, HEALTH AFF., Sep.–Oct. 1997, at 7.

34. *HMO Performance*, *supra* note 33, at 63.

35. *See Christensen*, *supra* note 27, at 106–08.

36. *Id.*

37. *Id.*

38. *See* John M. Eisenberg et al., *Subtituting Diagnostic Services: New Tests Only Partly Replace Older Ones*, 262 JAMA 1196, 1196 (1989) (concluding that new systems take place alongside, rather than replace, older ones).

39. *See* Richard A. Cooper, Tim Henderson & Craig L. Dietrich, *Roles of Nonphysician Clinicians as Autonomous Providers of Patient Care*, 280 JAMA 795 (1998).

regulation may initially have protected the managed-care market. By exempting self-insured, employer-sponsored benefit plans from state regulation, the Employee Retirement Income Security Act of 1974[40] effectively created a favorable climate for the expansion of managed-care programs.[41] Rather than evolve as a distinct business model, however, managed care developed as an extension of existing insurance networks and their nonexclusive relationships with multiple providers. The corporate practice of medicine and restrictive state laws precluded the evolution of truly new models of service delivery in many states.[42] As managed care grew rapidly throughout the 1990s, however, criticisms of managed care led to the introduction of more than a thousand pieces of legislation at the federal and state levels addressing consumer protection in managed-care settings.[43] From January to July 1996 alone, state legislatures introduced more than 400 bills to regulate managed-care programs.[44] Over time, then, managed care has come to look less like a new and distinct business model, and more like a close cousin of the indemnity insurance model that spawned the innovation.

IV

DISRUPTIVE INNOVATION IN THE DELIVERY OF PRIMARY CARE

The delivery of primary care has changed fundamentally over the past three decades. Throughout the 1970s, most patients experienced primary care in the form of "Marcus Welby medicine." The patient visited the primary care physician's private office for medical care or, if the patient was too ill, the physician visited the patient at home. The physician spent as much time as necessary to make the initial diagnosis and then coordinated the care of chronic conditions. Over time, the practice of medicine became increasingly specialized, and the use of high-end technology flourished. Although specialization and new technologies served the needs of a profitable sector of the market, the fragmentation of service delivery made health care less convenient for patients with basic needs. In the lexicon of disruptive innovation theory, increasing specialization and reliance on technology represent sustaining innovations—changes that move primary care further along the same performance trajectory at progressively higher cost.

How might disruptive innovation transform the delivery of primary care? The example of diabetes care describes a hypothetical system of care with the potential to disrupt the primary-care market:

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40. Employee Retirement Income Security Act of 1974 § 514(a), 29 U.S.C. § 1144 (2000).

41. PETER D. JACOBSON, STRANGERS IN THE NIGHT: LAW AND MEDICINE IN THE MANAGED CARE ERA 11 (2002).

42. *See id.* at 60.

43. Robert J. Blendon et al., *Understanding the Managed Care Backlash*, HEALTH AFF., July–Aug. 1998, at 80.

44. Tracy E. Miller, *Managed Care Regulation: In the Laboratory of the States*, 278 JAMA 1102, 1102 (1997).

Diabetes mellitus affects approximately eighteen million people in the United States, or about six percent of the population.[45] Diabetes care is often suboptimal, despite simple diagnostic criteria and effective treatment options. Although treatment guidelines from the American Diabetes Association are readily available and widely accepted, less than five percent of patients with diabetes receive basic care that conforms to those guidelines.[46] The clinical benefits of good glycemic control in patients with diabetes are well established.[47] Economic data suggest, moreover, that the cost of poor glycemic control may be substantial,[48] far surpassing the additional resources required for closer monitoring, increased patient education, greater clinical or telephone contact, and higher drug costs.[49] Despite these data, studies from a wide variety of practice settings confirm that glycemic control is suboptimal in most patients with diabetes.[50]

While physician education[51] and patient compliance[52] may account for some of the problem, "system" factors likely drive the low figures. Patients monitor their glucose, but there is no real-time interface with the physician to integrate the resulting data into treatment strategies. The acute symptoms and concerns

45. CENTERS FOR DISEASE CONTROL AND PREVENTION, NATIONAL DIABETES FACT SHEET: UNITED STATES 4 (2003), *available at* http://www.cdc.gov/diabetes/pubs/pdf/ndfs_2003.pdf.

46. *See* Gloria L. Beckles, et al., *Population-Based Assessment of the Level of Care Among Adults with Diabetes in the U.S.*, 21 DIABETES CARE 1432 (1998).

