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LEVERAGING QUALITY IN MANAGED CARE: MOVING ADVOCATES BACK INTO THE BOX

JOHN D. BLUM*

INTRODUCTION

While it may be an often-stated and time-worn phrase, the notion that we live in strange times seems even more apt in what has become the strangest of times, America post-September 11th.¹ Now added to the list of profound and complex challenges society must face is the multi-dimensional issue of terrorism. In a sense, contemplating health policy, and more specifically, the impact of managed care on quality and consumerism, allows us to return to a more comfortable set of issues, ones that were framed at the end of the last century. Louise Trubek's thoughtful piece on health advocacy and quality in the managed care context has a ring of familiarity in that it highlights (in a novel way) an ever-present irony of our health system; namely, that it is a system that often ignores the very interests of those it was created to serve: the patients.² While the need for patient advocacy brings us back to familiar ground, devising strategies for effective health care consumer representation in the midst of a fluid and complex delivery system quickly transports us into yet another area of current uncertainty.

This Article is written in response to Professor Trubek's article and is intended to provide a different perspective on the subject of consumer advocacy and quality in the context of managed care. The ultimate goal of producing more effective strategies for legal advocates in the health care arena is of critical importance, and the model articulated by

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1. There have been literally dozens of articles written attempting to analyze the impacts of the September 11, 2001 terrorism attacks. While a range of conclusions concerning the effects of terrorism on the United States is being reached, it seems clear that life in America post-September 11 has changed. Indeed, all sectors of our society have been affected, and certainly health care is no exception. With terrorism has come an economic recession that has stalled initiatives such as the patients' bill of rights, and it appears that the momentum for reforms in quality of health care and combating medical errors has stalled as well. See Jeff Tieman, *On the Front Lines: Anthrax Scare, Jittery Public Put Focus on the Healthcare Industry*, MODERN HEALTHCARE, Oct. 22, 2001, at 4; see also Mark A. Hofmann, *Rising Costs Pitted Against Patient Rights Bill*, BUS. INS., Sept. 24, 2001, at 30.

2. See generally Louise G. Trubek, *Public Interest Lawyers and New Governance: Advocating for Healthcare*, 2002 WIS. L. REV. 575.

Professor Trubek is one that must be heralded as an important template for future action.³ While sharing in the overall objective that underpins the Trubek model, this Article will present a different view of the underlying regulatory context within which new perspectives on advocacy should be forged. Specifically, this Article will review the status of managed care, present a broad reflection on the initiatives to measure and improve the quality of medical care, explore the dominance of cost concerns in managed care, consider a different, more convoluted model of governance, and focus on advocacy at the junction of federalism.

I. BACKGROUND

Unquestionably, managed care has framed American health delivery in the private and public sectors, representing both self-contained delivery systems and control techniques in health insurance programs.⁴ In all of its manifestations, managed care has had a profound impact on the dynamics of health delivery, as it has altered the treatment process and realigned the balances of power in American medicine.⁵ Historically, managed care represented a structural vision of health delivery, combining the delivery and financing of health care. Interestingly, its roots lie in both a liberal and conservative vision of health delivery.⁶ While the earlier vision of managed care represented by health maintenance organizations (HMOs) is linked to preventive health care, that vision was quickly usurped by private and public purchasers who saw managed care primarily as a mechanism to contain health care costs.⁷ Structurally managed care has moved from well-

3. *Id.*

4. See generally WALTER A. ZELMAN & ROBERT A. BERENSON, *THE MANAGED CARE BLUES AND HOW TO CURE THEM* (1998); Geoffrey E. Harris et al., *Managed Care at a Crossroads: A Wall Street View of Managed Care's Mistakes and Misfortunes, and a Prognosis for Survival in an Increasingly Hostile Environment*, *HEALTH AFF.*, Jan.-Feb. 2000, at 157.

5. The medical literature contains many examples, mostly cast in negative terms, of how managed care has impacted American health care and medicine. For a discussion concerning the impacts of managed care on medical education and teaching hospitals, see KENNETH M. LUDMERER, *TIME TO HEAL: AMERICAN MEDICAL EDUCATION FROM THE TURN OF THE CENTURY TO THE ERA OF MANAGED CARE* 349-69 (1999). See also Marvin L. Auerback, *Will Managed Care Alter the Art and Soul of Medicine?*, *W. J. MED.*, Mar. 1994, at 269.

6. ZELMAN & BERENSON, *supra* note 4, at 49-52; Peter D. Fox, *An Overview of Managed Care*, in *ESSENTIALS OF MANAGED HEALTH CARE* (Peter R. Kongstvedt ed., 4th ed. 2001).

7. James Maxwell et al., *Managed Competition in Practice: 'Value Purchasing' by Fourteen Employers*, *HEALTH AFF.*, May-June 1998, at 216-17.

defined entities such as HMOs, to a looser arrangement, like preferred provider organizations (PPOs), to large health care corporations that offer multiple plans which are akin to product lines. Managed care has evolved into a package of services, readily altered to meet the demands and pressures of public and private purchasers. There are few signature elements left in managed care beyond prepayment, aggressive cost control mechanisms, drug formularies, and patient rights are present only as a result of a governmental response to public and professional political pressures.⁸

Clearly, managed care is a creature of the marketplace, and its development continues to be driven by economic factors sparked by purchasers who, in turn, are affected by government, consumers, and providers alike. Managed care not only emerged from the market, but managed care organizations (MCOs) have had a profound impact on the structure and alterations of local health care delivery. Changes in hospital structures over the last ten years are illustrative of the pressures placed on acute care by MCOs, as hospitals have undergone considerable internal reorganization and dramatic business realignments.⁹ Only the most fiscally fortunate hospitals remain independent, and the majority of acute care entities has not been able to maintain the status quo in the face of escalating economic concerns, many of which can be traced to managed care practices. To a degree, government has been replaced in some areas as the primary force in shaping the complexities of local health markets by dominant managed care plans and health insurers, whose policies, in turn, are motivated by the demands of purchasers for cost effective products.¹⁰

Competition is present in local health markets as institutions and provider groups scramble to survive in the face of ever-tightening fiscal and operational constraints spawned, in part, by managed care. In addition, MCOs compete with each other for employer and union contracts. Here, too, only the strong survive. There have been dramatic consolidations in managed care, and what has emerged is a field dominated by large national operations that offer a range of coverage options to cater to corporate purchasers who have taken a more aggressive posture toward health care purchasing and benefit

8. *Id.*; see also Lauren M. Walker, *The Quality Thing*, BUS. & HEALTH, 2001, at 44.

