1-1-1994

Beyond Informed Consent

Anthony H. Szczygiel
University at Buffalo School of Law

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ANTHONY SZCZYGIEL*

I. INTRODUCTION

The role of a patient in determining the course of medical treatment has evolved over time in response to changes in the status of physicians and medical knowledge. Ideas about a patient's right of self determination are continuing to develop, increasingly emphasizing the patient-provider relationship as a cooperative venture. This trend is supported by newly articulated professional medical ethics. However, structural changes within the medical care industry and budget driven initiatives designed to change the way medicine is practiced threaten to overwhelm this movement toward fuller patient participation. One important issue in the evolving process of medical care giving is how the patient-provider relationship will be affected by these changes. A related concern is how best to define and support effective patient participation in the evolving process of medical decision making.

The legal system has had a limited, but important, impact on the evolution of the patient-provider relationship. In the twentieth century, we can identify two periods of intense development in the law directly focused on patient decision making: the Era of Consent (roughly 1905 to 1930) and the Era of Informed Consent (roughly 1957 to present). The courts played a leading role in both eras as the forum in which new interactive norms were articulated, publicized, and enforced.[1] Legal responsibilities placed on medical professionals reflect, in part, concerns about the risks borne by patients who rely on the professional's advice or treatment. Legal standards evolved to give greater weight to patient autonomy by creating a role for patients in determining whether to undertake the risks of treatment.[2]

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* Clinical Associate Professor at the SUNY at Buffalo School of Law. B.A., 1972, with honors in Economics, SUNY at Buffalo; J.D., 1975, University of California, Berkeley (Boalt Hall) Law School.

1. RUTH R. FADEN & TOM L. BEAUCHAMP, A HISTORY AND THEORY OF INFORMED CONSENT 142 (1986) [hereinafter FADEN & BEAUCHAMP]. State legislatures had a limited involvement during the Era of Informed Consent. They responded to limit the common law rejection of professional practice standards in informed consent cases. FADEN & BEAUCHAMP, *supra* at 114-143.

2. See FADEN & BEAUCHAMP, *supra* note 1, at 114-143.

The development of the informed consent doctrines in the courts and state legislatures is a story nearing its final chapter.[3] Every U.S. jurisdiction has adopted an informed consent doctrine and has chosen a minimal disclosure standard.[4] With few exceptions, the standards have not changed in the past ten years.[5] Surprisingly, the medical profession has recently revitalized the doctrine for one more round of policy development by providing a new definition of what is expected from a reasonable practitioner.[6] New ethics code provisions reassert the profession's role in defining the provider-patient relationship, while recognizing a patient's right to self determination.[7] The principles adopted go beyond the doctrines established by the courts and legislatures, both in their scope and the extent to which the patient's choices are to be respected.[8]

These developments raise the possibility that the patient-medical professional relationship may be moving beyond the minimal requirements of current informed consent doctrine. However, a host of developments, including budgetary restraints, increased reliance on management of care, a decline in the status of physicians, and the continuing depersonalization of individual medical care are challenging this opportunity. Choices being made now to reform the health care system will determine whether patient involvement will sink to the level of a "Medical Miranda Warning"[9] or evolve toward a process that more actively involves the patient.

In response to the problems of limited access to medical care and sharply rising costs, insurance companies, employers, government and other payers are experimenting with initiatives designed to change the practice of medicine. These programs have a special emphasis on the physician's role. One major change is the explicit consideration of cost in treatment decisions. Long standing deference to professional

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3. See FADEN AND BEAUCHAMP, *supra* note 1; PRESIDENT'S COMMISSION FOR THE STUDY OF ETHICAL PROBLEMS IN MEDICINE AND BIOMEDICAL RESEARCH, A REPORT ON THE ETHICAL AND LEGAL IMPLICATIONS OF INFORMED CONSENT IN THE PATIENT-PRACTITIONER RELATIONSHIP (October 1982) [hereinafter PRESIDENT'S COMMISSION].

4. *See infra* Section III(F) text and accompanying footnotes.

5. *Id.*

6. See AMA PRINCIPLES OF MEDICAL ETHICS, *reprinted in* JUDICIAL COUNCIL OF THE AMERICAN MEDICAL ASSOCIATION, CURRENT OPINIONS OF THE JUDICIAL COUNCIL OF THE AMERICAN MEDICAL ASSOCIATION - 1981 [hereinafter CURRENT OPINIONS - 1981]; AMERICAN COLLEGE OF PHYSICIANS, ETHICS MANUAL, *reprinted in* 101 ANNALS OF INTERN. MED., 129-37, 263-74 (1984) [hereinafter ETHICS MANUAL].

7. CURRENT OPINIONS - 1981; ETHICS MANUAL, *supra* note 6.

8. This codification in the professional ethic brought an end to the policy debate over the general desirability of patient participation. Patient participation is now a component of medical care quality, measured by the extent to which professional culture and practice match the expectations of patients and, more generally, society.

9. ALAN MEISEL, THE RIGHT TO DIE § 2.5, at 21, 22 (1989).

self-regulation is giving way to reimbursement methodologies and utilization review standards designed to encourage cost awareness in medical providers and to reduce variations in practice patterns. Reimbursement methodologies are being redesigned to influence the amount and type of medical care provided. New approaches to utilization review will intensify the pressure to make choosing the most cost-effective regimen of care a part of professional responsibility.

Further change is occurring because the medical care industry is restructuring itself in response to changing demographics and care needs, as well as in response to the new reimbursement trends. Managed care exemplifies these changes. The various forms of managed care share the characteristics of bringing the insurance risk to bear more directly on treatment decisions. Participating providers agree to abide by group practice protocols. In this process, physicians cede some of their clinical discretion to medical care administrators. Patients find themselves dealing with a medical care group rather than the prototypical family doctor.

The complexity of the systems and the novelty of the means of intervention are producing very mixed results. The changes have slightly narrowed the gap between the rate of medical care inflation and the overall rate of inflation. However, the private sector has been cutting back on the medical coverage it provides faster than the public sector has been expanding its coverage. This set the stage for the Clinton Administration's far-reaching proposal to extend medical coverage and impose cost containment mechanisms:[10] the Health Security Act.[11] Unlike in prior eras, federal policy is playing a leading role in how the new patient-provider relationship develops. The failure of Congress to enact the Health Security Act or any of the competing bills will slow, but not stop, the pace of change.[12]

The changes underway will significantly affect the interaction between medical professionals and patients in ways intended and unforeseen. The net impact on the role of the patient will be determined by the reaction of the medical providers, the balance struck

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10. *See* Renee Blankenau, *CBO Study Takes Technical Angle, Leaves Politics for Congress; Congressional Budget Office Study on Healthcare Reform*, HOSPITALS, Mar. 5, 1994, at 14; *Clinton Plan Will Reduce Deficit Less Than Earlier Estimated, Moynihan Says*, 2 HEALTH L. REP. (BNA) 42 (Oct. 25, 1993); Thomas Scarlett, *Killing Health Care Reform: How Clinton's Opponents Used a Political Media Campaign to Lobby Congress and Sway Public Opinion*, CAMPAIGNS & ELECTIONS (Nexis-Current News) (Oct. 1994).

11. H.R. 3600, 103d Cong., 1st Sess. (1993); S. 1757, 103d Cong., 1st Sess. (1993). Slightly altered versions were introduced in the Senate. S. 1775, 103d Cong., 1st Sess. (1993); S. 1779, 103d Cong., 1st Sess. (1993).

12. The Congress failed to enact any version of the Health Security Act prior to the close of the 1994 legislative session.

between cost and quality, the effectiveness of administrative oversight, and the extent to which patient participation can be statistically measured. Current informed consent doctrines will be relegated to a minor role as we move toward a cost conscious system of medical care with more standardized treatments.

Cost containment measures will limit the alternatives available to both patients and health care professionals. A more widespread and subtle impact will be reflected in the type of information provided to patients, as well as in the provider's assessment of the patient's needs.[13] Further, the ongoing changes greatly increase the supervision of providers' relationships with patients by third parties. Increased supervision and the concomitant setting of standards for quality and quantity of service may combine to enhance patient autonomy by making patient participation an explicit standard for job performance and reimbursement. To date, however, the utilization review standards and practice guidelines have focused on cost of care or the technical aspects of diagnosis and treatment. Expanded access will provide more individuals with the opportunity for meaningful participation in their own care, but will infringe on the providers' tradition of selecting who they will serve. The new organizational structure of care may limit the medical professional's sense of responsibility for the patient's welfare. These important and potentially contradictory effects of the new public agenda in medicine require careful consideration as the new era unfolds. There is a danger that these policy choices will denigrate the importance of the interaction of provider and patient.

This article will review the evolution of the provider-patient relationship and define some possibilities for the new era.[14] Parts II, III, and IV describe the law's response to increasing awareness of the importance of protecting patient autonomy. The legal rules affecting

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13. The difficulty in choosing the services to restrict has renewed efforts to develop better information on the impact and limitations of medical care. A growing body of outcomes research is being produced and processed into practice guidelines. Some professionals are concerned this will lead to "cookbook medicine," while patients may find a growing intolerance for personal values not reflected in the guidelines. *See generally* INSTITUTE OF MEDICINE, CLINICAL PRACTICE GUIDELINES: DIRECTIONS FOR A NEW PROGRAM (Marilyn J. Field & Kathleen N. Lohr eds., 1990).

14. The thorny issues related to medical decisions that may lead to death, the use of surrogate decision makers without statutory authorization and the standard of decision that courts are to apply when they are called upon to decide on medical care for an incompetent person are closely related to the topic of this article. However, this article will not directly deal with them. Much of the writing on these important issues assumes the starting point of a competent person's "right" to determine his or her own medical care, without examining the extent or limitations of that right. For a critique of this line of reasoning, see, Lee A. Albert, Cruzan v. Director, Mo. Dep't of Health; *Too Much Ado*, 12 J. LEG. MED. 331 (1990).

participation in decisions about medical treatment had their origin in tort law. These were the battery rules to protect bodily integrity (battery). These rules later evolved to take account of the fact that patients must understand the nature of a physical invasion before consent to it can be meaningful (informed consent). The early fight for patients' rights in the doctor-patient relationship was carried on largely in the courts.[15] In recent years, concerns for patient autonomy have become part of the fundamental health care policy debate and have been incorporated into the AMA's Revised Code of Professional Ethics.[16]

This history of the development of legal standards for informed consent provides a context for Part V which examines the changes defining the next era in medical delivery. These will, in turn, shape the evolution of the medical provider-patient relationship. The variety of forces at work, as well as the differing agendas of the interest groups most affected, make it difficult to predict the outcome. Nevertheless, immediate attention is needed to assess whether these major changes will erode the progress made toward involving patients in the decisionmaking process of their own health care.[17]

II. THE ERA OF CONSENT (1905-1930).

Changes in medical technology and the social context of medicine have repeatedly tested the limits of established legal doctrine. The early twentieth century saw a marked change in the delivery of medical care. What we now call conventional medicine overpowered the competing sects of medical care providers.[18] Government involvement in the form of restrictive licensing laws came at the request of the emerging profession.[19] The intent and effect of these rules were to eliminate or marginalize competing providers groups, to restrict entry into the profession, and to professionally define the minimum level of practice of conventional practitioners.[20] As new techniques of

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15. FADEN & BEAUCHAMP, *supra* note 1, at 142-3.

16. *See generally* AMERICAN MEDICAL ASSOCIATION, PRINCIPLES OF MEDICAL ETHICS.

17. In this article, "medical care" will mean the services licensed medical practitioners provide to specific individuals. "Health care" will encompass the more general notion of care an individual takes of herself, including the services sought from others. "Public health" will refer to those steps taken by governmental agencies designed to affect the health status of groups.

18. See FADEN & BEAUCHAMP, *supra* note 1, at 85; KENNETH M. LUDMERRER, LEARNING TO HEAL: THE DEVELOPMENT OF AMERICAN MEDICAL EDUCATION 234-54 (1985). It is curious that our society has failed to find a better title for the particular school of medicine that has dominated the 20th Century.

19. LUDMERRER, *supra* note 18, at 237-38, 240.

20. *Id.* at 249-54.

surgery and anesthesia came into widespread use, hospitals grew in size and importance.

These changes inevitably affected the patient-medical professional relationship. One aspect of that interaction, the surgeon's discretion to extend an operation on an anesthetized patient beyond that agreed to by the patient, produced a flurry of court decisions.[21] The cases affirmed a broad principle of patient autonomy and laid the groundwork for a later series of conflicts over the content of the disclosure by the provider.[22]

A. A Short History of 19th Century Medical Ethics and Practice.

We have very limited knowledge of the historical disclosure and consent practices of physicians or other medical professionals. Patients' medical records routinely include the provider's clinical observations, medications prescribed, and procedures performed but rarely the content of what was discussed between provider and patient. Nor do other sources enlighten us on this topic.[23] As one scholar concluded,

> [N]ever in the history of professionally articulated ethics had there ever been any acknowledgement of the patient as a dignified agent free to participate in and exercise self- determination over medical decisions. Not in the Hippocratic Oath, not in the prayer of Maimonides, not in Percival's ethics, the codes of the AMA or the World Medical Association.[24]

Not until the 1980's was the patient's role in decision making acknowledged in written medical ethics.[25] This absence has historical origins. The 19th century European codes of ethics for physicians and the later U.S. codes that emulated them were primarily intraprofessional rules of conduct. The 1803 *Code of Medical Ethics* authored by Thomas Percival in England is acknowledged as the most influ-

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21. Mohr v. Williams, 104 N.W.12 (Minn. 1905); Pratt v. Davis, 79 N.E. 562 (Ill. 1906); Schloendorff v. Society of New York Hospitals, 105 N.E. 92 (N.Y. 1914).

22. FADEN & BEAUCHAMP, *supra* note 1, at 120-25.

23. Scholars only began to seriously study the history of consent giving by medical patients in the 1960s. *See, e.g.*, William H. Karchmer, *Informed Consent: A Plaintiff's Medical Malpractice "Wonder Drug"*, 31 Mo. L. REV. 29 (1966); Marcus L. Plante, *An Analysis of "Informed Consent"*, 36 FORD L. REV. 639 (1968). Further research occurred in the 1970's and 1980's. *See, e.g.*, Alan Meisel & Lisa D. Kabnick, *Informed Consent to Medical Treatment: An Analysis of Recent Legislation*, 41 U. PITT. L. REV. 407 (1980); Alan Meisel, *The Expansion of Liability for Medical Accidents: From Negligence to Strict Liability By Way of Informed Consent*, 56 NEB. L. REV. 51 (1977).

24. Robert M. Veatch, *Autonomy's Temporary Triumph*, HASTINGS CENTER REPORT, Oct. 1984, at 38.

25. See CURRENT OPINIONS - 1981, *supra* note 6.

ential ethical treatise of modern times.[26] Percival's *Code* was an administrative response to a major upheaval within the medical staff of the Manchester Infirmary.[27] The *Code* focused extensively on the roles and interactions of physicians with the newly emerging specialties of surgeon and apothecary.[28]

The *Code* only indirectly addressed the patient-physician relationship. Percival saw the provision of spiritual support to patients as a primary function of the physician:

> For the physician should be the minister of hope and comfort to the sick; that by such cordials to the drooping spirit, he may smooth the bed of death, revive expiring life, and counteract the depressing influence of those maladies which rob the philosopher of fortitude and the Christian of consolation.[29]

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26. THOMAS PERCIVAL, MEDICAL ETHICS; OR A CODE OF INSTITUTES AND PRECEPTS, ADAPTED TO THE PROFESSIONAL CONDUCT OF PHYSICIANS AND SURGEONS (Manchester: S. Russell, 1803) *reprinted in* PERCIVAL'S MEDICAL ETHICS (Chauncey D. Leake ed., Robert E. Krieger Publishing Co., 1975) [hereinafter LEAKE].