47. *See, e.g.*, The Diabetes Control and Complications Trial Research Group, *The Effect of Intensive Treatment of Diabetes on the Development and Progression of Long-Term Complications in Insulin-Dependent Diabetes Mellitus*, 329 NEW ENG. J. MED. 977 (1993) [hereinafter *Intensive Treatment*] (concluding that intensive therapy effectively delays the onset and slows the progression of diabetic retinopathy, nephropathy, and neuropathy in patients with insulin-dependent diabetes mellitus); American Diabetes Association, *Standards of Medical Care for Patients with Diabetes Mellitus*, 20 DIABETES CARE S5 (1997) [hereinafter *Diabetes Standards*] (summarizing the standards of care for patients with diabetes and the benefits associated with optimal glycemic control); Andrzej S. Krolewski et al., *Glycosylated Hemoglobin and the Risk of Microalbuminuria in Patients with Insulin-Dependent Diabetes Mellitus*, 332 NEW ENG. J. MED. 1251 (1995) (establishing that poor glycemic control abruptly increases the risk of microalbuminuria, the first manifestation of diabetic nephropathy); GianCarlo Viberti, Editorial, *A Glycemic Threshhold for Diabetec Complications?*, 332 NEW ENG. J. MED. 1293 (1995); U.K. Prospective Diabetes Study (UKPDS) Group, *Intensive Blood-Glucose Control with Sulphonylureas or Insulin Compared with Conventional Treatment and Risk of Complications in Patients with Type 2 Diabetes (UKPDS 33)*, 352 LANCET 837 (1998) (concluding that intensive glycemic control reduces the incidence of microvascular complications).

48. *See* Todd P. Gilmer et al., *The Cost to Health Plans of Poor Glycemic Control*, 20 DIABETES CARE 1847 (1997).

49. *See* The Diabetes Control and Complications Trial Research Group, *Resource Utilization and Costs of Care in the Diabetes Control and Complications Trial*, 18 DIABETES CARE 1468, 1478 (1995).

50. *See* Jinan B. Saaddine, et al., *Improvements in Diabetes Processes of Care and Intermediate Outcomes,* 144 ANNALS INTERNAL MED. 469 (2006) (showing, based on data from the Behavioral Risk Factor Surveillance System, that one in five patients with diabetes has poor glycemic control).

51. *See* Sean R. Tunis et al., *Internists' Attitudes About Clinical Practice Guidelines*, 120 ANNALS INTERNAL MED. 956, 956 (1994) (concluding that many physicians were concerned about the guidelines' possible effects on clinical autonomy, costs, and satisfaction with clinical practice).

52. *See* David G. Marrero et al., *Nutrition Management of Type 2 Diabetes by Primary Care Physicians: Reported Uses and Barriers*, 15 J. GEN. INTERNAL MED. 818, 818 (2000) (detailing patient-centered barriers to effective nutrition therapy).

that give rise to an office visit may crowd out the relatively less-urgent need to manage blood-glucose levels optimally.[53]

Consider a hypothetical innovation for managing the care of patients with diabetes: a home glucose monitoring system that electronically transmits daily glucose levels to a database in the physician's office.[54] A companion software package automatically charts glucose levels over time. Using evidence-based guidelines, the software flags alarming trends in glucose levels and generates printed reports that trigger intervention by a health care provider. The specific intervention would depend upon the trend, and might range from an e-mail exchange to a telephone "check-up" to an office visit with the primary-care provider. In the disruptive-innovation framework, the innovation provides a basic, integrated product (an enhanced blood-glucose monitoring system) to less-demanding consumers (outpatients with diabetes, rather than hospitalized or acutely ill patients) at a lower cost (regular information is transmitted between patients and physicians without the cost and inconvenience of an office visit).

Initially, the basic product might appeal only to a small number of physicians and consumers. Over time, technology vendors would likely enter the market to enhance the system in a variety of ways. For example, an enhanced reporting module might be added to enable aggregation of data into cohorts defined by payer, employer, or disease severity. In addition, the stand-alone database might be linked to the office-based electronic medical record or scheduling system so that evidence-based practice guidelines, embedded in the system, could fuel reminders for primary-care teams. As the infrastructure costs would likely be prohibitive for solo- or small-group practices, "cooperatives" might emerge to allow small physician groups to achieve economies of scale. Alternatively, third-party vendors might bundle hardware, software, and technical support as a product for solo- and small-group practices. These approaches could lead to new ways of organizing providers around expensive capital equipment. Again, in a disruptive-innovation framework, these and other enhancements would move the disruptive product along the performance trajectory and enable it to eventually capture a significant portion of the market.