9. See Robin M. Weinick & Joel W. Cohen, *Leveling the Playing Field: Managed Care Enrollment and Hospital Use, 1987-1996*, HEALTH AFF., May-June 2000, at 178, 183.

10. See Meredith B. Rosenthal et al., *Managed Care and Market Power: Physician Organizations in Four Markets*, HEALTH AFF., Sept.-Oct. 2001, at 187.

determinations in their quest to control costs.¹¹ While competition is still the order of the day, competition in health care must be viewed against a backdrop of an evolving marketplace. Although it is difficult to generalize about the character of health markets, it appears that the MCO market has consolidated regionally and, in some instances, local health markets have also become dominated by key hospital groupings. What, then, is the nature of competition in consolidated markets? Can the benefits of competition be extracted from circumstances in which competition is limited by plan or provider entity dominance? To conclude that local markets have been shaped by managed care hits the mark, but seeing this as the end of the story sells the story short. It appears that local health markets experienced an evolution in market power, and now consolidation of hospital companies and medical groups has actually, for the moment, shifted the balance of power back to the health care side.¹² With cuts in the Balanced Budget Act of 1997, hospitals have had to be more aggressive in their negotiation demands with MCOs as they have sought to offset losses in the Medicare arena.¹³

II. QUALITY: THE LONG AND SHORT OF IT

It is against this backdrop of consolidated managed care plans, constrained local markets, and now an economic downturn, that the quality question must be evaluated. It is difficult to determine whether the current concerns over quality lie at the center of the managed care evolution, or are merely parallel to it. Clearly, it can be argued that some of the purchasers who drove the rise of managed care are now looking for more than just cost savings and related efficiencies in the delivery of health care programs. The fact is that the pricing of managed care and health insurance programs within the same markets is not likely to be drastically different, and so other factors, like scope of coverage and quality, become important barometers for purchasers. There are purchaser initiatives, such as the Leapfrog Group and regional business coalition programs, that are focused on quality improvement;

11. See Karen Titlow & Ezekial Emanuel, *Employer Decisions and the Seeds of Backlash*, 24 J. OF HEALTH POL'Y, POL. & L. 941, 944-46 (1999).

12. Leigh Page, *Doctors Find Bargaining Clout with HMO Contracts*, AM. MED. NEWS, Nov. 20, 2000, at 1; see also Julie A. Jacob, *Health Network Instability, Contract Disputes on Upswing*, AM. MED. NEWS, July 30, 2001, at 18.

13. See Page, *supra* note 12, at 1. There is an irony in this private sector evolution: although the actors may have been slightly different, a similar situation in terms of consolidation was envisioned in the Clinton health reform initiatives. James F. Blumstein, *Health Care Reform: The Policy Context*, 29 WAKE FOREST L. REV. 15, 17 (1994); See also Alain C. Enthoven, *A Good Health Care Idea Gone Bad*, WALL ST. J., Oct. 7, 1993, at A18.

this is indicative of expanding concerns about employee health plan performance.¹⁴ The rise of private managed care regulation and accreditation—in particular, the National Committee for Quality Assurance (NCQA) and the American Accreditation HealthCare Commission (URAC)—has been driven by purchaser concerns about quality.¹⁵ While noteworthy, however, it is not at all clear that the desire to achieve a higher level of quality in managed care settings has the same resonance or force of motivation as the overwhelming desire to find a cost-effective health care delivery system. Additionally, it is questionable whether quality initiatives can withstand the recent downturn in our economy.

A. Perspectives of Quality

Of the three major themes of American health care—cost, access, and quality—quality remains the most elusive. It is not a new quest to discover what quality health care is and how to promote it, but rather, it is an area of health policy that has been present throughout much of the last century.¹⁶ While it lies beyond the scope of this Article to review the details of how quality has been approached in American health policy, some reflections on developments in this area are warranted. The well-known health services researcher, Avedis Donabedian, has classified quality as being characterized by three primary perspectives: structure, process, and outcome.¹⁷ Using the three perspectives noted by Donabedian, the quest to identify and implement supporting strategies in the area of quality can be mapped out. The history of quality is not a linear one, but the perspectives noted are intertwined and continue to fuel the movement in this area, influencing the key players to identify and achieve higher levels of clinical effectiveness.

1. STRUCTURE

The original focus on quality was rooted in a structural approach and centered on the notion that if the physical circumstances of care

14. For information on the Leapfrog Group, see <http://www.leapfroggroup.org> (last visited Apr. 21, 2002).

15. Damon Adams, *Accreditation Extends to Trials, Offices*, AM. MED. NEWS, Aug. 27, 2001, at 11.

16. JOHN D. BLUM ET AL., PSROs AND THE LAW ch. 1 (1977).

17. 1 AVEDIS DONABEDIAN, EXPLORATIONS IN QUALITY ASSESSMENT AND MONITORING: THE DEFINITION OF QUALITY AND APPROACHES TO ITS ASSESSMENT 77 (1980).

could be controlled, the nature of the services would be optimized.¹⁸ Structural quality is reflected in licensure and in the broad initiatives sparked by the private sector to accredit individual health professionals and institutions. Few would argue that physical environments do not impact service delivery, but it seems unlikely that students of this subject would feel that structure alone is an adequate guarantor of quality health care. From a consumer standpoint, structural quality is perhaps the most understandable of the three quality perspectives; indeed, structure can have a profound influence on patient perspectives of health care delivery programs. Structure is also an area that regulators are best able to deal with, as it is subject to recognizable measurements which create a floor that is not as subjective as other aspects of quality.