The introductions to the ethical codes of the American Medical Association and the American College of Physicians acknowledge the influence of Percival's Code. *See* JUDICIAL COUNCIL OF THE AMERICAN MEDICAL ASSOCIATION, CURRENT OPINIONS OF THE COUNCIL ON ETHICAL AND JUDICIAL AFFAIRS OF THE AMERICAN MEDICAL ASSOCIATION, *History*, at vii (1992); see AMERICAN COLLEGE OF PHYSICIANS, ETHICS MANUAL, *reprinted at* 117 ANNALS INT. MED., at 947-960 (1992); *see also* FADEN AND BEAUCHAMP, *supra* note 1, at 67-74; LEAKE, *supra* at 33-57.

27. Thomas Percival (1740-1804) was an English physician and philosopher with a long association with the Manchester Infirmary. Percival's writing extended beyond the ethical role of the physician. LEAKE, *supra* note 26, at 25-28. He took an interest in public health policy and administration and published a great deal, championing such causes as accurate and consistent collection of vital statistics, improving the administration of hospitals, and increasing public health action to address problems of the growing urban areas. *Id.* Percival was instrumental in establishing a hospital for contagious diseases and arranging for free dispensary service for the poor. *Id.* His goal of expanding access to care, improving information gathering and administrative efficiency, and highlighting preventive care are strikingly similar to the goals of the Health Security Act of 1993 and many other current proposals.

28. Percival's Code consisted of four chapters: Of Professional Conduct Relative to Hospital or other Medical Charities; Of Professional Conduct in Private or General Practice; Of Conduct of Physicians to Apothecaries; Of Professional Duties in Certain Cases Which Require a Knowledge of Law. See LEAKE, *supra* note 26. This last chapter dealt with dying patients who did not have a will.

Apothecaries dispensed medicines and served as primary care providers for the urban population and full service medical providers to the poor and rural residents. Percival's description of the apothecary's function stresses the interaction with patients:

> [H]e will be a most valuable auxiliary through the whole course of the disorder, by his attention to varying symptoms; by the enforcement of medical directions; by obviating misapprehensions in the patient, or his family; by strengthening the authority of the physician; and by being at all times an easy and friendly medium of communication.

LEAKE, *supra* note 26, at 113.

29. LEAKE, *supra* note 26, at 22.

A physician needed to maintain a detached professional demeanor with patients, one that combined authority with benevolent optimism, in order to banish harmful emotions:

> The character of the physician is usually remote either from superstition or enthusiasm. And the aid, which he is now exhorted to give, will tend to their exclusion from the sick wards or the hospital, where their effects have often been known to be not only baneful, but even fatal.[30]

To accomplish his job, Percival advised the physician to develop some understanding of the patient as a person and tolerance for her idiosyncracies. Percival noted,

> And human nature must be intimately studied to acquire that full ascendancy over the prejudices, the caprices and the passions of the sick, and of their relatives, which are essential to medical success.[31]
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> The feelings and emotions of the patients, under critical circumstances, require to be known and to be attended to, no less than the symptoms of the disease. . . . Even the prejudices of the sick are not to be condemned or opposed with harshness. For though silenced by authority, they will operate secretly and forcibly on the mind, creating fear, anxiety and watchfulness.[32]

Given the limited diagnostic techniques, the physicians of that era knew little more about a patient's physical condition than did the patient. The available remedies were simple and often well known to the patient population. Through their experience, physicians might have had a better idea of the patient's prognosis. It was in discussing this subject that they exercised discretion. Percival advised that in "bleak cases" the physician is "not to make gloomy prognostications . . . but to give to the friends of the patients timely notice of danger . . . and even to the patient himself, if absolutely necessary."[33] Per-

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30. *Id.* at 73. The hospitals of that time serviced the poor who were not infectious or terminal but needed more care than the apothecary could provide. Physicians might make home calls on the poor, where the rural nature of the area made this care more appropriate or where diseases were "so infectious, malignant or fatal, as to be excluded from admission into Infirmaries." *Id.* at 83. The extent to which the Infirmary tended to sick, but not dying patients, is revealed in the statistics Percival appended to his Code as "Notes and Illustrations". For the ten year period from June 24, 1792 to June 24, 1802, 8,083 in-patients were admitted, and 361 of these died in the Infirmary. Hospitals had not yet become acute care sites. Even where administrative concerns led Percival to state that hospital patients could not choose their own doctor "consistently with the regular and established succession of medical attendance," he acknowledged the importance of attending to their feelings. *Id.* at 71. "Yet personal confidence is not less important to the comfort and relief of the sick-poor, than of the rich under such similar circumstance." *Id.*

31. LEAKE, *supra* note 26, at 84.

32. *Id.* at 72.

33. *Id.* at 91.

cival's *Code* did not advise withholding this information from the patient.[34] The doctor was to delegate this job of informing the patient "to any other person of sufficient judgment and delicacy" because such comments coming from the doctor would be "peculiarly alarming."[35] Thus, the *Code* promoted conversation with the patient for practical reasons. This role-modeling incorporated a certain respect for the patient's idiosyncracies and acknowledged the limited curing power of nineteenth century medicine.

The *Principles of Medical Ethics of the American Medical Association* (AMA), adopted at the first national meeting of the organization in 1847, relied heavily on Percival's *Code*.[36] The AMA *Principles* addressed primarily the relations within the profession and incorporated much of Percival's language on that subject.[37] This focus was appealing since the association was formed to differentiate members from the less respectable conventional practitioners as well as other schools of health care providers.[38]

The 19th century was notable for a true pluralism in medical care provision. Various sects vied for clients and respectability.[39] There was no common understanding of how one could go about correcting a medical condition, nor was there a common understanding of what even caused a medical condition. Homeopaths, eclectics, osteopaths, and patent medicine companies presented viable challenges to the

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34. *Id.*

35. *Id.* at 22.

36. CURRENT OPINIONS - 1981, *History*, at vii.

37. FADEN & BEAUCHAMP, *supra* note 1, at 69-72.

38. There was a debate in the 1880's over a simplified ethics code which the Medical Society of the State of New York (MSSNY) adopted and its favorable treatment of "irregular" medical providers. *See* AUSTIN FLINT, MEDICAL ETHICS AND ETIQUETTE: THE CODE OF ETHICS ADOPTED BY THE AMERICAN MEDICAL ASSOCIATION, WITH COMMENTARIES 23-24 (1883). MSSNY delegates had been refused seating at the 1882 AMA meeting as a result of their action. FADEN & BEAUCHAMP, *supra* note 1, at 73. The MSSNY remained separate from the AMA until 1903 when it merged with the New York State Medical Society, which had been formed by a group of "conservative" physicians in 1883 in order to retain their ties with the AMA. LEAKE, *supra* note 26, at 51-55.

The AMA's *Principles* eventually did change form and, more recently, its treatment of "cults." The principles were simplified to seven, single sentence standards of conduct "defining the essentials of honorable behavior for the physician." AMERICAN MEDICAL ASSOCIATION, PRINCIPLES OF MEDICAL ETHICS. However, there was a recognized need for a fuller explication of these principles. The full AMA code of ethics now includes the *Principles*, the *Current Opinions of the Council on Ethical and Judicial Affairs* and the *Reports of the Council on Ethical and Judicial Affairs*. One lasting change brought about by this conflict was the rejection of the requirement that local medical societies had to conform their ethical principles to those of the AMA. *Id.*

39. *See* PAUL STARR, THE SOCIAL TRANSFORMATION OF AMERICAN MEDICINE 93-109 (1982) [hereinafter STARR]. The regular medical profession constituted between 80% and 90% of all physicians in practice throughout the nineteenth century. *Id.* at 99.

basic principles of conventional medicine.[40] Martin Pernick suggests that this social context caused American physicians of that era to abide by an indigenous medical tradition including truth-telling and consent-seeking.[41] Pernick stated that

> [T]he variety of competing sects and the unrestricted number of practitioners gave the nineteenth-century patient a great deal of de facto autonomy without formal regulations. Neither the law nor medical ethics consistently required anything like informed consent in drug therapy, but the wide-open medical marketplace guaranteed that most paying patients who wanted either information or a particular kind of therapy could shop around for it.[42]

Professional control over medical education and entry into practice had been rejected during the Jacksonian period.[43] For the first forty years of its existence, the AMA was not yet ready to reverse that social policy.

A lack of status helped to keep the physician-patient interaction collaborative rather than professionally dominated. As one surgeon later noted,

> Abroad, the medical degree *per se* invested the physician with a social standing and authority unknown in America, where, in 1874, the meager educational requirements made it easy to secure a diploma after "two sessions of so many weeks a year." With some exceptions, the rank and file of the profession were—as far as general education went—little, if any, above the level of their *clientèle*. And the *clientèle* not only felt this, but knew it.
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> . . . .
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> . . . [T]he American physician of those days wielded less authority over his patients than did his European colleagues; he had to endure too much quizzing, and had to waste time in arguing patients into acquiescence.[44]

The care setting used by the 19th century physician was most often the patient's home, with family or friends in attendance.[45] The situs of care put the physician into the patient's world.[46] Women still bore

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40. *Id.* at 94-99. Some sects, such as the homeopaths and eclectics, were coopted after agreeing to work together toward restrictive licensing. *Id.* at 106-08. Others, such as the osteopaths, chiropractors and patent medicine companies, continued to compete until they were marginalized or driven out of business. *Id.* at 108-09.

41. Martin S. Pernick, *The Patient's Role in Medical Decision-making: A Social History of Informed Consent to Medical Therapy*, *in* PRESIDENT'S COMMISSION, *supra* note 3, vol.3, at 3. [hereinafter Pernick].

42. *Id.* at 17.

43. STARR, *supra* note 39, at 55-59.

44. ARPAD G. GERSTER, RECOLLECTIONS OF A NEW YORK SURGEON 162, 163 (1917).

45. STARR, *supra* note 39, at 32.

46. *Id.*

the traditional responsibility for providing primary care in their homes and in their communities.[47] Oral tradition and domestic medical manuals written by physicians guided them.[48]

Even at the turn of the century, available heroic medical interventions were often futile, if not harmful.[49] However, scientific understanding of the causes of disease were beginning to distinguish the services of conventional medicine. The impact is described by George Annas, a health law scholar, as follows:

> Only slowly did the edicts of science for the practice of medicine emerge and take hold. If germs, not moral failure or a vindictive deity, caused disease then a properly trained physician could diagnose an illness, evaluate and prescribe a remedy. If infections could be prevented by antiseptic technique—the advantages of cleanliness in the operating room were not discovered in this country until the 1870s—then surgery could be less a heroic, last ditch effort to save life and more a restorative, professional skill. Above all, if science could rationalize medical practice, then both the therapeutic value of medicine and the social and economic status of its practitioners could be greatly enhanced.[50]

B. Professionally Defining Medical Care Quality.

The AMA and its state and local affiliates had substantial control over medical licensing and education during the first quarter of the century.[51] State legislatures delegated to medical boards the responsibility and power of setting the minimum standards for licensure.[52] The boards were filled with representatives from organized medicine.[53]

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47. *Id.*

48. *Id.* Two of the most prominent manuals were entitled "Domestic Medicine." STARR, *supra* note 39, at 32-34. William Buchan's was published in 1769 and had at least thirty reprintings in the U.S. through the middle of the century. *Id.* at 32-33. John C. Gunn's was published in 1830 and soon replaced Buchan's as the popular favorite. *Id.* at 34.

49. *See* Harrman L. Blumgart, *Caring for the Patient*, 270 NEW ENG. J. MED. 449, 449 (1964). "Somewhere between 1910 and 1912 in this country, a random patient, with a random disease consulting a doctor chosen at random had, for the first time in the history of mankind, a better than fifty-fifty chance of profiting from the encounter." *Id.*

50. GEORGE J. ANNAS ET AL., AMERICAN HEALTH LAW 3 (1990) [hereinafter ANNAS ET AL.].

51. LUDMERER, *supra* note 18, at 235-40 (1985). In 1889, the United States Supreme Court had approved medical licensing by the states and its corollary, prohibiting those without licenses from practicing medicine. Dent v. State of West Virginia, 129 U.S. 114 (1889). All states (then twenty-seven) and the District of Columbia had a requirement of physician licensing by 1901. STARR, *supra* note 39, at 104.

52. LUDMERER, *supra* note 18, at 236. State licensing boards also have the authority to discipline physicians for professional misconduct, a power they have been reluctant to use.

53. *Id.* at 237. The AMA initially agreed to work with the homeopaths and eclectics on

The boards evaluated and accredited medical schools.[54] Graduation from an approved institution was a common prerequisite for state licensure.[55]

The educational process for physicians that developed under AMA supervision focused on individual medicine, rather than public health. However, it put little emphasis on the issue of physician-patient relations. Funding source incentives, combined with institutional pressure to improve a school's ranking, encouraged an emphasis on research and specialized practice by those who were educating medical students.[56] The lesson was not lost on the students. The ranking within the profession that resulted, which still persists today, has been described by one writer as follows:

> On the first rung of the medical hierarchy are the various primary-care physicians: general practitioners, family-practice specialists, and internists. These physicians must deal with such an enormous variety

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the state licensing boards. STARR, *supra* note 39, at 102, 106-08. These alternative voices were soon overwhelmed by the growth of the larger organization as a major restructuring of the AMA into a federal organization in 1901 helped to swell its membership from 8,000 to 70,000 by 1910. *Id.* at 110.

54. *Id.* at 249-254. One goal of the AMA at the time of its formation was to standardize and upgrade the medical education required of physicians. As early as 1870, the House of Delegates, the elected policy making body of the AMA, resolved "that the American Medical Association has the power to control the subject of medical education in the United States and the power to exercise that control in any manner upon which it may become agreed." *Official Proceedings of the AMA House of Delegates*, May 1870, at 35.

In 1902, the AMA House of Delegates authorized a permanent Council on Medical Education to help achieve the goal of "obtaining a uniform and elevated standard of requirements for the degree of M.D. . . ." 28 JAMA 1659, 1662 (1902). By 1910, the Council had developed the guidelines, *Essentials for an Acceptable Medical School*, to govern the accreditation process. While various associations worked with the state boards, the AMA's voice was strongest and came to have the force of law. LUDMERER, *supra* note 18, at 237.

Medical school accreditation by the AMA's Council on Medical Education was essentially mandatory in all states by 1920. *Id.* at 121. This exclusive control over medical education by the AMA continued for almost fifty years. In 1957, the *Essentials for an Acceptable Medical School* was replaced by a new set of guidelines, *Functions and Structures of the Modern Medical School*, developed by the AMA Council on Medical Education and the Association of American Medical Colleges (AAMC). *See Official Proceedings of AMA House of Delegates*, June 1957, 31, 33-36. Currently all states rely on accreditation by the Liaison Committee on Medical Education (a joint venture of the AMA and the AAMC) or the American Osteopathic Association. Until 1960, the AMA opposed the provision of federal funds to directly subsidize medical school education. ANNAS ET AL., *supra* note 50, at 27. This was due, in large part, to concerns about losing control over the educational process.