Perhaps surprisingly, under the current regulatory structure there are substantial disincentives to developing and adopting innovations like the one imagined above. First, there is no reimbursement mechanism for investments in information infrastructure. Although the basic innovation might be attractive for a subset of technology-savvy and technology-seeking physicians, continued implementation would likely depend on the widespread presence of an

53. Thomas Bodenheimer, Edward. H. Wagner & Kevin Grumbach, *Improving Primary Care for Patients with Chronic Illness*, 288 JAMA 1775, 1775 (2002).

54. Telemetric, home-based blood glucose monitoring devices have emerged in recent years, although they are not as automated as the hypothetical device we describe. *See*, *e.g.* , MetrikLink® at http://www.imetrikus.com/prod_ML.asp (last visited Aug. 22, 2006).

infrastructure that supports an electronic medical record. Under the current encounter-based reimbursement system, providers have little incentive to acquire technologies that enhance service but do not generate revenue.[55] Physicians are not able to bill for technology directly, or they are not able to share in the benefit of the service—improved efficiency and quality for patients reduces revenue for providers. Second, the hypothetical innovation might increase demand for unbilled, informal communications between patients and care providers while decreasing the demand for acute office visits. Again, the current system reimburses for office visits, not informal exchanges (for example, telephone conversations or e-mail exchanges). Physicians who adopt the innovation would likely see their revenues decline.

V

CONCLUSION: THE CHALLENGE OF REGULATION

The regulatory framework that governs the U.S. health care system is flawed. Complex and highly detailed regulations increase costs through paperwork, duplication of effort, and mandated inefficiency. In addition, and perhaps more significantly, the regulatory framework escalates costs by stifling innovation in service delivery. The example provided here is hypothetical, but it aptly describes the kind of quality-enhancing, lower-cost innovation that may never reach the market under the current regulatory structure.

The current structure may be inhospitable to innovation because regulators do their jobs extremely well; that is, they develop regulations that address narrowly defined program goals. The role of the regulator is analagous to the role of the manager in Christensen's framework.[56] Managers who listen carefully to consumers successfully push products along the performance trajectory through sustaining innovations. In a competitive market, this practice creates a situation ripe for disruptive innovation. Regulators fine-tune regulations and, similarly, force a product along a performance trajectory. Disruptive innovation cannot occur, however, because a new product is prohibited from entering below the threshold established by the regulation.

What regulators do not do is evaluate how regulations affect overarching goals for quality and efficiency in the marketplace. In addition, although forgone disruptive innovation is a substantial opportunity cost of regulation, regulatory bodies neither acknowledge the cost nor adjust for it in their analyses of the costs and benefits of new regulations. Finally, the public rulemaking process closely attunes regulators to the interests of majority stakeholders, not to the interests of isolated innovators.

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55. *See* Edward H. Shortliffe, *Strategic Action in Health Information Technology: Why the Obvious Has Taken So Long*, 24 HEALTH AFF. 1222, 1223–29 (2005) (describing financial and structural barriers to widespread adoption of information technology in health care).

56. *See* CHRISTENSEN, *supra* note 15, at xiv–xxiv.

Making the regulatory environment more hospitable to innovation will not be a trivial task. Disruptive innovations cannot be identified prospectively, so systematically collecting basic information on all innovations may help us to understand the circumstances that are most (or least) hospitable to disruptive innovation. At a minimum, we should begin to catalog innovations as they arise. In addition, the regulatory process should incorporate the opportunity costs of forgone disruptive innovation in the calculation of the costs of regulation. While imprecise, this "thumb on the scale" would have the desired effect of reducing the net benefit of many proposed regulations. Finally, and more fundamentally, a regulatory process that stifles innovation and increases costs calls into question the role of the government in a private health care system. A careful examination of the regulatory process and its consequences may be in order.

Disruptive innovation theory provides one lens through which to describe how regulations may stifle innovation and increase costs. Can disruptive innovation deliver better quality and lower cost over time, and does the regulatory structure preclude achievement of these goals? Empirical work is essential and might include reexamining the fundamental theory of regulation and its application to health care, quantifying the cost of regulation to the health care system, and using game theory to understand how well alternative regulatory structures might accommodate innovation. To be clear, we do not propose deregulation of the health care market. Regulations are necessary to assure basic protections, prevent fraud, maintain and promote access to care, and provide governing direction for large public programs. Rather, we present one way of understanding how the current system of regulation often precludes cost-saving, quality-enhancing innovations from reaching the market. To the extent that disruptive innovation cannot occur, health care will continue on a high-cost trajectory without commensurate gains in quality.