2. PROCESS

Process as a perspective of quality has rather diffuse roots. To a certain extent, medical malpractice can be viewed as a system driving a process analysis of medical care in that it requires a deconstruction of events and a finding of error based on recognized standards. While the impact of medical malpractice on quality remains a contentious issue, it has been the catalyst for loss control and risk management efforts, which have resulted in consideration of the elements that collectively constitute patient care, primarily in the institutional setting.¹⁹ In a more conventional sense, consideration of process (or the elements that go into medical care) has been part of our medical culture for many years, dating back to surgical review committees (so-called tissue committees).²⁰ Utilization review (UR), a broad-based system of analysis of relevant aspects of medical care based on comparative statistical analysis, typifies a process-oriented approach to medical care.²¹

Even more process-oriented than utilization review were the methodologies devised by the Foundations for Medical Care (forerunners of the Independent Practice Association model of HMOs) for assessing whether hospital admissions were appropriate; these were

18. See, e.g., Troyen A. Brennan et al., *Hospital Characteristics Associated with Adverse Events and Substandard Care*, 265 JAMA 3265, 3269 (1991).

19. See generally Troyen A. Brennan & Marilyn Rosenthal, *Medical Malpractice Reform: The Current Proposals*, 10 J. GEN. INTERNAL MED. 211 (1995).

20. See generally Turner Osler & Lisa Horne, *Quality Assurance in the Surgical Intensive Care Unit: Where It Came from and Where It's Going*, 71 SURGICAL CLINICS N. AM. 887, 887-904 (1991).

21. 42 U.S.C. § 1395x(k) (1994); see also S. Rep. No. 89-404, pt. 1, at 47-48 (1965), reprinted in 1965 U.S.C.C.A.N. 1943, 1987-89.

known as certified hospital admission programs.²² Both UR and the Foundation review methodologies were incorporated into public and private payer assessments of medical care claims. The federal government, desperate to find ways to contain Medicare costs, adopted both UR and a hospital-based review program (Professional Standards Review Organizations), and these programs were heavily oriented to process review.²³ Public and private initiatives in quality assurance were based on processes that evolved over time and, as such, experienced continual reinvention and were affected by changes in methodologies and information technology.²⁴

3. OUTCOME

Beginning in the late 1970s, there was growing concern over discrepancies in clinical approaches to routine medical conditions, triggered by findings in studies that demonstrated widespread variations in practice.²⁵ Concern over variation in medical practice resulted in a broad based movement in health services research circles to evaluate current medical care in virtually all areas of medicine. This movement in evaluation, in turn, led to the development of multiple clinical practice guidelines, guidelines accompanied by outcome measures for treatment.²⁶ While process elements were inherent in practice guidelines, considerable attention was devoted toward assessment of how different approaches to care affected patient treatment outcomes. The movement of quality toward outcome research was driven also by data technologies, which provided new statistical armament for evaluation of medical practices regionally and nationally and sparked the field of clinical epidemiology.²⁷ While government, as a major payer of health care fees, continued to be consumed by cost concerns, it did move off its process-oriented focus toward quality and even supported a

22. C. Steinwald, *An Introduction to Foundations for Medical Care* (1971) (paper on file with National Blue Cross Blue Shield Association).

23. BLUM, *supra* note 16, at 11-13, 27-33.

24. See D. Blumenthal, *Part I: Quality of Care—What Is It?*, 335 NEW ENG. J. MED. 891, 892 (1996).

25. John Wennberg & Alan Gittelsohn, *Small Area Variations in Health Care Delivery*, 182 SCIENCE 1102, 1107 (1973).

26. See generally Arnold J. Rosoff, *The Role of Clinical Practice Guidelines in Health Care Reform*, 5 HEALTH MATRIX 369 (1995).

27. David Blumenthal, *Part 4: The Origins of the Quality-of-Care Debate*, 335 NEW ENG. J. MED. 1146, 1147 (1996).

small agency, the Agency for Healthcare Research and Quality, to spearhead federal initiatives in the area of outcomes research.²⁸

4. THE CONSUMER PERSPECTIVE

There is a fourth perspective concerning quality, one originating outside health services research and instead coming from a consumer vantage point. Reactions against managed care practices have galvanized the consumer movement to focus on health care abuses and have resulted in the public's partnership with organized medicine.²⁹ This Article's presence in a volume dedicated to public interest law is indicative of a new approach toward quality of care that was not present in earlier efforts to guarantee patient rights. The tools of consumer law endeavors—namely, community organization, grass-roots lobbying, and litigation—have been used against health plans as levers to protect the interests of patients and physicians alike.³⁰ The roots of this fourth perspective on quality can be found in consumer protection law, with its heavy emphasis on information access and the development of consumer rights to redress in administrative contexts.³¹ The consumer quest for quality, unlike the health services research movement, is not one which is searching for “clinical truths” but, rather, is a reaction to the corporatization of health delivery and is a movement seeking practical protections for patients. To be successful, however, the consumer movement must be cognizant of developments in the quality arena and discerning enough to utilize the new analytical tools of health services research to buttress its arguments.

B. A Struggle Toward Meaningful Change for Patients

All of the approaches noted in quality—structure, process, outcome, and public interest perspectives—are intertwined and, as such, have evolved and continue to develop together. A strong case can be made that the collective impact of health services research methodologies is the success of the quality of medical care; with

28. For more information on the Agency for Healthcare Research and Quality, visit their website at <http://www.ahrq.gov> (last visited Apr. 21, 2002).

29. Jeffrey N. Katz, *Patient Preferences and Health Disparities*, 286 JAMA 1506 (2001); see also Kenneth W. Kizer, *Establishing Health Care Performance Standards in an Era of Consumerism*, 286 JAMA 1213, 1213-14 (2001).

30. Louise G. Trubek, *Informing, Claiming, Contracting: Enforcement in the Managed Care Era*, 8 ANNALS HEALTH L. 133, 136 (1999); see also John V. Jacobi, *Patients at a Loss: Protecting Health Care Consumers Through Data Driven Quality Assurance*, 45 U. KAN. L. REV. 705, 731 (1997).