55. Internships and residency programs became a regular part of the medical training for virtually all U.S. medical school graduates in the 1950's. These programs were also subject to AMA accreditation as they were developing. The accrediting body for residency programs is now the Accreditation Council for Graduate Medical Education (ACGME).

56. The initial funding sources for medical education in the beginning of the century were tuition and endowments. JAMES R. SCHOFIELD, NEW AND EXPANDED MEDICAL SCHOOLS, MID-CENTURY TO THE 1980'S 125-130 (1984). By 1970 these were largely supplanted by patient care revenues and federal research grants. *Id.* at 132-34.

> of human ailments that much of the time they can only apply hundreds upon hundreds of rules learned mostly by rote. Primary-care physicians will refer the cases that cannot be dealt with by that approach to the physicians on the next rung, the specialists. Specialists are likely to know and understand a much greater fraction of the scientific literature in their field. Their therapies may depart more frequently from what they were taught.

At the top of the hierarchy are the academic faculty of medical schools and teaching hospitals.[57]

While massive investments were made in hospitals and the training of medical doctors, the availability of alternative approaches to health care decreased. Some methods were proven ineffective or even dangerous. Active steps, taken by organized medicine to discourage patient usage of other approaches, also eliminated or delayed the development of alternatives.[58]

As the AMA and its physicians gained prestige and control over medical education and delivery, the tradition of patient involvement in decision making suffered. The practice of medicine became more technical and specialized. Improved diagnostic techniques and the accumulating body of medical knowledge that was safeguarded by the profession put a distance between physician and patient. Physicians changed their language and their capacity to talk with their patients. The evolving medical capabilities presented new situations that tested the developing professional control over medical care. On one particular question, whether the physician could extend an operation without the consent of the patient, physicians found that their assumptions were not shared by patients or the courts.[59]

C. Developing the Legal Doctrine of Consent.

After 1904, medical consent cases began to appear in state courts, starting slowly and then gradually increasing in number after 1913.[60]

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57. Thomas J. Moore, *The Cholesterol Myth*, THE ATLANTIC MONTHLY Sep. 1989, 38, at 44.

58. *See, e.g.*, Wilk v. American Medical Ass'n, 671 F. Supp. 1465 (N.D. Ill. 1987) (AMA and its members conspired against the chiropractic profession), *aff'd*, 895 F.2d 352.

59. *See* FADEN & BEAUCHAMP, *supra* note 1, at 119-25; Pratt v. Davis, 79 N.E. 562 (Ill. 1906); Mohr v. Williams, 104 N.W. 12 (Minn. 1905); Rolater v. Strain, 137 P. 96 (Okla. 1913); Schloendorff v. Society of New York Hospitals, 105 N.E. 92 (N.Y. 1914).

60. *See, e.g., Mohr*, 104 N.W. 12; *Pratt*, 79 N.E. 562; Luka v. Lowrie, 136 N.W. 1106 (Mich. 1912); Schloendorff, 105 N.E. 92 (N.Y. 1914); Rolater, 137 P. 96 (Okla. 1913). A separate, and somewhat earlier, line of consent cases involved the question of the status of the person consenting to his/her own care. *See* State v. Housekeeper, 16 A. 382 (Md. 1889) (married woman's ability to consent without husband's agreement); Bakker v. Welsh, 108 N.W. 94 (Mich. 1906) (ability of minor to give effective consent to surgery).

The issue in most cases was the extent to which surgeons could exercise their discretion to alter the surgical plan for anesthetized patients.[61] A theory of implied consent would have accorded broad discretion to the surgeons. Courts declined, however, to trust the surgeons with that decision making power in the absence of a medical emergency.[62]

The courts built the legal doctrine of consent to medical treatment from the ancient notion that one's body should not be touched without one's approval.[63] Enforcement of this right to be left alone is by a civil action of battery, with money damages as the remedy.[64] The relevant facts and applicable doctrine are uncomplicated. Where a patient had allegedly rejected a proposed surgery, the courts could easily fit the issue into the analytical framework of battery.[65] Similarly, where the surgeon operated on a part of the body other than one discussed with the patient, there was liability for battery.[66] The central issue is whether an intentional "touching" occurred.[67] If so, and there

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61. *See, e.g., Mohr*, 104 N.W. 12; *Pratt*, 79 N.E. 562.

62. *Pratt*, 79 N.E. at 565. The following proposition of law was submitted by defendants in the *Pratt* case:

> The court holds, as a proposition of law, that when a patient places herself in the care of a surgeon for treatment without instructions to the surgeon or limitations upon his authority, she thereby, in law, consents that he may perform such operation as in his best judgment, care and skill is necessary, proper and essential to her welfare, and in case the surgeon performs an operation upon the plaintiff, and there is no complaint against the surgeon for want of the exercise of care and skill, there can be no recovery.

Id. The court rejected the defense because the facts did not suggest an emergency condition arose during the surgical procedure. *Id.*

63. Union Pac. Ry. Co. v. Botsford, 141 U.S. 250, 251 (1891). In that case, the United States Supreme Court clearly expressed its support for the underlying notion of bodily integrity. It stated "no right is held more sacred, or is more carefully guarded, by the common law, than the right of every individual to the possession and control of his own person, free from all restraint or interference of others, unless by clear and unquestionable authority of law." *Id.* at 251.

The defendants in this personal injury action sought an order requiring the plaintiff to submit to an examination to assess her physical condition. *Id.* at 250. The court concluded that "such an order has no warrant of law." *Id.* at 256. Federal Rule of Civil Procedure 35 now provides for such orders where the physical condition is in controversy and good cause is shown for the examination. FED. R. CIV. P. 35.

64. In the history of the common law, there is perhaps no right which is older than a person's right to be free from unwarranted personal contact. As early as the middle of the thirteenth century, English law, through the writ of trespass *vi et armis*, provided a method of monetary recovery for unpermitted contacts with the person. F. W. MAITLAND, THE FORMS OF ACTION AT COMMON LAW 40, 43, 53 (1971 ed.). *See generally* George F. Dreiser, *The Development of Principle in Trespass*, 27 YALE L.J. 220 (1917); George E. Woodbine, *The Origins of the Action of Trespass*, 33 YALE L.J. 799 (1924).

65. *See, e.g.*, Mohr v. Williams, 104 N.W. 12 (Minn. 1905); Schloendorff v. Society of N.Y. Hosp's, 105 N.E. 92 (N.Y. 1914).

66. *Mohr*, 104 N.W. at 15-16. More recently *see*, Cobbs v. Grant, 502 P.2d 1, 8 (1972).

67. *Mohr*, 104 N.W. at 16.

was no express or implied consent, there is liability.[68] This classification of the claim stresses respect for bodily integrity and distinguishes the legal claim from the more common form of action involving medical professionals, medical malpractice. It also has the effect of removing the case from the realm and rules of negligence and into that of an intentional tort.[69]

The basic principle that consent was necessary before a physician could operate on a patient was well accepted at the turn of the century. The inherent dangers of surgery made the choice a very personal one. A 1903 torts treatise explained the law as follows: "The patient must be the final arbiter as to whether he will take his chances with the operation, or take his chances of living without it. Such is the natural right of the individual, which the law recognizes as a legal one."[70]

The dramatic increase in the use of hospitals in the early 1900's removed the patient from her home in the event of a serious illness.[71] The separation was especially severe when surgery was to be performed. Family and friends were excluded from the hospital's surgical area as part of the new aseptic protocols.[72]

The widespread use of anesthesia complicated matters regarding a patient's consent to treatment.[73] In a 1912 case, the New Jersey Supreme Court explained that the use of anesthesia

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68. *See* W. PAGE KEETON ET AL., PROSSER AND KEETON ON LAW OF TORTS § 9, at 39-42 (5th ed. 1984); RESTATEMENT (SECOND) TORTS § 8 (1965); 6 N.Y. JUR. 2d *Assault—Civil Aspects* 2 (1980).

69. Some practical consequences of this distinction are that: 1) a shorter statute of limitations would apply to the intentional tort. *Compare* N.Y. CIV. PRAC. L. & R. § 215(1) (McKinney 1993) - One year statute of limitations for assault, *with* N.Y. CIV. PRAC. L. & R. 214-a - Statute of limitations for medical malpractice is two years and six months; 2) In an assault, the skill with which the procedure was done is irrelevant, while in a malpractice action that issue is central. This framing of the issue may preclude the need for expert testimony. Liability based on battery is not denied because the plaintiff was not aware of the touching. *See, e.g., Mohr*, 104 N.W. 12; or the touching was beneficial or otherwise harmless. *See, e.g.*, Lacey v. Laird, 139 N.E.2d 25, 26 (Ohio 1956); *Mohr*, 104 N.W. at 15-16.

70. *Mohr*, 104 N.W. at 14-15, *quoting* 1 KINKEAD'S COMMENTARIES ON THE LAW OF TORTS, § 375 (1903).

71. *See* STARR, *supra* note 39, at 156-57.

72. *Id.*

73. Anesthesia was introduced by William Morton in 1846, and by 1853, it was available at every hospital in the country. MARTIN S. PERNICK, A CALCULUS OF SUFFERING: PAIN, PROFESSIONALISM AND ANESTHESIA IN NINETEENTH CENTURY AMERICA 3-4 (1985) [hereinafter PAIN]. Despite this availability, it was not until the 1880's that the disability of being anesthetized during medical treatment came to be seen as an ethical or legal problem. *The Patient's Consent to an Operation and the Surgeon's Discretion*, THE MEDICAL RECORD Dec. 1880, at 715. Hospital surgery was performed far less frequently in the nineteenth century. It was still a crude and dangerous undertaking. STARR, *supra* note 39, at 156. Most of the competing medical philosophies rejected surgical intervention.

At least until the turn of the century, anesthesia was used only on selected patients. Adult

> [r]enders the patient unable to consent at the very time that the rule of the common law required that his consent be obtained; for in those days the patient (such was the horror of it) was a conscious participant in such surgical operations as were then performed, and as his consent could be obtained the rule of the common law was that it must be obtained.[74]

Virtually all the court decisions on consent, and later, informed consent, arise out of the surgical context.[75] The discussion of consent cases often starts with quotation of Associate Justice Cardozo's opinion in the 1914 decision, *Schloendorff v. Society of New York Hospitals*.[76] In *Schloendorff*, the New York Court of Appeals was defining

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males were the least anesthetized group as their tolerance of pain was seen as greater than women and children. Anesthesia was used at times to subdue objecting patients or to render them unconscious so the physician could perform surgery without the awareness of the patient. Women were anesthetized involuntarily far more frequently than men since their autonomy was much less respected. PAIN, *supra* at 149-50, 229.

74. Bennan v. Parsonnet, 83 A. 948, 949 (N.J. 1912). The court overturned a jury award for the plaintiff since it found that the unauthorized operation was necessary to save the patient's life. *Id.*

75. Tracing the development of a legal concept through reported cases is not entirely satisfying nor accurate. Most litigation effort is at the trial level, but these courts rarely produce substantial written opinions. Only those issues that generate opposition, either from the adversary or the court, can proceed to the appellate levels. Where the litigation opponents accept one legal theory, or decide for any of a variety of reasons not to pursue an appeal, there is little chance to bring the issue before an appellate court for its determination.

76. 105 N.E. 92 (1914). Mary Schloendorff's complaint alleged that surgery was performed contrary to her express direction. *Id.* at 93. The court accepted her allegations as true for purposes of reviewing the directed verdict in favor of the defendant hospital entered by the trial judge. *Id.* The patient had agreed to an "ether examination." *Id.* While the patient was under the effects of the anesthesia, the surgeon removed a fibroid tumor discovered during the examination. *Id.* An infection, gangrene and the amputation of several fingers allegedly resulted from the operation. *Schloendorff*, 105 N.E. 93.

The court's opinion provides a taste of a very different medical world:

> In the year 1771, by royal charter of George III, the Society of the New York Hospital was organized for the care and healing of the sick. During the century and more which has since passed, it has devoted itself to that high task. It has no capital stock; it does not distribute profits; and its physicians and surgeons, both the visiting and the resident staff, serve it without pay. Those who seek it in search of health are charged nothing if they are needy, either for board or for treatment. The well-to-do are required by its by-laws to pay $7 a week for board, ...
>
> To this hospital the plaintiff came in January, 1908. She was suffering from some disorder of the stomach. She asked the superintendent or one of his assistants what the charge would be, and was told that it would be $7 a week. She became an inmate of the hospital, and after some weeks of treatment, the house physician, Dr. Bartlett, discovered a lump, which proved to be a fibroid tumor. He consulted the visiting physician, Dr. Stimson, who advised an operation. The plaintiff's testimony is that the character of the lump could not, so the physicians informed her, be determined without an ether examination. . . . Following the operation, and, according to the testimony of her witnesses, because of it, gangrene developed in her left arm, some

a non-profit hospital's liability for acts performed by the doctors and nurses it employed and not any claim of liability against the individual physician or nurse.[77]

Two theories were offered supporting the conclusion that the hospital was immune from liability for the patient's damages.[78] One theory implied a waiver of the right to sue for negligent treatment when the patient turned to a charity for help (charitable immunity).[79] In rejecting the application of this doctrine to the facts alleged by Schloendorff, Justice Cardozo summarized the state of the common law regarding consent to surgery:

> In the case at hand, the wrong complained of is not merely negligence. It is trespass. Every human being of adult years and sound mind has a right to determine what shall be done with his own body; and a surgeon who performs an operation without his patient's consent commits an assault, for which he is liable in damages.[80]

The decision proceeded to its major holding that the hospital could not be held liable for acts of its employed physicians: "[T]here is no relation of master and servant between a hospital and its physicians, and it does not undertake to act through them, but merely to procure them to act upon their own responsibility."[81]

Schloendorff relied upon the earlier decisions of *Pratt v. Davis*[82] and *Mohr v. Williams*[83] in classifying the cause of action.[84] In these

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of her fingers had to be amputated, and her sufferings were intense.

Id.

The court continued:

> There may be cases where a patient ought not to be advised of a contemplated operation until shortly before the appointed hour. To discuss such a subject at midnight might cause needless and even harmful agitation. About such matters a nurse is not qualified to judge. She is drilled to habits of strict obedience. She is accustomed to rely unquestioningly upon the judgment of her superiors. No woman occupying such a position would reasonably infer from the plaintiff's words that it was the purpose of the surgeons to operate whether the plaintiff forbade it or not.

Id. at 95.

77. *Schloendorff*, 105 N.E. at 93.

78. *Id.*

79. *Id.*

80. *Id.* Rather than an assault, Mary Schloendorff's injuries resulted from a battery. A civil assault is "an intentional attempt to do injury or commit a battery upon the person of another." 6 N.Y. JUR. 2d *Assault-Civil Aspects* § 1 (1980). The assault requires an intent to inflict injury or put the victim in apprehension of such injury. 6 N.Y. JUR. 2d *Assault-Civil Aspects* § 1. A battery consists of the slightest touching, with the only intent required being the intent to make contact, not intent to do injury. *Id.* at § 4.