31. Trubek, *supra* note 30, at 136.

concerted efforts, knowledge gained from these different methodologies can be harnessed to improve the system. The challenge, though, is to translate the conceptual frameworks of quality into broader public policies that have meaningful implications for patients. The ability of the health system to direct concepts of quality improvement into practice no doubt exists, but a growing awareness of deficiencies in medicine calls into question the overall effects of quality initiatives, particularly those notions originating in the world of health services research.³²

1. COST CONTROLS

The shortcomings in realizing quality improvements are further magnified when medical care is placed into the managed care context, and while such a statement may be unfair, the negative perceptions surrounding managed care are difficult to overcome.³³ The cost control focus of managed care programs raises serious doubts about whether quality can be optimized in such environments. In theory, a managed care system which stresses primary care and prevention could yield both cost savings and health benefits, but much of managed care has simply deteriorated into discounted product offerings. The capstone characteristic of managed care—capitation, or the payment of a set fee per patient independent of treatment rendered—raises serious questions about whether a physician can make clinically prudent choices reflecting current quality of care in the face of concerns over balancing financial risks.³⁴ While MCO plans loudly argue that quality is not deterred by capitation or the more common discounted fee for service arrangement, aggregate statistical defenses do not easily change the biases of the medical profession and patient representatives—that reimbursement mechanisms wielded by managed care are not compatible with clinical excellence.³⁵

Linked to the visceral reactions against capitation, the code word for MCO cost containment, is a clear perception that public and private purchasers have gravitated to managed care first and foremost as a way

32. See INST. OF MED., *CROSSING THE QUALITY CHASM: A NEW HEALTH SYSTEM FOR THE 21ST CENTURY* 118 (2001).

33. Brian Vastag, *HMOs Report Quality Improvements*, 286 JAMA 1568, 1568 (2001). For a detailed review of the most recent report on HMO quality, see Nat'l Comm. for Quality Assurance, *The State of Managed Care Quality 2001*, <http://www.ncqa.org/somc2001/> (last visited Apr. 21, 2002).

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

35. See Vastag, *supra* note 33.

to contain health care expenditures.³⁶ Whatever developments are occurring in quality on the purchaser side are overwhelmed by a reality that health care costs are the major concern of government and business alike. The recent explosion in managed care does not rest on a vision of enhanced primary and preventive care but is founded upon a commitment to find the most appropriate delivery vehicles to meet mandates in the health care coverage area and to offer some hope that increasing costs can be controlled. MCO contracts are not renewed on the basis of cost alone, but if an MCO plan's charges are not competitive in a given market, high quality measures will not likely keep it in business. Indeed, the evolution of managed care into health care operations with multiple product lines is a development reflective of the fact that it is economics, not quality, that is underlying the movement toward buying and delivering medical care. Managed care corporations need flexibility in tailoring product offerings and creating physician networks, and while quality is an important variable, it is just that—one of several key variables. Even the most optimistic spin on purchasers' attitudes toward quality will need to be questioned in the future as recession economics shift even greater emphasis to cost control strategies. While it is foolhardy to draw conclusions about corporate and government behavior in recessions, it could be argued that the recent concerns about quality may prove to be a luxury of stronger economic times.

2. THE INSTITUTE OF MEDICINE REPORT

In late 1999, the Institute of Medicine (IOM) released a report on medical errors that created a sensation with its finding that between 44,000 and 98,000 deaths per year are caused by hospital errors.³⁷ The IOM findings resulted in a flurry of activity in both the public and private sectors, sparking efforts to examine the causes of medical errors, as well as finding ways to prevent them.³⁸ The IOM report not only highlighted a startling problem—the fact that so many serious errors occurred—but it also called into question the effectiveness of risk management and quality improvement efforts generally.³⁹ In light of the study's findings, it is certainly reasonable to consider whether the

36. Arnold S. Reisman, *What Market Values Are Doing to Medicine*, ATLANTIC, Mar. 1992, at 98, 105.

37. INST. OF MED., TO ERR IS HUMAN: BUILDING A SAFER HEALTH SYSTEM 26 (Linda T. Kohn et al. eds., 2000).

38. Elise C. Becher & Mark R. Chassin, *Improving Quality, Minimizing Error: Making It Happen*, HEALTH AFF., May-June 2001, at 68, 68.

39. See INST. OF MED., *supra* note 37, at 3.

longstanding efforts in quality measurement and improvement have had as significant an impact on the day-to-day operations of health care delivery organizations and the behavior of clinicians as may have been assumed. The medical error findings also resurrect the link between quality and medical malpractice, giving credence to an argument that tort law sanctions, regardless of the random nature of their application, have not yet outlived their usefulness.

The follow-up IOM report to the medical error study dealt directly with the broad issue of medical care quality.⁴⁰ The IOM's quality report presented an insightful analysis of the deficiencies in the quality of our present medical care system and, in so doing, underscored the disconnect between progress in quality improvement methodologies and applications. The study described a lack of coordination and communication among providers and between providers and patients, as well as a general lack of accountability to consumers.⁴¹ The IOM concluded its analysis with nine recommendations, in part calling for increased collaboration among all the stakeholders, more funding for quality initiatives, and expanded information capabilities.⁴² One IOM recommendation suggested that private and public purchasers work in a partnership with patients and clinicians to devise strategies to improve quality of care. This recommendation provides a springboard for creative approaches, such as the local advocacy model presented by Professor Trubek.⁴³ The IOM report on quality, viewed in conjunction with the 1997 Clinton Health Care Quality Commission Report, indicates quite clearly that managed care and the current delivery system generally have ignited widespread concerns over quality.⁴⁴ The issues raised, and solutions posited, have moved the public policy debate over quality into a broader forum, and the scope of this discussion is unprecedented.

3. THE FUTURE OF THE QUALITY MOVEMENT

We need to exercise some degree of caution before summarily dismissing years of efforts through health services researchers into measuring and improving quality. The problems we are experiencing with quality do not all stem from a lack of awareness about how to

40. See INST. OF MED., *supra* note 32, at 1-2.

41. *Id.* at ch. 1, "A New Health Care System for the 21st Century."

42. *Id.* at ch. 2, "Improving the 21st-Century Health Care System."

43. See Trubek, *supra* note 2, at 583-88.

44. PRESIDENT'S ADVISORY COMM'N ON CONSUMER PROTECTION & QUALITY IN THE HEALTH CARE INDUS., QUALITY FIRST: BETTER HEALTH CARE FOR ALL AMERICANS 1 (1998).

improve medical care but can be clearly traced to our collective inability to develop an efficient and safe delivery system. Still, from the prior discussion, it seems reasonable to conclude that there are various factors—practice objectives, medical errors, and a broad lack of policy direction in healthcare—that call into question the efficacy of the quality movement, as well as our abilities to innovate in this arena. Further compounding the problems of quality are concerns about providers' and payers' ability to effectively absorb the rapidity of scientific and technological advances and to efficiently integrate information technologies, such as the Internet, into the delivery of medical care.

Achieving quality in our complex medical care system is both a multi-faceted and multi-disciplinary challenge. Certainly, the IOM's call for partnerships will be essential to insuring that the necessary stakeholders are represented in future quality debates. It is only through alliances with medicine that consumers will get access to information and acquire the requisite knowledge that will be needed to gain leverage in this area. There is, however, a need to be wary of alliances, because parties in the struggle to develop and maintain a quality health care system may not always have similar agendas. As a result, there is a need for patient groups to avail themselves of legal representation as one strategy for maintaining their presence in health policy.

The impact of broad legal strategies has already been realized in managed care, as lobbying groups have made their presence felt in Washington, D.C., and state capitols, as well as in federal and state courts, litigating issues from narrow coverage disputes to major questions of health benefits law.⁴⁵ What the Trubek article demonstrates is that the lobbying and litigation roles of public interest groups must be expanded in current and future debates about quality of care and refocused into non-traditional advocacy roles at the local level. It is hard to take issue with Professor Trubek's premise that a new advocacy model is warranted, but that focus must not come at the expense of the more traditional roles of public interest law in courts and legislative bodies. The Trubek model rests on a premise that the nature of governance has shifted away from the traditional federal/state regulatory structure to action at the local level. While the arguments Trubek makes in support of the movement of power away from a more traditional framework are intriguing, an alternative approach to this argument

45. Ellen M. Yacknin, *Helping the Voices of Poverty to be Heard in the Health Care Reform Debate*, 60 BROOK. L. REV. 143, 146-47 (1994); see also Louise G. Trubek & Elizabeth A. Hoffmann, *Searching for a Balance in Universal Health Care Reform: Protection for the Disenfranchised Consumer*, 43 DEPAUL L. REV. 1081, 1084 (1994).

yields a different interpretation of where advocacy belongs in future health care policy debates.

III. REVISITING STRATEGIES AND GOVERNANCE

Undoubtedly, the charge of the advocate is rooted in a practical need to represent the public interest. Health care is no different in that regard, but how advocates map their strategies rests on an understanding of where there are points of leverage that can be influenced. As such, Professor Trubek's concepts of governance provide an essential framework for her vision of a new advocacy and are clearly worth revisiting, for it is important that the model fits the landscape.⁴⁶ This Article will consider, in reverse order, each of the three trends in governance identified by Trubek: movement downward, movement outward, and movement outside the regulatory box. In considering the movements outside and outward, these trends may be novel in consumer advocacy circles and do not seem off the mark, but neither one is a new development.

A. Governance Trends

1. MOVEMENT OUTSIDE THE REGULATORY BOX

In the quality arena, it can be argued that much of the action has been outside the regulatory box for some time. In fact, all major quality initiatives have originated outside of government; only later in their development have they been incorporated into federal and state programs as bureaucrats desperately sought solutions to the fundamental ills of publicly-funded health programs.

2. MOVEMENT OUTWARD

In the area of governance's movement outward, it is clear that the market has become a major factor in molding health policy. To a large extent, government has acquiesced to market forces and, in recent years, has taken a hands-off posture toward regulating markets, as evidenced by declining federal and state antitrust actions.⁴⁷ Managed care, as previously noted, is a creature of the market, and even in the highly bureaucratic reform mechanisms of the Clinton health plan, it was

46. See Trubek, *supra* note 2, at 583-88.

47. For an interesting analysis of the role of antitrust law in a market-driven health care system, see James C. Robinson, *The Dynamics and Limits of Corporate Growth in Health Care*, HEALTH AFF., Summer 1996, at 155.

competition which would have been the ultimate tool of control.⁴⁸ Professor Trubek points out that it is not only the market, but other creatures of the private sector—such as the National Committee for Quality Assurance (NCQA), with its program of private regulation through accreditation—that have come to set the health care agenda.⁴⁹ There seems to be no question that the private sector is having a profound influence on both the design and control of health care, and effective advocacy must follow this shift outward. In relationship to quality, the outward movement as characterized by Trubek seems to be, in a sense, more novel than the movement outside the box. The history of quality regulation demonstrates that a fairly heavy-handed and process-oriented series of programs have been tried by government.⁵⁰ It is only more recently that government has backed off from its more regulated approach to quality and allowed greater flexibility in quality improvement initiatives.⁵¹ Still, the outward movement of governance into the market is not entirely new. Health care, both publicly and privately supported, is traditionally delivered in the private sector, and health policies of every ilk have been shaped there as much as in the corridors of government.

3. MOVEMENT DOWNWARD

The first area of movement touched on by Professor Trubek concerns the movement of regulation downward from the federal to the state level. Certainly, there is an interesting and complicated series of federalism issues that underpin the area of health policy.⁵² Starting with the state's role as guarantor of health and welfare through the Tenth Amendment, states have played a critical part in health care policy and delivery. However, the more recent history of state health policy in the managed care context does not so much reflect a conscious devolution of policy or a concerted attempt to bolster state powers, as much as it reflects a vacuum in federal power or a deliberate attempt to transfer

48. Theda Skocpol, *The Rise and Resounding Demise of the Clinton Plan*, HEALTH AFF., Spring 1995, at 66, 69.

49. Gail R. Wilensky, *Promoting Quality: A Public Policy View*, HEALTH AFF., May-June 1997, at 77, 78 (describing the emergence of the NCQA as a leading voice in quality).