81. *Schloendorff*, 105 N.E. at 94. The New York Court of Appeals has since rejected the "Schloendorff rule" and held that the principles of respondeat superior should be applied to render a hospital liable for the negligence of the physicians and nurses that it employs. Bing v. Thunig, 143 N.E.2d 3, 9 (1957).

82. 79 N.E. 522 (Ill. 1906).

83. 104 N.W. 12 (Minn. 1905).

84. *Schloendorff*, 105 N.E. at 93.

and other reported cases of this era, the allegations focused on surgery that went beyond the procedure discussed with and agreed to by the patient.[85] Often, the allegations were that the patient had clearly rejected the additional work or had been misled.[86]

By the late 1920's, there was little controversy over the substance of the legal rule.[87] Lawful consent was clearly limited to the procedure specifically agreed to by the patient. The case law moved from policy making to enforcing compliance with the accepted professional norm of obtaining consent for each separate procedure.[88] Observance of

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85. *See Schloendorff*, 105 N.E. 92 (ether examination which ended with removal of a tumor); *Pratt*, 79 N.E. 562 (examination turned into hysterectomy); *Mohr*, 104 N.W. 12 (operation to be conducted on right ear but undertaken on left). *See also* Wells v. Van Nort, 125 N.E. 810 (Ohio 1919) (surgeon to perform appendectomy removed fallopian tube without consent); Rolator v. Strain, 137 P.96 (Okla. 1913) (consent to foot operation to drain infection but bone removed).

86. *See Pratt*, 79 N.E. at 562. A second surgery, removing a woman's ovaries to deal with her epilepsy and depression was done without her consent. Therefore, an action based on battery was appropriate. The physician defendant testified that: "I worked her deliberately and systematically, taking chances which she did not realize the full aspect of, deliberately and calmly deceiving the woman; that is, I did not tell her the whole truth." *Id.* at 564. In *Mohr*, 104 N.W. at 12, a physician who had been authorized to operate on a woman's right ear, found that it was the left which required medical attention. *Id.* The surgery was done in a professional manner and no negligence was alleged or proven. *Id.* This constituted a technical assault and battery. *Id.* In *Rolater*, 137 P. at 97, a surgeon, in operating to drain an infected toe, removed a bone. *Id.* The patient had explicitly told him she wanted to retain all of her bones. *Id.* Rishworth v. Moss, 159 S.W. 122 (Tex. Civ. App. 1913), *aff'd* 222 S.W. 225 (Tex. Com. App. 1920). The removal of tonsils and adenoids from an 11-year old, without the consent of her parents, was unlawful irregardless of whether there was negligence in the actual performance of the operation. *Id.* at 124. *See also* McClees v. Cohen, 148 A. 124 (Md. 1930); (judgment affirmed against dentist who removed two molars rather than two "baby roots" as sought by plaintiff); Franklyn v. Peabody, 228 N.W. 681 (Mich. 1930) (doctor who extended an operation beyond the agreed upon hand surgery was liable for assault when no emergency existed); *Wells*, 125 N.E. 910 (1919) (plaintiff agreed to "an operation for appendicitis" but the physician went on to remove her Fallopian tubes which he observed to be in "bad shape"); Francis v. Brooks, 156 N.E. 609 (Ohio Ct. App. 1926) (dentist, who broke a woman's jaw extracting an impacted, unerupted bicuspid, was held liable for assault since she had directed him only to extract nine of her teeth); White v. Hirshfield, 236 P. 406 (Okla. 1925) (physician, authorized to perform a Caesarian section, who extended operation to remove the plaintiff's fallopian tubes committed an assault and battery); King v. Carney, 204 P. 270 (Okla. 1922) (surgeon may be justified in extending an operation, where he has a general authorization to "fix" what was wrong and he encountered unanticipated conditions that posed a danger to the life of the patient); Hively v. Higgs, 253 P. 363 (Ore. 1927) (surgeon employed to operate on plaintiff's septum, liable for assault when he removed her tonsils instead). *See also* Ericson v. Charles, 194 P. 652 (1921).

All these cases had female plaintiffs. The percentage of female plaintiffs in medical malpractice cases continued to be high after the Era of Consent. A study of appellate court medical malpractice decisions handed down from 1946 to 1955 found that in 70% of the cases the plaintiff was female. Sandor, *The History of Professional Liability Suits in the United States*, 163 AMERICAN MED. ASS'N J. 459 (1957).

87. FADEN & BEAUCHAMP, *supra* note 1, at 125.

88. A steady trickle of cases on consent were reported with the consent standards routinely applied. *See* WILLIAM A. KELLY, THE PHYSICIAN, THE PATIENT AND THE CONSENT, 8 U. KANSAS L. REV. 405 (1960) for a discussion of these cases.

this rule in clinical medicine was not uniform. The lack of consistent and effective enforcement from either within or without the profession allowed for lax practices of disclosure with many patients.

As the century progressed, advancing medical technology and techniques put powerful new tools in the hands of the medical profession. Use of these new tools carried the risk of severe harm to patients even without negligence. The courts began to inquire whether the patients had been informed of the risks of, and alternatives to, the medical intervention.[89] The underlying rationale of patient self-determination moved the case law from fact patterns of total non-disclosure or misrepresentation to those raising a question of whether the patient was given enough information to decide intelligently on the use of a treatment.[90] This legal analysis initially explored the patient-provider relationship as a matter of contract law, as shown in this opinion from the Fifth Circuit:

> [I]f a physician advises his patient to submit to a particular operation and the patient weighs the dangers and results incident to its performance and finally consents, he thereby in effect enters into a contract authorizing his physician to operate to the extent of the consent given but no further. The same principle which supports the holding that a surgeon performing an operation without his patient's consent, express or implied, commits a battery or trespass for which he is liable in damages, also supports the holding that a surgeon may not perform an operation different in kind from that consented to or one involving risks and results not contemplated.[91]

The disparity in status and information between physicians and patients made a contract analysis unsatisfactory. In time the courts developed new malpractice doctrines to compensate those who suffered serious injury that would have been avoided had the authorization to proceed been an informed decision.[92]

III. The Era of Informed Consent (1957 to Present).

Between 1957 and 1984, every state, except Georgia, adopted a litigation remedy for a failure to obtain informed consent.[93] A burst

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89. Faden & Beauchamp, *supra* note 1, at 125.

90. *See, e.g.*, Salgo v. Leland Stanford Jr. University Bd. of Trustees, 317 P.2d 170, 181 (1957); *see also* Faden & Beauchamp, *supra* note 1, at 125-90.

91. Wall v. Brim, 138 F.2d 478, 481 (5th Cir. 1943); *see also* Giambozi v. Peters, 16 A.2d 833 (Conn. 1940); Chambers v. Nottebaum, 96 So. 2d 716 (Fla. App. 1957); Bang v. Charles T. Miller Hosp., 88 N.W.2d 186 (Minn. 1958); Robert E. Powell, *Consent to Operative Procedures*, 21 Md. L. Rev 189 (1961).

92. *See* Natanson v. Kline, 350 P.2d 1093, *reh'g denied*, 354 P.2d 670 (Kan. 1960); Wilkinson v. Vesey, 295 A.2d 676 (R.I. 1972); Canterbury v. Spence, 464 F.2d 772 (D.C. Cir. 1972); Cobbs v. Grant, 505 P.2d 1 (Cal. 1972).

93. President's Commission, *supra* note 3, vol. 3, App. L. As of the time of that

of activity between 1972 and 1982 identified the elements of the cause of action in over two-thirds of the jurisdictions.[94] Georgia remained the lone holdout against informed consent until 1988, when a new Georgia statute mandated disclosure of a specific list of medical risks.[95] Two notable features of the Era of Informed Consent are the departure from the controlling force of professional norms in setting a malpractice standard and the reaction of the medical professionals to the imposition of practice standards by the courts and legislatures.

The cases and statutes use varying formulations to set a minimum level of disclosure the medical professional is responsible for providing before conducting an invasive procedure.[96] Under one of the least demanding standards, the provider can meet the informed consent requirements either by apprising the patient, in general terms, of a short list of the most significant risks of serious harm or by having the patient sign a consent form that contains the warnings.[97] The doctrine, in its most individualized form, requires full disclosure of the details of the treatment and of all risks and alternatives that are relevant to the particular person's decision on treatment.[98] Most commonly, the standard makers viewed the choice as between a professionally established norm and one measured by the information needs of a reasonable patient.[99] The jurisdictions are almost evenly split between the professionally oriented and the lay standard of disclosure.[100] Legislatively chosen rules primarily follow the professionally

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Report, one state (Georgia) had rejected the informed consent doctrine and three states (Connecticut, South Carolina and West Virginia) had not addressed the issue in either forum. *Id.*

The Georgia Legislature rejected the informed consent doctrine in 1971. The Georgia Medical Consent Law provided for disclosure "in general terms" of the treatment or course of treatment. GA. CODE ANN. § 31-9-6(d) (Michie 1991). The court cases made clear that this did not require the treating physician to discuss any risks or alternatives. Simpson v. Dickson, 306 S.E.2d 404 (Ga. Ct. App. 1983); Young v. Yarn, 222 S.E.2d 113 (Ga. Ct. App. 1975). The courts of Connecticut, South Carolina, and West Virginia recognized the cause of action soon after the President's Commission report was written. *See* Logan v. Greenwich Hosp. Ass'n, 465 A.2d 294 (Conn. 1983); Hook v. Rothstein, 316 S.E.2d 690 (S.C. Ct. App. 1984), *cert. denied*, 320 S.E.2d 35 (1984); Cross v. Trapp, 294 S.E.2d 446 (W. Va. 1982).

94. FADEN & BEAUCHAMP, *supra* note 1, at 139. *See also* Alan Meisel & Lisa Kabnick, *Informed Consent to Medical Treatment*, 41 U. PITT. L. REV. 407 (1980).

95. *See* GA. CODE ANN. § 31-9-6 (Michie 1991) (effective Jan. 1, 1982). The act also provides for acceptance of signed consent forms as proof of informed consent. *Id.* at § 31-9-6.1(b)(2).

96. *See infra* notes 161, 166-85, 190-241 and accompanying text.

97. *See* GA. CODE ANN. § 34-9-6.1(a)(1)-(6), (b)(2) (Michie 1991).

98. *See, e.g.*, Scott v. Bradford, 606 P.2d at 554 (Okla. 1979); Cross v. Trapp, 294 S.E.2d at 455 (W. Va. 1982).

99. *Scott*, 606 P.2d at 554; *Cross*, 294 S.E.2d at 446.

100. *See infra* Section III(F) and accompanying notes.

oriented standards, while court made rules most often choose the lay standard.[101] While "material risks" and "reasonable patient" are standard terms in the lay rule, the professionally oriented standards rely on the medical malpractice standards of care.[102]

The state doctrines of the Era of Informed Consent evolved in stages. Before 1975 informed consent doctrines were developed only in lawsuits against medical professionals for their failure to provide meaningful disclosure of the risks inherent in a medical intervention.[103] The state courts hearing these cases unanimously held that medical professionals had a legally enforceable duty to provide information to the patient on the nature and purpose of the procedure as well as its risks and alternatives.[104] Their reasoning was based on the concept of respect for personal autonomy central to the earlier consent cases.[105] A meaningful consent requires that the patient have some understanding of what she is agreeing to and how that course of treatment compares to alternative therapies and to non-treatment.[106]

The earliest of these informed consent cases did not directly challenge professional self regulation.[107] Organized medicine was active and successful in advocating for the use of a professional disclosure standard in these cases. The courts adopted the customary professional practice, or what a reasonable physician would have done in similar circumstances, as the standard of disclosure.[108] Professionals were allowed considerable discretion to withhold information for therapeutic reasons. The courts held the physician liable only where disclosure about an invasive procedure fell below the professional norm and serious harm resulted.[109] This continued the role of the courts as one of several mechanisms for enforcing medical care standards defined within the profession.

Criticism of the professional practice of disclosure by legal and medical scholars as well as patient advocates had been building since the end of World War II. The critics focused first on medical research, and later, on clinical medicine. In 1972, the case law took a dramatic turn toward imposing a patient-oriented disclosure standard rather than enforcing compliance with the professional practice in therapeutic care.[110] Courts in several jurisdictions established disclosure standards

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101. *Id.*
102. *Id.*
103. *See, e.g., Salgo*, 317 P.2d 170. *See also supra* notes 60-93 and accompanying text.
104. *See Salgo*, 317 P.2d at 181; *Natanson*, 350 P.2d at 1101-04.
105. *See, e.g., Schloendorff*, 105 N.E. at 93; *Mohr*, 104 N.W. at 14-15.
106. *See infra* Section III(F) and accompanying notes.
107. *Salgo*, 317 P.2d at 181. *See also* FADEN & BEAUCHAMP, *supra* note 1, at 126-27.
108. *See, e.g., Natanson*, 350 P.2d at 1103.
109. *Id.* at 1107. *See also* FADEN & BEAUCHAMP, *supra* note 1, at 131.
110. *See infra* Section III(F) and accompanying notes.

for the profession that required more information than the physicians customarily provided.[111] The nonprofessional disclosure standard most widely used requires that the provider of care disclose risks and alternatives that would be material information to a reasonable person.[112]

Physician lobbying groups quickly turned to the state legislatures to stem the tide of court adoption of this standard.[113] The state legislatures, already dealing with a medical malpractice insurance crisis, added the new informed consent doctrines to the debate.[114] In the short span of 1975 to 1977, almost half the states enacted statutes that made the legal doctrine less threatening to the medical profession.[115] The state legislatures that clearly addressed the disclosure standard unanimously opted for the professional perspective if there was no clear state common law standard.[116] Where there was a state common law on informed consent, the acts either froze those disclosure standards or replaced non-professional disclosure rules with professional practice standards.[117]

New statutory formulations adding diversity to disclosure requirements were written.[118] Several jurisdictions established procedures for disclosure without incorporating either perspective.[119] Many acts encourage the use of consent forms as evidence of compliance with disclosure requirements.[120] There were notable legislative efforts in Hawaii and Texas to authorize an administrative process to specifically list the risks the provider is expected to disclose.[121]

The legislative activity on the informed consent cause of action waned almost as suddenly as it had developed. Arkansas codified its common law on informed consent in 1979.[122] In 1988, Georgia became the final jurisdiction to accept the doctrine.[123] No other legislature

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111. *See* Canterbury v. Spence, 464 F.2d 772 (D.C. Cir.), *cert. denied* 409 U.S. 1064 (1972); Cobbs v. Grant, 502 P.2d 1 (Cal. 1972); Wilkinson v. Vesey, 295 A.2d 676 (R.I. 1972).

112. *See, e.g., Canterbury*, 464 F.2d at 783, 784.

113. FADEN & BEAUCHAMP, *supra* note 1, at 139-40.

114. *Id.* at 139.

115. *Id.*

116. *Id.* at 139-40.

117. *Id.*

118. *See, e.g.*, UTAH CODE ANN. § 78-14-5.1(d), (e) (1992) (requiring the disclosure of the substantial and significant risks of causing the patient serious harm).

119. *See, e.g.*, HAW. REV. STAT. § 671-1(2), 671-3 (1985).

120. In fact, the statutes passed in Iowa, Nevada and Ohio were limited to definitions of the elements of a valid written consent form, without directly defining the cause of action. IOWA CODE ANN. § 147.137 (West 1989); NEV. REV. STAT. ANN. § 41A.110 (Michie 1986); OHIO REV. CODE ANN. § 2317.54 (Anderson 1991).