50. See Stephen F. Jencks & Gail R. Wilensky, *The Health Care Quality Improvement Initiative: A New Approach to Quality Assurance in Medicare*, 268 JAMA 900, 900 (1992).

51. *Id.*

52. John D. Blum, *Overcoming Managed Care Regulatory Chaos Through a Restructured Federalism*, 11 HEALTH MATRIX 327 (2001).

responsibilities away from Washington.⁵³ Welfare reform is a good case in point: it reflects a broad-based movement to shift responsibilities off the shoulders of the federal government to the states.⁵⁴ If politics had allowed for it, health care would have experienced a similar transference in the area of Medicaid, as the parallel goal of welfare reform was to place Title 19 of the Social Security Act into a block grant format.⁵⁵

The recent shifts in authority downward do not reflect a belief in state governments' abilities, but rather reflect an ongoing belief on the part of federal lawmakers that the national government needs to be released of some of its obligations. Transference can be a strategy for Washington to seemingly do more without being burdened with daily administrative responsibilities.⁵⁶ The states, for their part, are often willing to take on new mandates if it gets them "out from under" federal controls and allows states to increase their budgets. The posture of most state governors toward federalism can be bluntly summed up with the phrase: "give me the money and leave us alone." This attitude is further underscored by the National Governor Association's ongoing campaign against unfunded mandates.⁵⁷

A great deal of legal commentary has focused on federalism in light of the United States Supreme Court's recent opinions in the area.⁵⁸ A careful examination of the current federalism opinions demonstrates that these decisions do nothing to alter Congress's ability to use the power of the purse to circumvent the states, and if an arm of the federal government is limited by the Court, it is the federal courts, not Congress, that are most directly affected.⁵⁹ The Clinton administration

53. Douglas A. Hastings provides a detailed review of managed care legislation and regulation geared toward system reforms. It is clear from his review that states have actually accomplished more in this area than the federal government, where politics has stalled reforms. See generally Douglas A. Hastings, *Patient Rights Meet Managed Care: Understanding the Underlying Conflicts*, 31 J. HEALTH L. 241 (1998).

54. Rachel Batterson, Note, "States' Rights" and Self-Sufficiency or Federally-Imposed Draconia? The Personal Responsibility and Work Opportunity Reconciliation Act's Impact on Vermont's Welfare Policy, 7 GEO. J. ON POVERTY L. & POL'Y 21, 23 (2000).

55. See Michael S. Sparer, *Great Expectations: The Limits of State Health Care Reform*, HEALTH AFF., Winter 1995, at 191, 191.

56. See *id.* Sparer points out that states are not good substitutes for federal inaction. *Id.* at 192.

57. Cf. FEDERALISM & SEPARATION OF POWERS PRACTICE GROUP, FEDERALIST SOC'Y, FEDERALISM: A TENTH AMENDMENT AND ENUMERATED POWERS REVIVAL?, <http://www.federalismproject.org/whatsnew/fedsoc.html> (last visited Apr. 15, 2002).

58. See generally Frank B. Cross & Emerson H. Tiller, *The Three Faces of Federalism: An Empirical Assessment of Supreme Court Federalism Jurisprudence*, 73 S. CAL. L. REV. 741 (2000).

59. See generally MICHAEL S. GREVE, REAL FEDERALISM: WHY IT MATTERS, HOW IT COULD HAPPEN 21 (1999).

issued Executive Order 13,083, which dealt with federalism and bolstered federal power, but it was rescinded as a result of opposition from state governors.⁶⁰ During the George W. Bush administration, a seemingly more conciliatory approach towards the states was included as an early administration agenda item,⁶¹ but this appears to have given way to the realities of a post-September 11th world in which Washington needs to retain considerable power, particularly in areas involving public health threats such as bioterrorism.

As far as managed care is concerned, there is no question that the states have rushed to fill in the gaps left by federal inaction.⁶² Washington has debated the merits of a patient bill of rights addressing consumer and provider concerns alike, but the debate has been deadlocked on political issues for several years, and the best that the federal government can do is to usher in new protections through administrative processes.⁶³ State legislators have discovered that addressing managed care abuses has a certain appeal and that laws in this area are popular with most constituencies. The result has been an explosion of state laws requiring coverage mandates, limiting perceived abusive practices of managed care programs, and providing consumer remedies such as access to information and third-party appeals.⁶⁴ The difficulty with this legislative activity is that state laws which touch on health plans regulated by the federal Employee Retirement Income Security Act (ERISA) may be subject to federal preemption, and this possibility has triggered a number of rather complicated and tortured judicial tests.⁶⁵ In trying to regulate managed care plans, states are further challenged by the fluidity in MCO operations and structures and by the lack of bureaucratic regulatory infrastructures to deal with such rapid change as state departments of insurance have been overwhelmed with new mandates.

60. Exec. Order No. 13,083, 63 Fed. Reg. 27,651 (May 14, 1998).

61. Ruben Barrales, *Federalism in the Bush Administration*, SPECTRUM, Summer 2001, at 5-6.

62. Robert L. Roth, *The Little Red Hen Syndrome: States and "Anti-Managed" Care Laws*, in 2 ALICE G. GOSFIELD, GUIDE TO KEY LEGAL ISSUES IN MANAGED CARE QUALITY 133 (1996).

63. See new patient right provisions under ERISA, 66 Fed. Reg. 70246 (Nov. 21, 2000) (codified at 29 C.F.R. pt. 2560.503-1). See generally DEP'T OF HEALTH & HUMAN SERVS., STATUS OF IMPLEMENTATION OF THE CONSUMER BILL OF RIGHTS AND RESPONSIBILITIES IN THE DEPARTMENT OF HEALTH AND HUMAN SERVICES (Nov. 2, 1998), <http://aspe.hhs.gov/health/vpreport.htm> (last visited Apr. 15, 2002).