121. *See infra* Section III (D) and accompanying notes.

122. ARK. CODE ANN. § 16-114-206 (Michie 1987).

123. GA. CODE ANN. § 31-9-6.1 (Michie 1991).

has defined this doctrine in the past fifteen years, nor have any legislatures taken the initiative to alter the statutory disclosure standards they chose between 1975 and 1977. With the help of administrative enforcement, there have been new statutes requiring the disclosure of specific information as a means of discouraging the use of some medical procedures.[124]

State courts, when not preempted by legislation, have continued to develop disclosure standards.[125] They have not felt constrained to apply the professional disclosure standards. The courts of Oklahoma and West Virginia wrote the strongest formulations of the patient-oriented standards just after the flurry of legislative activity.[126] Other courts adopted the reasonable person standard in the face of legislation giving consent forms meeting the professional standard of disclosure presumptive effect.[127] Patient autonomy continued to be the chief value honored by the courts.

Just as the medical practice of obtaining consent existed before the Era of Consent, there was a level of informed consent which existed in clinical practice before the courts began to rule on the issue.[128] Members of the profession have routinely disclosed treatment risks and alternatives in situations other than the invasive procedures addressed by the legal doctrine. However, limited professional support and scant monitoring of this aspect of care allowed for wide variations in clinical practice.

This situation began to change in 1980 as the medical profession dramatically reasserted control in defining the patient-physician relationship.[129] The profession articulated new medical ethics that respect the patient's collaborative role in the decision-making process.[130] This professional initiative increased the possibility of treating patient involvement in medical decisions as an important element in quality care.

A. The Special Case of Informed Consent in Medical Research

The concept of informed consent to medical interventions, if not the particular phraseology and formulation, gained prominence after

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124. *See infra* Section III(E) and accompanying notes.

125. *See, e.g.*, Scott v. Bradford, 606 P.2d 554 (Okla. 1979); Cross v. Trapp, 294 S.E.2d 446 (W. Va. 1982).

126. *See Scott*, 606 P.2d 554; *Cross*, 294 S.E.2d 446.

127. *See infra* Section III(D) and accompanying notes.

128. FADEN v. BEAUCHAMP, *supra* note 1, at 125-129.

129. *See infra* Section IV(A) and accompanying notes.

130. FADEN & BEAUCHAMP, *supra* note 1, at 96.

World War II.[131] Attention was initially focused on medical experimentation. However, attention eventually crossed over the elusive lines between research, innovative treatments, and accepted medical practice.

The war crimes trial of twenty Nazi physicians and three medical administrators gave the public a view of the horrible acts, done to allegedly improve scientific knowledge, perpetrated upon World War II concentration camp prisoners.[132] The judgment entered against the defendants included the *Nuremberg Code*,[133] the first major set of substantive protections for human subjects in medical experimentation.[134] The Code emerged in reaction to the defense that voluntary, informed participation in medical research was the exception, rather than the rule.[135] The Code set the "absolutely essential" prerequisite of a voluntary, competent, informed, and comprehending consent for human experiment subjects.[136]

Despite the high visibility of, and strong feelings engendered by, the war crimes trials, the research culture was slow to respond to the ethical declarations. Later efforts, such as the 1964 World Medical Assembly, *Declaration of Helsinki*,[137] and Henry K. Beecher's 1966 article[138] detailing ethical violations in twenty-two reported research cases, were needed to stimulate reform efforts.

Open abuses of informed consent in medical experimentation continued into the early 1970's. Several of the research studies generated significant controversy when the public media reported the details of the experiments.[139] Two such studies generated the most

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131. *Id.* at 151-56.

132. *See* United States v. Karl Brant, TRIALS OF WAR CRIMINALS BEFORE THE NUREMBERG MILITARY TRIBUNALS UNDER CONTROL COUNCIL LAW NO. 10, THE MEDICAL CASE, vols. I & II (1948-49) [hereinafter TRIALS]. Despite a continuing debate over the ethics of citing these studies, and serious doubts about the methodology "[a]t least forty-five research articles published since World War II draw upon data from the Nazi experiments." Kristine Moe, *Should the Nazi Research Data Be Cited?*, 14 HASTINGS CENTER REPORT, Dec. 1984, at 5. The greatest use of these studies has been in the field of hypothermia research. *Id.* The Nazi studies measured the rate of body cooling when Dachau prisoners were submerged in ice water for up to five hours. The prisoners often died as a result of the experiments. *Id.*

133. TRIALS, *supra* note 132, at 181-84.

134. FADEN & BEAUCHAMP, *supra* note 1, at 153-56.

135. *Id.*

136. TRIALS, *supra* note 132, at 181.

137. Declaration of Helsinki: Recommendations Guiding Medical Doctors in Biomedical Research Involving Human Subjects, *adopted by* the 18th World Medical Assembly, Helsinki, Finland, 1964, *reprinted in* 271 NEW ENG. J. MED. 473 (June 1964).

138. HENRY K. BEECHER, *Ethics & Clinical Research*, 274 NEW ENG. J. MED. 1354 (1966). *See also* HENRY K. BEECHER, EXPERIMENTATION IN MAN, Monograph (1959).

139. *See* FADEN AND BEAUCHAMP, *supra* note 1, at 161-67 (discussing The Jewish Chronic Disease Hospital Study and the Tuskegee Syphillis Study); *see also* Carel B. Ijsselmuiden & Ruth R. Faden, *Research and Informed Consent in Africa - Another Look*, 326 NEW ENG. J. MED. 830 (1992).

discussion. One study was the 1963 Jewish Chronic Disease Hospital study where researchers injected live cancer cells into patients without disclosing that fact.[140] The other was the Tuskegee Syphilis Study where the United States Public Health Service observed, but did not treat, the progress of syphilis in approximately 400 black males from 1932 to 1972.[141]

Public reaction to the methodology of the research studies eventually took the matter out of the hands of the professionals.[142] Government grants fund the vast majority of research projects. Consequently, federal and state regulations can govern the conduct of most medical research.[143] This supervisory power allowed the funding sources to develop and to enforce regulations requiring an informed consent procedure.

The subjects of an experiment must have the risks, benefits, and alternatives fully disclosed in a language understandable by them.[144] A written document must substantiate the consent.[145] Before commencing an experiment on human subjects, the researcher must convince an Institutional Review Board (IRB) that they have minimized risks and that the expected benefits exceed the risks.[146] Unfortunately, there is no requirement of post-experiment surveys or other means to determine whether the disclosure, as understood by the subject, met the reality of the experiment.[147]

The development of protections for human subjects helped to focus the issues and to involve practitioners and scholars in the related issues of consent to therapeutic medical interventions.[148] However, therapeutic medical care lacks the "single payer" with the power to mandate informed consent procedures. Slow improvement is being made through revisions in medical education and professional ethical codes, resulting from the pressure applied by the state courts and legislatures.

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140. *See* Hyman v. Jewish Chronic Disease Hosp., 251 N.Y.S.2d 818 (1964), *rev'd* 206 N.E.2d 338 (1965).

141. JAMES H. JONES, BAD BLOOD, THE TUSKEGEE SYPHILIS EXPERIMENT (1981).

142. *See* 39 Fed. Reg. 18,914 (1974) (codified at 45 C.F.R. pt. 46) for the first comprehensive set of federal informed consent regulations on human subject research.

143. *See, e.g.*, 45 C.F.R. 116 pt. 46 (1993); N.Y. PUBLIC HEALTH LAW §§ 2440-46 (McKinney 1993).

144. 45 C.F.R. § 46.116 (1993).

145. 45 C.F.R. § 46.117 (1993).

146. 45 C.F.R. § 46.111 (1993).

147. 45 C.F.R. § 46.113. The IRB's are authorized "to suspend or terminate approval of research that is not being conducted in accordance with the IRB's requirements. . . ." *Id.*

148. The President's Commission concluded that even though they developed from different sources and in different times, the concepts of informed consent for experimentation and for therapy "are today basically the same." *See* PRESIDENT'S COMMISSION, *supra* note 3, at 20, n.19.

B. Therapeutic Care and Informed Consent - State Common Law from 1957 to 1972

The consent doctrine is used to compensate patients who had not given a valid consent to surgery and who suffer a negative outcome.[149] Consent cases, as a legal battery, present a simple legal issue.[150] A more complex analysis and factual predicate is required when the legal issue changes from a lack of consent to a consent that is based on an inadequate level of disclosure of the risks and alternatives of that procedure. With some prompting from the medical professionals and from plaintiffs' attorneys, the courts soon came to analyze the cases as a form of medical malpractice.[151]

The labeling of the cause of action as medical malpractice has important practical consequences that have helped drive the case law analysis.[152] The greatest significance of the change for the doctor is that with a malpractice standard, she can rely upon expert testimony that she has followed the professional standard of care. Once the plaintiff establishes that the medical professional did not meet the standard of disclosure, the inquiry moves to the causation stage. The plaintiff must show that actual damages were suffered and that the actions of the defendant were the proximate cause of those damages. The causation question is whether the procedure would have been undergone even with appropriate disclosure.[153]

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149. The majority of claims from 1930 to 1960 dealt with misrepresentations and reflected the professional ethical concern that the physician not actively mislead the patient. "The physician shall neither exaggerate nor minimize the gravity of the patient's condition." CURRENT OPINIONS-1957 § 9, Opinion 2.

150. The court stated "[i]If Dr. Wilson did not have Scott's informed consent to operate upon him he would be guilty of assault and battery on Scott, and liable for the damages caused by the operation." Scott v. Wilson, 396 S.W.2d 532, 535 (Tex. Civ. App. 1965) *citing* Moss v. Rishworth, 222 S.W. 225 (Tex. Comm'n Civ. App. 1920).

151. *See, e.g., Natanson*, 350 P.2d 1093.

152. *See generally* Allan H. McCoid, *A Reappraisal of Liability For Unauthorized Medical Treatment*, 41 MINN. L. REV. 381 (1957). In the period of transition to an informed consent action modeled on malpractice there was some inconsistency in the courts' categorization of the cause of action. That variance resulted primarily from the practical litigation consequences influencing the courts' decisions. The assault cause of action carried with it several favorable consequences for plaintiffs, such as limited need for expert medical testimony, limited defenses, and the possibility of punitive damages. *Id.* at 383-89. A major advantage for the defendants was the shorter statute of limitations for intentional torts as opposed to negligence or medical malpractice. *Id.* at 389. Often the issue of categorization during this period was raised on a motion to dismiss for inadequate pleading or for missing the filing deadline. *Id.*

Courts often categorized the action as negligence rather than assault and battery to avoid the shorter Statute of Limitations that would have barred an intentional tort claim. *Id.* at 422-23. Another factor determining the classification was whether a claim received was the only legal claim alleged in the complaint. *Id.* at 422-23, n.146.

153. This article will not discuss the causation standard in detail. The matter relates primarily to the limitations of the litigation forum as a means of dispute resolution rather than directly bearing on the patient-physician relationship. The use of an "objective" standard on causation is seen as protecting against self-serving testimony from the plaintiff.

The 1957 case of *Salgo v. Leland Stanford Jr. University Board of Trustees*[154] used the phrase "informed consent" for the first time in a reported medical malpractice case.[155] The application of *res ipsa loquitur* was the prime issue addressed by the appellate court.[156] The court discussed informed consent only to give further guidance to the trial court on remand.[157] The trial court was directed to add to its jury charge explicit language on the therapeutic exception to disclosure.[158] The Court suggested a broad reading of that exception, allowing the physician to withhold information that would be harmful to the patient while acknowledging, but not resolving, the conflict with patient self-determination.[159]

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154. 317 P.2d 170 (1957).

155. *Salgo* did not announce the informed consent doctrine as a new, judicially imposed, professional obligation. The case had been tried with the lack of informed consent as an issue. *See* FADEN & BEAUCHAMP, *supra* note 1, at 125-26.

156. The court held that the doctrine didn't apply to the facts of this case and therefore reversed the verdict for the plaintiff. *Id.* at 182. The "locality rule" makes the local medical custom definitive of the professional standard of care. Malpractice defense through control over the sole source of expert testimony on the topic was one service local medical societies had long made available to members. STARR, *supra* note 39, at 111. This "conspiracy of silence" made it very difficult to get the expert medical witnesses necessary in negligence suits to show both the standard of care and overcome the expert testimony presented by defendants. *Id.* Reliance on the *res ipsa loquitur* doctrine was an effort to obviate the need for experts on the local custom. In *Salgo*, the court did recognize the complaints of plaintiff's attorneys on the "conspiracy of silence." *Salgo*, 317 P.2d at 175.

> But gradually the courts awoke to the so-called 'conspiracy of silence.' No matter how lacking in skill or how negligent the medical man might be, it was almost impossible to get other medical men to testify adversely to him in litigation based on his alleged negligence. Not only would the guilty person thereby escape from civil liability for the wrong he had done, but his professional colleagues would take no steps to insure that the same results would not again occur at his hands.

Salgo, 317 P.2d at 175. *See also* Carl R. Robinson, *Why the Conspiracy of Silence Won't Die*, MEDICAL ECONOMICS Feb. 20, 1984, at 180.

Plaintiff's attorneys had limited success in avoiding the need for expert testimony by applying *res ipsa loquitur* to medical care injuries. *See, e.g.*, Ybarra v. Spangard, 154 P.2d 687 (1944). They also had virtually no success in establishing a standard of strict liability. *See* Marc L. Carmichael, Annotation, *Liability of Hospital or Medical Practitioner Under the Doctrine of Strict Liability in Tort, or Breach of Warranty, for Harm Caused by Drug, Medical Instrument, or Similar Device Used in Treating Patient*, 54 A.L.R.3d 258. Over time, most states have rejected the strict locality rule and moved toward applying a reasonable physician standard. *See, e.g.*, Hall v. Hilbun, 466 So. 2d 856 (Miss. 1985). The similarity of medical school admission standards and curricula, the national availability of professional journals and computer databases, and the mobility of physicians have been cited as supporting this substitution. *Hall*, 466 So. 2d at 870.

157. *Salgo*, 317 P.2d at 181.

158. *Id.*

159. The court saw two ways to handle informed consent:

> One is to explain to the patient every risk attendant upon any surgical procedure or operation, no matter how remote; this may well result in alarming a patient who is already unduly apprehensive and who may as a result refuse to undertake surgery in which there is in fact minimal risk; it may also result in actually increasing the risks

The 1960 opinion in *Natanson v. Kline*[160] served as the leading citation in the United States on the topic for the next twelve years. The *Natanson* court was very conscious of the importance attached to its decision by the medical profession, and it continued the tone of deference set in *Salgo*:[161]

> The primary basis of liability in a malpractice action is the deviation from the standard of conduct of a reasonable and prudent medical doctor of the same school of practice as the defendant under similar circumstances. Under such standard the patient is properly protected by the medical profession's own recognition of its obligations to maintain its standards.[162]

Natanson shared one notable characteristic with other major appellate

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> by reason of the physiological results of the apprehension itself. The other is to recognize that each patient presents a separate problem, that the patient's mental and emotional condition is important and in certain cases may be crucial, and that in discussing the element of risk a certain amount of discretion must be employed consistent with the full disclosure of facts necessary to an informed consent. [citations omitted]. . . .
>
> The instruction given should be modified to inform the jury that the physician has such discretion consistent, of course, with the full disclosure of facts necessary to an informed consent.