64. See Hastings, *supra* note 53.

65. Clark C. Havighurst, *American Health Care and the Law—We Need To Talk!*, HEALTH AFF., July-Aug. 2000, at 84, 92-93.

B. The Role of the Federal Government

In considering the shift in governance from the federal to state and local levels highlighted by Professor Trubek, transference of power in health policy may not be an entirely downward and outward movement. Perhaps in the wake of September 11th, the power of the federal government has come into sharper focus, but it seems reasonable to argue that government power in health care, while somewhat diffused, has resided, and continues to reside, at the national level. Since the dawn of Medicare and Medicaid in the mid-1960s, Washington has played a central role in the financing and delivery of health care. Federal policy, and reactions to it, often dominate local health care enterprises. Indeed, the recent history of Medicare demonstrates a willingness on the part of Washington to expand its role in the face of state rigidity, as shown by the creation of federal licensure for certain managed care plans, such as provider sponsored organizations (PSOs).⁶⁶ The ongoing and massive Medicare/Medicaid fraud and abuse initiatives are examples of federal policies that have had dramatic impacts on the structure and practices of local health care delivery systems.⁶⁷ Local health care issues that spark national debate often find their way into federal policy, as can be seen most vividly in Congress's enactment of requirements for hospital emergency rooms to not deny care to uninsured or indigent patients under the Emergency Medical Treatment and Active Labor Act (EMTALA).⁶⁸

In 1996, the federal government enacted the Health Insurance Portability and Accountability Act (HIPAA).⁶⁹ HIPAA illustrates the willingness of the federal government to expand its regulatory orbit into areas that were traditionally left to the exclusive purview of the state.⁷⁰ In particular, HIPAA establishes a regulatory scheme that affects group and individual health insurance markets in unprecedented ways. Insurance regulation, traditionally a matter of state control, is now

66. 42 U.S.C. § 1395w-25 (Supp. V 1999); 42 C.F.R. § 422 (2001).

67. Thomas H. Stanton, *Fraud-and-Abuse Enforcement in Medicare: Finding Middle Ground*, HEALTH AFF., July-Aug. 2001, at 28, 29.

68. Caroline J. Stalker, Comment, *How Far is Too Far?: EMTALA Moves From the Emergency Room to Off-Campus Entities*, 36 WAKE FOREST L. REV. 823 (2001).

69. Health Insurance Portability and Accountability Act, Pub. L. No. 104-91, 110 Stat. 1936 (1996).

70. Karen Pollitz et al., *Early Experience with 'New Federalism' in Health Insurance Regulation*, HEALTH AFF., July-Aug. 2000, at 7, 8; Jack A. Rovner, *Federal Regulation Comes to Private Health Care Financing: The Group Health Insurance Provisions of the Health Insurance Portability and Accountability Act of 1996*, 7 ANNALS HEALTH L. 183, 213 (1998).

dictated in some areas by federal policies.⁷¹ HIPAA has also introduced an elaborate set of regulatory controls affecting the privacy of medical records, another area that was typically a matter of state law.⁷² In addition, as private employers have become the major suppliers of health care coverage,⁷³ most of the employer-sponsored health plans are governed by ERISA, which complicates state regulation of health insurance considering the complex federal preemption provision. ERISA-qualified plans are not regulated at the state and local level, but are largely subject to the jurisdiction of the United States Department of Labor.⁷⁴ In the areas mentioned above, states still play a major role, but the recent federal initiatives have ushered in an increasingly confused regulatory landscape in which harmonization between federal and state controls poses major challenges.

In the area of managed care, Congress may still be debating patient protection legislation, but it has taken action by requiring a series of coverage mandates that are directed at managed care plans or clearly implicate them. Examples include regulatory schemes, such as mental health parity, a ban on drive-through deliveries, and a renewed initiative on children's health care.⁷⁵ It appears to be only a matter of time before a federal patients' bill of rights will be enacted, directed toward providing federal remedies for abuses in the managed care sector. While it is likely that whatever scheme Washington constructs for patient rights will be based on creating a federal floor that states can build on, once such legislation is in place, much of the local action in patient advocacy in managed care will be dependent on resultant federal policies and regulations. The variability of state responses to managed care problems may offer interesting laboratories in which to experiment on new regulatory approaches, but the need for consistency and uniformity in consumer rights is a powerful argument underlying a national scheme of protections. The fact is, with the current dominance of ERISA in private sector health care coverage, the federal government

71. Rovner, *supra* note 70, at 184.

72. Rob Cunningham, *Old Before Its Time: HIPAA and E-Health Policy*, HEALTH AFF., Nov.-Dec. 2000, at 231, 231.

73. Judith R. Lave et al., *Changing the Employer-Sponsored Health Plan System: The Views of Employees in Large Firms*, HEALTH AFF., July-Aug. 1999, at 112, 112.

74. Gregory Acs et al., *Self-Insured Employer Health Plans: Prevalence, Profile, Provisions, and Premiums*, HEALTH AFF., Summer 1996, at 266, 266; see also Karl Polzer & Patricia A. Butler, *Employee Health Plan Protections Under ERISA*, HEALTH AFF., Sept.-Oct. 1997, at 93, 94.

75. Parity in Application of Certain Limits to Mental Health Benefits, 42 U.S.C. § 300gg-5(a)(1)-(2) (Supp. V 1999); Standards Relating to Benefits for Mothers and Newborns, 29 U.S.C. § 1185 (Supp. V 1999); State Children's Health Insurance Program, 42 U.S.C. § 1397aa-ij (Supp. V 1999).

has a structure in place to mold consumer rights in ways unavailable to the states.