Salgo, 317 P.2d at 181.

The year after the *Salgo* decision, a Minnesota court recognized the right of patients to have enough information to make an intelligent choice whether to accept the proposed treatment, to seek to modify the proposal, or to reject it. Bang v. Charles T. Miller Hospital, 88 N.W.2d 186 (Minn. 1958). The court made it clear that it did not wish to impose any onerous burdens on the medical profession:

> While we have no desire to hamper the medical profession in the outstanding progress it has made and continues to make in connection with the study and solution of health and disease problems, it is our opinion that a reasonable rule is that, where a physician or surgeon can ascertain in advance of an operation alternative situations and no immediate emergency exists, a patient should be informed of the alternative possibilities and given a chance to decide before the doctor proceeds with the operation. By that we mean that, in a situation such as the case before us where no immediate emergency exists, a patient should be informed before the operation that if his spermatic cords were severed it would result in his sterilization, but on the other hand if this were not done there would be a possibility of an infection which could result in serious consequences. Under such conditions the patient would at least have the opportunity of deciding whether he wanted to take the chance of a possible infection if the operation was performed in one manner or to become sterile if performed in another.

Id. at 190.

160. 350 P.2d 1093 (1960), *reh'g denied*, 354 P.2d 670 (1960).

161. The *Natanson* court recognized the professional practice as the standard of disclosure, but found that it was appropriate to dispense with expert testimony regarding the accepted practice in the case before it since the physician had not disclosed any of the dangers associated with the relatively new and dangerous cobalt treatment. The court stated:

> But on the state of the record here presented the appellant was not required to produce expert medical testimony to show that the failure of Dr. Kline to give any explanation or make any disclosures was contrary to accepted medical practice. To hold otherwise would be a failure of the court to perform its solemn duty.

Natanson, 354 P.2d at 673.

162. *Natanson*, 350 P.2d at 1107.

cases establishing informed consent, the presence of organized medicine as *amicus curiae*.[163]

The early reaction of organized medicine to the informed consent cause of action was barely distinguishable from their general dislike of malpractice. The Journal of the American Medical Association published its first article on informed consent in 1960 shortly after the *Natanson* decision.[164] Written by the Director of the AMA's Law Department, it opened and closed with the following paragraphs:

> To be legally valid, the consent given to a procedure must be an intelligent or informed consent, with an understanding of what is to be done and the risks involved.
>
> . . . .
>
> The holdings in the recent cases involving alleged lack of consent may make the physician a frequent target for malpractice claims whenever a bad result occurs. Since the gist of the action does not involve negligent treatment but negligence in failing to explain the hazards to the patient, the claim of alleged lack of informed consent may become attractive to those attorneys who seek new "theories" of liability against physicians . . . . The physician's best protection is to inform the patient fully regarding any unusual risks that may be involved and to insist upon a consent in writing in which the patient acknowledges this explanation.[165]

The intensity of feeling against informed consent cases was soon to increase, as common law developments cut to the heart of the profession's self regulation.

C. Challenging the Professional Disclosure Standard (1972-1975)

The courts have been accustomed to deferring to the standard of practice established within the medical profession in malpractice cases.[166] However, when the fact patterns brought before the court moved beyond the complete failure to disclose in new and high risk proce-

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163. In *Salgo*, 317 P.2d 170, the American College of Surgeons participated while in *Bang*, 88 N.W.2d 186, it was the Minnesota State Medical Association, and in *Natanson*, 350 P.2d 1093, it was the Kansas Medical Society.

164. Bernard D. Hirsh, *Informed Consent to Treatment - Medicologal Comment*, 176 JAMA 436, 438 (1960).

165. *Id.* at 438.

166. The courts identified exceptions to the duty to disclose. An exception for emergency situations is universally recognized. Medical professionals are not under a duty to discuss commonly known risks even if the risk is not known to the individual. A therapeutic exception is also allowed where the physician believes that broader disclosures carry significant risks to the patient's well being. In the professional model it is assumed that the physician can withhold information whenever she feels it is in the best interests of the patient to do so. *See, e.g.*, *Salgo*, 317 P.2d 170.

dures, there was some difficulty in finding a professional custom of disclosure to the patient.[167] As the *Canterbury* court stated,

> [T]he reality of any discernible custom reflecting a professional consensus on communication of option and risk information to patients is open to serious doubt. We sense the danger that what in fact is no custom at all may be taken as an affirmative custom to maintain silence, and that physician-witnesses to the so-called custom may state merely their personal opinions as to what they or others would do under given conditions.[168]

Additionally, there was little professional writing on the topic.[169] The professional codes of ethics were silent as to any duty to disclose risks or otherwise involve the patient in the decision-making process.

The paucity of guidance from the profession emboldened lower courts in some jurisdictions to look outside the profession for a standard.[170] The 1972 decisions in *Canterbury v. Spence*,[171] *Cobbs v. Grant*,[172] and *Wilkinson v. Vesey*[173] marked a movement toward the reasonable person disclosure standard.[174] The most widely adopted

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167. Canterbury v. Spence, 464 F.2d 772 (D.C. Cir. 1972).

168. *Id.* at 783.

169. A review of medical literature found only nine U.S. medical journal articles addressing patient consent in the 27 years up to 1957. The pace picked up as authors had case decisions to write about, with 12 articles found in the period of 1957 to 1959, and 50 for the 1960's. The 1970's saw a veritable explosion of articles on the topic, in large part because of the change in standards away from those set by professional practice. FADEN AND BEAUCHAMP, *supra* note 1, at 88, 95. Some part of the increase could be the result of the use of computerized data bases for the search of the post-1970 literature.

170. *See, e.g.*, Berkey v. Anderson, 82 Cal. Rptr. 67 (1969); Cooper v. Roberts, 286 A.2d 647, 650 (Pa. Super. Ct. 1971); Hunter v. Brown, 484 P.2d 1162, 1167 (Wash. Ct. App. 1971), *aff'd* 502 P.2d 1194 (1972).

171. 464 F.2d 772 (D.C. Cir. 1972), *cert. denied*, 409 U.S. 1064 (1972).

172. 502 P.2d 1 (Cal. 1972).

173. 295 A.2d 676 (R.I. 1972).

174. The courts in *Canterbury* and *Cobbs* modified the impact of their choice of a non-professional disclosure standard by opting for a reasonable person causation standard. *Canterbury*, 464 F.2d at 791 (the prudent person in the patient's position); *Cobbs*, 502 P.2d at 11-12 (citing *Canterbury*, 464 F.2d at 791). The standard attempts to gauge the response of a hypothetical "reasonable person" to the information on risks and alternatives that should have been provided. The reliance on the objective reasonable person has been criticized as little more efficacious than having a professional standard of disclosure. FADEN AND BEAUCHAMP, *supra* note 1, at 32-33.

This model incorporates a significant degree of professional practice since the acceptable response of the average person depends on the opinion of their treating physician. This is due, in part, to the deference given medical professionals. In a trial setting, the "expert" opinion can be additionally persuasive. Thus, the determination of what a reasonable person would do can be very difficult to distinguish from a professional judgment as to what is proper treatment.

A subjective causation standard would have the case turn on whether that particular individual would have consented if there had been the proper disclosure. *Wilkinson*, 295 A.2d 676, followed the lead of the early informed consent cases in adopting a subjective measure of proximate cause; *see also* Di Filippo v. Preston, 173 A.2d 333 (Del. 1961); *Natanson*, 350 P.2d

nonprofessional model requires disclosure of information that would be material to an "objective," but hypothetical, reasonable person. This standard introduces the view of the nonprofessional community as to what information should be made available to patients.[175] That the *Canterbury* court saw this as necessary to protect the rights of the patient is illustrated in the following excerpt:

> [T]o bind the disclosure obligation to medical usage is to arrogate the decision on revelation to the physician alone. Respect for the patient's right of self-determination on particular therapy demands a standard set by law for physicians rather than one which physicians may or may not impose upon themselves.[176]

The adoption of a lay standard of disclosure may dispense with the need for expert testimony on whether a material risk should have been disclosed.[177] This has significant implications for the cost of litigation and the prospects of a plaintiff's recovery. Much of the legal argumentation in informed consent cases is framed around the issue of whether expert testimony is needed on the disclosure standard.[178]

The challenge to its sense of professionalism was another reason organized medicine became more vociferous in opposing the informed consent doctrine with a lay standard for disclosure.[179] All professions attach importance to control of the "role definition vis-a-vis his client."[180] In few professions are the adult socialization processes and continuing social and professional controls so pronounced as they are in medicine. Through these processes, clinical practitioners internalize the values that guide them in making medical decisions in a manner acceptable to their fellow practitioners. In professional training, they

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at 1106 (1961); *Bang*, 88 N.W.2d 186 (1958); Gray v. Grunnagle, 223 A.2d 663 (Pa. 1966). Although most jurisdictions follow the objective test on causation, a number of the more recent cases have adopted a subjective standard. *See, e.g.*, McPherson v. Ellis, 287 S.E.2d 892, 896-7 (N.C. 1982); Scott v. Bradford, 606 P.2d 554 (Okla. 1979); Arena v. Gingrich, 733 P.2d 75 (Or. Ct. App. 1987).

There have been some variations on these standards. The Alabama Supreme Court adopted an "objective" test wherein causation was to be determined according to the response of a reasonable person "with all the characteristics of the plaintiff, including his idiosyncracies and religious beliefs." Fain v. Smith, 479 So. 2d 1150, 1155 (Ala. 1985). Massachusett's courts limit recovery to cases where neither the plaintiff, nor a reasonable person, would have proceeded. Harnish v. Children's Hosp. Medical Ctr, 439 N.E.2d 240 (Mass. 1982). *See* FADEN & BEAUCHAMP, *supra* note 1, at 30-35 for a discussion of the disclosure & causation standards.

175. FADEN & BEAUCHAMP, *supra* note 1, at 32-33.

176. *Canterbury*, 464 F.2d at 784.

177. FADEN & BEAUCHAMP, *supra* note 1, at 32.

178. *See, e.g.*, Culbertson v. Mernitz, 602 N.E.2d 98, 103-04 (Ind. 1992).

179. *Canterbury*, 464 F.2d at 790.

180. *See generally*, William J. Goode, *Community Within a Community: The Professions*, 22 AM. SOC. REV. 194 (1957).

also develop role images of themselves and their patients, which serve as the presumptive starting points for the physician-patient relationships.

The threat of assessment of money damages for a failure to abide by standards of conduct set outside the profession evoked a strong negative response from physicians. In a 1976 article published in the Journal of the American Medical Association, a surgeon reviewed the new patient oriented disclosure standards and concluded,

> Informed consent is a legalistic fiction that destroys good patient care and paralyzes the conscientious physician . . . . The term has no place in the lexicon of medicine. The integrity of the physician continues to represent the most effective guarantee of the rights of the patient and of the experimental subject.[181]

An editorial note at the end of that article stated that

> The AMA has recognized the need for remedial legislation to correct problems arising from the legal doctrine of "informed consent." A model state law that has been distributed to all state medical associations would specify what significant information about medical risks must be given to a patient to assure valid consent to a medical or surgical procedure.[182]

The model law drafted by the Office of the General Counsel of the AMA proposed a very restrictive formulation of informed consent.[183] It required disclosing "in general terms the nature and purpose of the procedure" with a specifically limited list of risks.[184] A signed consent form "shall be conclusively presumed to be valid and effective . . . no evidence shall be admissible to impeach, modify or limit the authorization for performance of the procedure" absent "clear proof" that fraudulent misrepresentation of material facts induced the signing of the form.[185] The AMA and its state and local affiliates next took

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181. EUGENE G. LAFORET, *The Fiction of Informed Consent*, 235 JAMA 1579, 1584-85 (1976). One example the author provides of how the courts and some medical academicians "twist the concept of informed consent to the point where, if it does not break, it at least buckles unrecognizably," regards breast cancer. *Id.* at 1581. He strongly criticized the recommendation that "every woman about to undergo surgery for breast cancer be told that the superiority of the traditional radical mastectomy has not been proved and that there may be suitable alternatives." *Id.*

182. *Id.* at 1585 (alteration in original) (emphasis omitted).

183. *See* MODEL INFORMED CONSENT LAW, Section XXX, *Consent to Treatment, reprinted in* Letter from S.E. Schonberg, *Letters*, 236 JAMA 1011, 1011 (1976).

184. *Id.* at 1011.

185. *Id.* The complete text of Section XXX provides for:

A consent in writing to any medical or surgical procedure or course of procedures which (a) sets forth in general terms the nature and purpose of the procedure or procedures, together with the known risks, if any, of death, brain damage, quadri-

their proposals on limiting the informed consent doctrines to the state capitols.

D. The Legislative Brake (1975-1977)

The values promoted by the informed consent ethic, promotion of well-being and autonomy, are said to "transcend partisan ideologies and the politics of the moment."[186] Whether that is true, history shows that the same cannot be claimed of the legal doctrines of informed consent. The most intense period of development, from 1972 to 1980, overlapped with a medical malpractice insurance crisis.[187] Insurance premiums for many specialties were raised precipitously, and several carriers stopped writing policies, threatening the availability of malpractice insurance in some areas.[188] The politics of the moment put the informed consent doctrines high enough on legislative priority lists to prompt action in a political climate that was favorable to physicians' interests. The medical profession had its concerns heard in the legislative halls and chambers more clearly than in the courtroom.

Before 1975, Georgia was the only state with legislation directly affecting the legal doctrine.[189] In the three year span of 1975 through 1977, twenty-five state legislatures enacted statutes directly impacting the informed consent doctrine.[190] In no instance was the statutory

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plegia, paraplegia, the loss or loss of function of any organ or limb, or disfiguring scars associated with such procedure or procedures, with the probability of each such risk if reasonably determinable, (b) acknowledges that such disclosure of information has been made and that all questions asked about the procedure or procedures have been answered in a satisfactory manner, and (c) is signed by the patient for whom the procedure is to be performed, or if the patient for any reason lacks legal capacity to consent by a person who has legal authority to consent on behalf of such patient in such circumstances, such consent shall be conclusively presumed to be valid and effective, in the absence of clear proof that execution of the consent was induced by fraudulent misrepresentation of material facts. Except as herein provided, no evidence shall be admissible to impeach, modify or limit the authorization for performance of the procedure or procedures set forth in such written consent.

Id.

186. PRESIDENT'S COMMISSION, *supra* note 3, at 17.

187. FADEN & BEAUCHAMP, *supra* note 1, at 139.

188. Glen O. Robinson, *The Medical Malpractice Crisis of the 1970's - a Retrospective*, 49 LAW AND CONTEMP. PROB. 5, 7-9, n.23 (1986).

189. See FADEN & BEAUCHAMP, *supra* note 1, at 139.

190. FADEN & BEAUCHAMP, *supra* note 1, at 139. *See* ALASKA STAT. § 09.55.556 (1994); ARIZ. REV. STAT. ANN. § 12-561.2, 563 (1992); DEL. CODE ANN. tit. 18, § 6852 (1989); FLA. STAT. ANN. § 766.103 (1994); HAW. REV. STAT. § 671-1(2), 671-3 (1985); IDAHO CODE § 39.4301, .4304 - .4306 (1993); IOWA CODE ANN. § 147.137 (West 1993); KY. REV. STAT. ANN. § 304.40-320 (Michie/Bobbs-Merrill 1988); LA. REV. STAT. ANN. § 40:1299.40 (West Supp. 1994); ME. REV. STAT. ANN. tit. 24, § 2905 (West Supp. 1977); NEB. REV. STAT. § 44-2816, 2820 (1988); NEV. REV. STAT. § 41A.110 (Michie 1986); N.H. REV. STAT. ANN. § 507-C:2(II) (1983); N.Y.

language designed to be more favorable to plaintiffs than the existing common law standards.[191] Nineteen jurisdictions substantially defined the cause of action.[192] In four jurisdictions, including New York State, the legislatures chose to replace the patient oriented standards of the case law with professional disclosure standards.[193] Nine more states joined in adopting standards based on the customary practice of the medical profession, the accepted standard of disclosure, or the practice expected from a "reasonable and prudent" professional.[194] Only two

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PUB. HEALTH LAW § 2805-d (McKinney 1993); N.C. GEN. STAT. 890-21.13 (1975); N.D. CENT. CODE § 26-40.1-02(5) and .05 (1977); OHIO REV. CODE ANN. § 2317.54 (Anderson 1975); OR. REV. STAT. § 677.097 (1993); 40 PA. CONST. STAT. ANN. § 1301.103; R.I. GEN. LAWS § 9-19-32 (1985); TENN. CODE ANN. § 29-26-118 (1975); TEX. REV. CIV. STAT. ANN. art. 71 & 6.01-.07 (West Supp. 1994); UTAH CODE ANN. § 78-14-5 (1992); VT. STAT. ANN. tit. 12, § 1909 (Supp. 1994); WASH. REV. CODE ANN. § 7.70.050, 7.70.060 (West 1992).

At the time enacted, the Rhode Island law merely provided a merit screening role for the courts in informed consent cases. See R.I. GEN. LAWS § 9-19-32. The Iowa, Ohio and Nevada laws listed the contents of signed consent forms that established a presumption of informed consent without further defining the informed consent cause of action. See IOWA CODE ANN. § 147.137; OHIO REV. CODE ANN. § 2317.54; NEV. REV. STAT. § 41A-110,-120. The Hawaii and Texas laws created panels to promulgate disclosure standards for specific medical treatments. See HAW. REV. STAT. § 671-1(2),-3; TEX. REV. CIV. STAT. ANN., art. 71 § 6.01-.07. The Texas law was unclear as to the standard to be applied in other cases, and the Hawaii statute was silent.

Alabama's general malpractice statute, passed during this period, has been held to apply to informed consent cases even though that term is not in the law. *See* ALA. CODE § 6-5-484 (1975) *and* Fain v. Smith, 479 So. 2d 1150, 1152 (Ala. 1985).

191. *See* Meisel & Kabnick, *Informed Consent to Medical Treatment*, *supra* note 94, at 563. These commentators read the unclear Texas statute as maintaining the professional disclosure standard set by *Wilson v. Scott*. 412 S.W.2d 299 (Tex. 1967). The Texas Supreme Court later held that the proper standard for cases not covered by the Texas Medical Disclosure Panel lists was the objective lay standard. *See* Peterson v. Shields, 652 S.W.2d 929 (Tex. 1983).

192. *See, e.g.*, ME. REV. STAT. ANN. tit. 25 § 2905 (West Supp. 1977).

193. *See* Meisel & Kabnick, *supra* note 94, at 562 (identifying Maine, Nebraska, New York and Vermont). See ME. REV. STAT. ANN. tit. 24, § 2905 (Supp. 1977); NEB. REV. STAT. § 44-2816 (1988); N.Y. PUB. HEALTH LAW § 2805-d(1) (McKinney 1993); VT. STAT. ANN. tit. 12, § 1909(a)(1) (Supp. 1994).

The Nebraska Supreme Court has clearly reiterated its preference for the common law standard:

> The material risk theory protects a patient's "right of physical self-determination [because it] mandates that the scope of a physician's duty to disclose therapeutic risks and alternatives be governed by the patient's informational needs." (citation omitted). Also, the professional theory "paternalistically leaves the right of choice to the medical community, in derogation of the patient's right of self- determination." (citation omitted). [N]otwithstanding voluminous criticism of the professional theory of informed consent, this court is bound by § 44-2816 as a statutory standard and prescription for an informed consent.

Eccleston v. Chait, 492 N.W.2d 860, 864 (Neb. 1992).

194. ARIZ. REV. STAT. ANN. § 12-563 (1992); DEL. CODE ANN. tit. 18, § 6852 (1989); FLA. STAT. ANN. § 766.103(3)(a)(1) (West Supp. 1994) (originally codified at § 768.132); IDAHO CODE §§ 39-4304 (1993); KY. REV. STAT. ANN. § 304.40-320(1) (Michie/Bobbs-Merrill 1988); N.H. REV. STAT. ANN. § 507-C:2(II)(a) (1983); N.C. GEN. STAT. § 90-21.13(a) (1993); N.D. CENT. CODE § 26-40.1-02(5) and -05 (1977); TENN. CODE ANN. § 29-26-118 (1980).

jurisdictions clearly opted for the patient oriented material risk standard and these states codified their preexisting common law standards.[195]

The enactments introduced more variety into both the substance and procedure of disclosure. As examples, the Oregon and Louisiana statutes incorporated two disclosure standards, depending on whether the patient asks for more information after an explanation in general terms.[196] Other states created standards without reference to either professional standards or the reasonable patient.[197] The State of Hawaii has empowered an administrative board to set statewide standards for providing informed consent.[198] Texas has likewise done so through

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195. *Compare* 40 PA. CONST. STAT. ANN. § 1301.103 (1975); *and* Cooper v. Roberts, 286 A.2d 647 (1971); WASH. REV. CODE ANN. §§ 7.70.050(1)(c) (West 1992) *and* Miller v. Kennedy, 522 P.2d 852 (Wash. Ct. App. 1974), *aff'd* 530 P.2d 334 (1975).

The Pennsylvania statute utilizes the material risk/reasonable patient disclosure standard, but has no causation requirement. This maintains the essence of the battery cause of action, wherein the affront of not obtaining informed consent establishes liability, whether or not this patient, or a reasonable patient, would have proceeded even if properly informed. 40 PA. CONST. STAT. ANN. § 1301.103.

196. The Oregon statute, OR. REV. STAT. § 677.097, provides for a three step process. The medical provider must explain the procedure in general terms, informing the patient that there are risks and may be alternatives. *Id.* at § 677.097(1)(a). Then the provider must ask the patient if he/she desires further explanations. *Id.* at § 677.097(2). If so, the provider must disclose "in substantial detail" more about the procedure, its risks and its alternatives. *Id.* The case law applied the material risk standard to the detailed explanation, along with a subjective patient standard of causation. Zacher v. Petty, 826 P.2d 619 (Or. 1992); Arena v. Gingrich, 733 P.2d 75 (Or. Ct. App. 1987).

Louisiana likewise has maintained a material risk standard for cases outside the statute. *Compare* LA. REV. STAT. ANN. § 40:1299.40 (West 1975) *and* Hondroulis v. Schuhmacher, 553 So. 2d 398 (La. 1988).

197. Utah's statute requires the disclosure of the substantial and significant risks of causing the patient serious harm. UTAH CODE ANN. § 78-14-5.1(d), (e) (1989). Hawaii's law, HAW. REV. STAT. §§ 671-3, empowers the Board of Medical Examiners to develop lists similar to those in the Texas law, but also to develop the substance of the disclosure. The standard would be admissible in a law suit on informed consent. For unlisted procedures, the courts were left without statutory guidance. The case law has not filled in this gap. *See* Mroczkowski v. Straub Clinic & Hosp. Inc., 732 P.2d 1255, 1258-59 (Haw. Ct. App. 1987); Leyson v. Steuermann, 705 P.2d 37, 47 n.10 (Haw. Ct. App. 1985). ALASKA STAT. § 09-55-556(a) (1994), requires the disclosure of "common risks and reasonable alternatives." *Id.* Recent caselaw has chosen the material risk/reasonable patient perspective for measuring the adequacy of disclosure. Korman v. Mallin, 858 P.2d. 1145, 1149 (Alaska 1993).

198. *See* HAWAII REV. STAT. ANN. § 671-3 which directs the Board of Medical Examiners to establish standards for health care providers to follow in giving information to a patient to insure that the patient's consent to treatment is an informed consent. *Id.* at § 671-3(a). The established standards "may include the substantive content of the information to be given, the manner in which the information is to be given by the health care provider and the manner in which consent is to be given by the patient or the patient's guardian." *Id.* at § 671-3(a).

The statute also defines the content of standards that can be used in litigation:

> If the standards established by the board of medical examiners include provisions which are designed to reasonably inform a patient, or a patient's guardian, of: (1) The condition being treated; (2) The nature and character of the proposed treatment

its Texas Medical Disclosure Panel which has created lists of procedures requiring disclosure and non-disclosure of risks.[199]

Legislation that codified the states' common law reliance on a professional standard held back movement toward a more patient-oriented common law.[200] In several states, the common law had not directly addressed the issue.[201] Informed consent statutes stifled the debate over the appropriate standard.[202] Some acts followed the AMA

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or surgical procedure; (3) The anticipated results; (4) The recognized possible alternative forms of treatment; and (5) The recognized serious possible risks, complications, and anticipated benefits involved in the treatment or surgical procedure, and in the recognized possible alternative forms of treatment, including nontreatment, then the standards shall be admissible as evidence of the standard of care required of the health care providers.

Id. at § 671-3(b).

This mandate proved to be overwhelming. As of 1983, no standards had been developed. *See* STAND. COMM. REP. 823, on S.B. 236 of the HEALTH & JUDICIARY COMMITTEES 1983 HOUSE JOURNAL at 1219-20; *reprinted in Steuerman*, 705 P.2d at 45.

199. TEXAS REV. CIV. STAT. ANN. art. 4590i, § 6.03(a) (West Supp. 1994) created the Texas Medical Disclosure Panel charged with developing a list of procedures requiring disclosure (List A) and a list of procedures that do not require risk disclosure (List B). *Id.* at § 6.04(a). A failure to disclose List A risks when required creates the presumption of a lack of informed consent. *Id.* at § 6.07(a)(2). For procedures not in the list, the physician is "under the duty otherwise imposed by law." *Id.* at § 6.07(b). Case law has held that this duty is not the pre-existing professional practice standard of Wilson v. Scott, 412 S.W.2d 299 (Tex. 1967), but the reasonable patient/material risk standard. *See* Peterson v. Shields, 652 S.W.2d 929 (Tex. 1983). The Texas Administrative Code incorporates, by reference, List A (required disclosure), List B (no disclosure), and a standard disclosure and consent form. TEX. ADMIN. CODE tit. 25, § 601.1-.3.

200. FADEN & BEAUCHAMP, *supra* note 1, at 139-40.

201. The case law in Arkansas prior to its 1979 enactment on informed consent consisted of only one federal court decision. *See* Pegram v. Sisco, 406 F. Supp. 776 (W.D. Ark. 1976), *aff'd without opinion*, 547 F.2d 1172 (8th Cir. 1976). The federal district court looked to the ARKANSAS MODEL JURY INSTRUCTIONS, Ch. 14 (1974) in the absence of case law on the issue.

The parties tried the case with the issue being compliance with "standard medical practice" in the community or similar communities. *Pegram*, 406 F. Supp. at 778. The court found that the physician had violated that standard in failing to inform the patient of risks, but also stated, "A patient must be reasonably informed of all material elements of the procedure and all material risks which may affect his decision to undergo the treatment." *Id.* at 779. The next informed consent case, Fuller v. Starnes, 597 S.W.2d 88 (1980), concerned treatment provided in 1976. The case reached the Arkansas Supreme Court after passage of the informed consent statute. Acts 1979, No. 709, § 2 (effective Apr. 12, 1979) *codified at* § 16-114-206. The statute "persuaded" the court to adopt the professional standard of disclosure. *Fuller*, 597 S.W.2d at 90.

202. The courts offset some of the favorable treatment accorded the medical profession in the legislatures. Several reform efforts were found to be unconstitutional while restrictions on the common law cause of action were read narrowly, or in some instances, ignored. The North Dakota State Supreme Court declared the entire North Dakota Medical Malpractice Act unconstitutional and specifically mentioned the legislative restriction on the informed consent cause of action in *Arneson v. Olson*. 270 N.W.2d 125 (N.D. 1978); N.D. CENT. CODE § 26-40.1-05 (repealed 1983). In *Parikh v. Cunningham*, the court stated that a "conclusive presumption" of informed consent from a signed form would be unconstitutional. 493 So.2d 999, 1001 (Fla. 1986) The statute, FLA. STAT. ANN. § 766.103, was amended before the case was finally

Model Code[203] to provide that signed consent orders are presumptive evidence of a valid consent, although the content requirements varied.[204] In 1979, Arkansas passed its informed consent statute.[205] The intense period of legislative activity on the topic was over. Apart from the unique case of Georgia, no state legislature has since enacted legislation defining or amending the informed consent doctrine.[206]

E. Legislating Informed Consent Without the Cause of Action

Limited legislative action on the informed consent cause of action has taken place since 1977, although several states have been active in defining administratively enforced informed consent.[207] These state laws replace the lay and professional disclosure standards with a specified minimum level of disclosure.[208] Conveying this information is a necessary element of professional conduct with respect to the particular services or service providers. Commonly, the statutes provide for monitoring of the requirement by the state board or agency overseeing the profession and disclaim any expansion of legal liabil-

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decided. 1985 Fla. Laws 1985 ch. 175, § 21 (substituting a rebuttable presumption).

Several statutes used professional disclosure standards in defining a written consent that presumptively establishes valid informed consent. Courts rejected the use of the professional standard when no signed consent was obtained. *Compare* IOWA CODE ANN. § 147.137 (West 1989) *with* Pauscher v. Iowa Methodist Medical Center, 408 N.W.2d 355 (Iowa 1987) (objective patient standard) *and* OHIO REV. CODE ANN. § 2317.54 (Anderson 1991) *with* Nickell v. Gonzalez, 477 N.E.2d 1145 (Ohio 1985) (objective patient standard).

The Texas Supreme Court has been criticized for applying a lay standard to informed consent cases that are not covered by the listings of the Texas Medical Disclosure Panel. See the discussion of Peterson v. Shields, 652 S.W.2d 929 (1983) *in* D. Michael Wallach & Steven J. Berry, *Informed Consent in Texas: A Proposal for Reasonableness and Predictability*, 18 ST. MARY'S L.J. 835, 860-62 (1987). The statute is not clearly written, but the prior common law standard was a professional practice standard and several commentators read the law as maintaining that standard. *See* Meisel and Krabnick, *supra* note 95, at 537.

LePelley v. Grefenson, 614 P.2d 962 (Idaho 1980) and Rook v. Trout, 747 P.2d 61 (Idaho 1987) read a patient oriented standard of disclosure into Idaho Code § 39.4304. IDAHO CODE § 39.4304 (Michie 1993). The statute set the required disclosure as that which "would ordinarily be made and given under the same or similar circumstances, by a like physician . . . of good standing practicing in the same community." *Id.* The holdings were overruled in Sherwood v. Carter, 805 P.2d 452, 460, 462 (1991).