C. Practical Implications

This Article's evaluation of the movements in health care governance clearly differs from Professor Trubek's, but ultimately the question arises about the practical implications of what a different vision of governance may mean for health care advocacy. If the movement in health care governance is less clearly downward than Professor Trubek suggests, and if going outside and beyond the regulatory box is more a matter of strategy than a new vision of regulatory structure, do such conclusions diminish the model of local level advocacy? Indeed, from a practical standpoint, it appears that Professor Trubek presents a model of advocacy that forges new partnerships and stresses decision-making processes that are both promising and novel. Clearly, advocates in the future need to step out of traditional roles, look beyond legislative and judicial forums, and focus activities at points where key decisions are made and implemented. Health advocates need to capitalize on the mutuality of interests that managed care has sparked between patients and providers and build on the partnership as long as it lasts. In the area of quality improvement, this partnership opens up ways to tap into recent innovations in medicine, which stress preference-based care standards, or the emerging standards of the National Quality Forum, which contain a strong consumer bias.⁷⁶ While consumers may make great progress in self-education and use the Internet to empower their movement, the technical nature of medical care quality will pose a barrier to patient advocates without meaningful medical partnerships in this area.

While Professor Trubek's model of advocacy is noteworthy, it certainly rests on the analysis of the three changes in governance previously referenced. Because this Article presents a different vision of governance, it is only natural that it will result in an alternative view of advocacy as well. There is nothing inherently wrong with the Trubek model of local advocacy, and much of it is commendable, but future health advocacy needs to cast its net more broadly.⁷⁷ Advocates will

76. Tracy Miller & Sheila Leatherman, *The National Quality Forum: A 'Me-Too' or a Breakthrough in Quality Measurement and Reporting?*, HEALTH AFF., Nov.-Dec. 1999, at 233, 233.

75. There is no question that politics is a reality that any health care advocacy group will need to confront, and so the Trubek model of governance, and any other such model, must be implemented with a keen sense of the political dynamics of a given environment. The political barriers found at the national and state levels may make local advocacy a more attractive and feasible venue for grass-roots organizations. Local

need to maintain and even increase their presence at the federal level, since Washington continues to wield considerable power over health delivery through Medicare and Medicaid, as well as a broad range of health care issues previously noted.

A particular area of vigilance for advocates must lie at the points where federal and state policies intersect. It will be critical for consumer groups to appreciate the implications of federalism within the framework of established and emerging areas of health policy.⁷⁸ As noted, we have been in a period recently in which the federal government has been inclined to move into areas traditionally within the exclusive purview of the states. We are likely to have a federal patient protection bill that will create challenges of harmonization, since virtually every state has existing laws in this area. As more overlap in legislation occurs, advocates will need to have a clear view of the practical implications of dual regulatory schemes and work in support of positions which are most beneficial to individual patients. State regulation may appear more accessible, and may be more easily influenced, but there will be occasions where a federal regulatory

governments, however, present formidable political challenges, and a sense that progress can be achieved more easily at this level may soon be tempered by an understanding that politics at all levels of government is a variable that should never be overlooked.

Cook County, Illinois, represents a good case in point. Local politics has skewed health policy in ways that may not be in the public interest. In recent years, a decision has been made by the Cook County Board to replace its aging hospital, Cook County Hospital, with a new, scaled-down facility. The new facility will cost the county \$550 million to build. It is a project that has been agreed upon by County Commissioners in the face of a declining census at the current hospital, and a strong sense on the part of local health care leaders that sufficient bed capacity in the county exists to absorb indigent and public aid patients in other hospitals. In addition, many in the health policy community believe that the poor (the constituency of Cook County Hospital) would be better served by creating a coordinated delivery system, focused on community and public health services, rather than the creation of a costly, unnecessary new acute care facility. In commenting on the new facility, the Chicago Tribune editorialized that "the hospital has become just another political fiefdom in the county's patronage-rich domain," and went on to characterize the county's approval of a new hospital as an example of "clubbiness and clout." Editorial, *The Loss of a World Famous Name*, CHI. TRIB., Dec. 20, 2001, 2001 WL 30803828. Further illustrating the political overlay affecting Cook County Hospital is the fact that a facility whose name has been synonymous with indigent health care for over one hundred years will have its name changed to Stroger Hospital, in honor of a current county board president who was not even the catalyst behind building the new facility.

While I am not suggesting that Cook County is the world, the current building of a new public hospital is illustrative of the power of local politics. For example, the existence of local political forces working for their own interests may buttress the need for governance models such as the one advocated by Professor Trubek, but it should also give advocates pause, as they must realize that influencing local government policies will present formidable political challenges in their own right.

78. Blum, *supra* note 52, at 343-47.

scheme may be more patient-friendly. In addition to monitoring and advocating in areas concerning federalism and health policy, health advocates will need to be engaged in matters of budget policy. Recession economics will place all government programs under tighter fiscal control, and there will be a temptation on the part of bureaucrats to put quality initiatives on the back burner. A general reluctance may emerge regarding promotion of new approaches to quality, particularly those that have major budget implications.⁷⁹

IV. CONCLUSION

In light of the uncertainties in the delivery system and the economy, consumer advocates will need to be vigilant on all fronts. Indeed, local strategies, such as the ones suggested by Professor Trubek, will need to be pursued, but not at the expense of a focus on other levels of health policy-making. While new advocacy strategies will need to be created, old ones such as litigation and engagement in the administrative process still need to be pursued. Future movements in governance are unpredictable in our current state of fluidity, and even in the “good old days” before September 11th, the movement of governance has been far more convoluted than the Trubek analysis indicates. Not only has the future of health policy-making been clouded after September 11th, but the viability of the quality of care debate of the 1990s must also be called into question. It seems likely that in times of recession, new federal deficits, and strained state budgets, the high end of quality—acute care medicine—will be pitted against broad-based population and public health needs. Consumer advocates in our new world of recession and terrorism need a clear grasp of the focal points in the quality debate and will have to make hard choices about priorities and strategies. Uninformed choices could splinter the public-professional coalitions of the late 1990s. Advocates will need to consider a range of approaches concerning how best to influence quality of care issues and, in making such determinations, be cognizant of how much power over the health care system still resides at the federal level. The business of health care may be local (or at most regional), and ultimately quality resides at the bedside, but the levers of power in health policy are diffuse. As such, consumer health advocates in the future will need to adopt strategies pointed in multiple directions.

79. Elizabeth White, *Congress: Much Talk, Little Action on Health Care Issues Expected in 2002*, 10 BNA'S HEALTH CARE POLICY REPORT 99 (2002).

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