203. See *Consent to Treatment*, Section XXX, AMA MODEL INFORMED CONSENT LAW, *reprinted in* 236 JAMA at 1011.

204. *See, e.g.* IOWA CODE ANN. § 147.137 (West 1989); GA. CODE ANN. § 31-9-6.1.

205. ARK. CODE ANN. § 16-114-206 (Michie 1987).

206. *See* GA. CODE ANN. § 31-9-6.1 (1988).

207. *See, e.g.*, N.Y. PUB. HEALTH LAW § 2404 (McKinney 1993). Section 2404(1) deals with the physician's duty to inform the patient about alternative treatments for breast cancer. *Id.* See also Section 2496 which establishes the disclosure requirements regarding a hysterectomy. N.Y. PUB. HEALTH LAW § 2496.

208. *See* N.Y. PUB. HEALTH LAW §§ 2404 & 2496.

ity.[209] The monitoring agency may be responsible for producing the materials that are to be provided to patients.[210]

Two common instances of this mandated disclosure concern medical services used exclusively by women: abortion and treatment for breast cancer. The statutes commonly require that practitioners provide women considering an abortion or being treated for breast cancer with a uniform, written summary of the risks and alternatives.[211] In both cases the information is provided to discourage the use of a service, *i.e.*, abortion or mastectomy. This is typically the motive with other service specific enactments as well.[212]

The provider specific laws are concerned with non-traditional medicine such as hospice and midwifery[213] or the use of specific procedures by professionals who do not have a M.D. or D.O., such as surgery by podiatrists or dentists.[214] The recent repeal of a number

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209. *See, e.g.*, N.Y. PUB. HEALTH LAW § 2404(4) & 2499.

210. *See, e.g.*, N.Y. PUB. HEALTH LAW § 2497.

211. Regarding abortion, *see* West's FLA. STAT. ANN. § 390.001(4) (West 1993); IDAHO CODE § 18-609(2), (3)(ii) (1987); KY. REV. STAT. ANN. § 311.726(2)(b) (Michie/Bobbs-Merrill 1990); LA. REV. STAT. ANN. § 40:1299.35.6 (West 1992); ME. REV. STAT. ANN. tit. 22, § 1599 (West Supp. 1994); MASS. ANN. LAWS ch. 112 § 12S (Law. Co-op. 1991); MO. ANN. STAT. § 188.039 (Vernon Supp. 1994); NEB. REV. STAT. § 28-327.326(8)(a), (c) (1989); N.D. CENT. CODE § 14-02.1-02; 13 PA. CONST. STAT. ANN. §§ 3205 & 3208; P.R. LAWS ANN. tit. 33, § 4010 (1989); R.I. GEN. LAWS, § 23-4.7-3 (1989); UTAH CODE ANN. § 76-7-305.5 (Supp. 1994).

Regarding breast cancer treatments, see CAL. HEALTH & SAFETY CODE § 1704.5 (West Supp. 1994); FLA. STAT. ANN. §§ 458.324 (West Supp. 1994); HAW. REV. STAT. § 671-3(c) (1985); KY. REV. STAT. ANN. § 311.935 (Michie/Bobbs-Merrill 1990); ME. REV. STAT. ANN. tit. 24, § 2905-A; MICH. COMP. LAWS ANN. §§ 333.17013, 17513 (West 1992); N.J. STAT. ANN. § 45:9-22.2 (West 1991); N.Y. PUB. HEALTH LAW § 2404 (McKinney 1993); 35 PA. CONST. STAT. ANN. § 5641 (1993).

212. A sampling of state laws shows specific legislation concerning informed consent to the following services: chelation therapy, *see, e.g.*, ARIZ. REV. STAT. ANN. § 32-1401 (Supp. 1993); provision of laetrile, *see e.g.*, LA. REV. STAT. ANN. § 37:1285.1 (West 1992); breast implant, *see, e.g.*, NEV. REV. STAT. ANN. § 449.740 (Michie 1991); artificial insemination, *see, e.g.*, N.H. REV. STAT. ANN. § 168-B:1; hysterectomy, *see, e.g.*, CAL. HEALTH & SAFETY CODE §§ 1690 & 1691 (West 1990); N.Y. PUB. HEALTH LAW § 2495 (McKinney 1993); electro-shock treatments, *see, e.g.*, P.R. LAWS ANN. tit. 24, § 4020; sterilization, *see, e.g.*, VA. CODE ANN. § 54.1-2974 (Michie 1991).

213. For legislation specifically addressed to hospice *see, e.g.*, FLA. STAT. ANN. § 400.608 (West Supp. 1994) (repealed 1993); ILL. ANN. STAT. ch. 60, ¶ 8; MISS. CODE ANN. § 41-85-15 (repealed 1983); 63 OKLA. STAT. ANN. tit. 63, § 1-860.4 (West Supp. 1995). For laws concerning birth centers or midwifery *see, e.g.*, FLA. STAT. ANN. § 383.31 (birth centers) (repealed 1994); *Id.* at § 467.015 (midwifery) (repealed 1994); IOWA CODE ANN. § 135G.8 (West 1989) (birth centers). Other targets are naturopathy, *see, e.g.*, ARIZ. REV. STAT. ANN. § 32-1501 (Supp. 1993); homeopathy, *see, e.g.*, NEV. REV. STAT. ANN. § 630A.370 (Michie 1992); cardiac catheterization laboratories, *see, e.g.*, CAL. HEALTH & SAFETY CODE §§ 444.4 & .8 (West Supp. 1994) (repealed 1994); and acupuncturists, *see, e.g.*, FLA. STAT. ANN. § 458.331 (West Supp. 1994) (repealed); and N.J. STAT. ANN. § 45:2C-1 (West 1991).

214. ARIZ. REV. STAT. ANN. § 32-854.01 (Supp. 1993) (podiatrists performing surgery); CAL. BUS. & PROF. CODE § 1682(e) (West 1990) (dentists using conscious sedation or general anesthesia must obtain written informed consent).

of the provider specific laws can be read as an acceptance of non-traditional medical practice.

F. Counting the Jurisdictions

The last holdout against the informed consent cause of action ended when the Georgia Legislature enacted its informed consent law, effective January 1, 1989.[215] Besides Georgia, the few jurisdictions that emerged from the 1970's without a defined informed consent cause of action soon recognized the claim in their common law.[216] The standards chosen by the legislatures and those developed through the common law have proven to be durable. None of the legislative choices as to the perspective for determining the adequacy of disclosure have been amended.[217] The courts have overturned three common law standards since 1980.[218] This quietude allows an opportunity to assess the outcome to date of the court and legislative battles over the informed consent doctrines.

A head count of the jurisdictions shows there is no majority position. Twenty-five jurisdictions have accepted professionally oriented standards of disclosure[219] while twenty-two states use the pa-

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215. 1988 GA. LAWS 1443 (codified at GA. CODE ANN. § 31-9.6.1).

216. *See, e.g.*, Logan v. Greenwich Hosp. Ass'n, 465 A.2d 294 (Conn. 1983); Hook v. Rothstein, 316 S.E.2d 690 (S.C. Ct. App.), *cert. dismissed*, 320 S.E.2d 35 (S.C. 1984); Cross v. Trapp, 294 S.E.2d 446 (W. Va. 1982).

217. However, there have been several changes of note. North Dakota repealed its statute and Florida amended its statute in response to constitutional challenges. N.D. CENT. CODE § 26-40.1-05, *repealed by* ch. 82, 1983 N.D. LAWS § 154. *Arneson v. Olson* declared the entire North Dakota Medical Malpractice Act unconstitutional, 270 N.W.2d 125, 138 (N.D. 1978). FLA. STAT. ANN. § 766.103 changed the written consent presumption from conclusive to rebuttable. FLA. STAT. ANN. § 766.103, *amended by* 1985 FLA. LAWS ch. 85-175, § 21 (1985). In *Parikh v. Cunningham*, the Florida Supreme Court stated that a conclusive presumption established by the statute would be unconstitutional. 493 So. 2d 999, 1001 (1986). Several other states have made statutory adjustments. *See* IND. CODE § 16-9.5-1-4(b) & (c) *as amended by* 1987 IND. ACTS 207, § 1) (defining the evidentiary weight of a signed consent form) (Burns 1993) (repealed); 1981 WIS. LAWS ch. 375, § 2 (codified as WIS. STAT. ANN. § 448.30) (supplementing the common law lay disclosure standard with disclosure of alternatives) (West 1988); LA. REV. STAT. ANN. § 40:1299.40(E)(3)(a) (*amended by* 1990 LAW. ACTS 1093, § 1) (creating a Medical Disclosure Panel to develop disclosure standards); and HAW. REV. STAT. § 671-3 (*amended by* 1983 HAW. SESS. LAWS 223, § 1) (slightly altering the charge to the promulgator of disclosure standards).

218. *See* Largey v. Rothman, 540 A.2d 504 (N.J. 1988) overruling the professional perspective adopted in Kaplan v. Haines, 241 A.2d 235 (1968); Culbertson v. Mernitz, 602 N.E.2d 98 (Ind. 1992) overruling a line of lower court cases by adopting a professional standard (with direct reference to the AMA ethic on patient involvement); Sherwood v. Carter, 805 P.2d 452 (Idaho 1991) overruling the lay standard read into the Idaho informed consent statute by Rook v. Trout, 747 P.2d 61 (1987).

219. Alabama, Arizona, Arkansas, Colorado, Delaware, Florida, Idaho, Illinois, Indiana, Kansas, Kentucky, Maine, Michigan, Missouri, Montana, Nebraska, Nevada, New Hampshire, New York, North Carolina, South Carolina, Tennessee, Vermont, Virginia, and Wyoming.

tient's material risk perspective.[220] Four jurisdictions have not defined the causes of action without using either the patient or physician perspectives.[221] Fourteen of the sixteen states that have made a legislative choice on disclosure use professionally oriented standards.[222] Twenty jurisdictions with no statutorily defined cause of action have adopted a patient oriented standard; however, only eleven such common law states have adopted a professional standard.[223] As a supplement to their informed consent doctrines, three states have empowered

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220. Alaska, California, Connecticut, District of Columbia, Iowa, Louisiana, Maryland, Massachusetts, Minnesota, Mississippi, New Jersey, New Mexico, Ohio, Oklahoma, Oregon, Pennsylvania, Rhode Island, South Dakota, Texas, Washington, West Virginia, Wisconsin.

221. They are: Georgia, *see* GA. CODE ANN. § 31-9-6(d) *and* § 31-9-6.1; Hawaii, *see* HAW. REV. STAT. § 671-3; North Dakota, *see, e.g.*, Wasem v. Laskowski, 274 N.W.2d 219 (N.D. 1979); Utah, *see* UTAH CODE ANN. § 78-14-5.

222. The statutes with professionally oriented disclosure standards are ALA. CODE § 6-5-484 (1975); ARIZ. REV. STAT. ANN. § 12-561(2) & 563 (1992); ARK. CODE ANN. § 16-114-206 (Michie 1987); DEL. CODE ANN. tit. 18, § 6852(a)(2) (1989); FLA. STAT. ANN. § 766.103 (West Supp. 1994); IDAHO CODE §§ 39.4304 (1993); KY. REV. STAT. ANN. § 304.40-320 (Michie/Bobbs-Merrill 1988); ME. REV. STAT. ANN. tit. 24, § 2905(1)(A); NEB. REV. STAT. §§ 44-2816, 2820 (1988); N.H. REV. STAT. ANN. § 507-C:2(II) (1983); N.Y. PUB. HEALTH LAW § 2805-d (McKinney 1993); N.C. GEN. STAT. § 90-21.13 (1993); TENN. CODE ANN. § 29-26-118 (1980); VT. STAT. ANN. tit. 12, § 1909 (Supp. 1994). The statutes with a material information (i.e., reasonable person) standard are 40 PA. CONST. STAT. ANN. § 1301.103 (1992); WASH. REV. CODE ANN. §§ 7.70.050 (West 1992).

223. The states with a lay common law disclosure standard are: Alaska, *see* Korman v. Mallin, 858 P.2d 1145, 1993 WL 333558 (Alaska Sept. 3, 1993); California, *see* Cobbs v. Grant, 502 P.2d 1 (1972); Connecticut, *see* Logan v. Greenwich Hosp. Ass'n., 465 A.2d 294 (1983); District of Columbia, *see* Canterbury v. Spence, 464 F.2d 772, (D.C. Cir. 1972); *cert. denied*, 409 U.S. 1064, (1972); Iowa, *see* Pauscher v. Iowa Methodist Med. Cntr., 408 N.W.2d 355, (1987); Louisiana, *see* Hondroulis v. Schuhmacher, 553 So. 2d 398 (1988); *see also* LA. REV. STAT. 40:1299.40(E)(2)(a); Maryland, *see* Sard v. Hardy, 379 A.2d 1014 (1977); Massachusetts, *see* Harnish v. Children's Hosp. Med. Cntr., 439 N.E.2d 240 (1982); Minnesota, *see* Cornfeldt v. Tongen, 262 N.W.2d 684 (1977), *modified on appeal after remand*, 295 N.W.2d 638 (1980); Mississippi, *see* Hudson v. Parvin, 582 So. 2d 403 (1991); New Jersey, *see* Largey v. Rothman, 540 A.2d 504 (1988); New Mexico, *see* Gerety v. Demers, 589 P.2d 180 (1978); Ohio, *see* Nickell v. Gonzalez, 477 N.E.2d 1145 (1985); Oklahoma, *see* Scott v. Bradford, 606 P.2d 554 (1980); Oregon, *see* Zacher v. Petty, 826 P.2d 619 (1992); *see also* OR. REV. STAT. § 677.097 (1993); Rhode Island, *see* Wilkinson v. Vesey, 295 A.2d 676 (1972); South Dakota, *see* Wheeldon v. Madison, 374 N.W.2d 367 (1985); Texas, *see* Peterson v. Shields, 652 S.W.2d 929 (1983) (construing TEX. REV. CIV. STAT. ANN. art. 4590i, §§ 6.07(b); West Virginia, *see* Cross v. Trapp, 294 S.E.2d 446 (1982); and Wisconsin, *see* Scaria v. St. Paul Fire and Marine Ins., Co., 227 N.W.2d 647 (1975).

States with a professional common law standard of disclosure are Colorado, *see* Bloskas v. Murray, 646 P.2d 907 (1982); Illinois, *see* Guebard v. Jabaay, 452 N.E.2d 751 (Ill. Ct. App. 1983); Indiana, *see* Culbertson v. Mernitz, 602 N.E.2d 98 (1992); Kansas, *see* Funke v. Fieldman, 512 P.2d 539 (1973); Michigan, *see* Roberts v. Young, 119 N.W.2d 627 (1963); Missouri, *see* Aiken v. Clary, 396 S.W.2d 668 (Mo. 1965); Montana, *see* Negaard v. Feda's Estate, 446 P.2d 436 (1968); Nevada, *see* Smith v. Cotter, 810 P.2d 1204 (1991); South Carolina, *see* Hook v. Rothstein, 316 S.E.2d 690 (S.C. Ct. App. 1984), *cert. denied*, 320 S.E.2d 35 (1985); Virginia, *see* Bly v. Rhoads, 222 S.E.2d 783 (1976); and Wyoming, *see* Roybal v. Bell, 778 P.2d 108 (1989).

boards to develop risk-oriented disclosure lists without specifying the perspective of disclosure for those lists.[224]

The doctrine is most personalized where it has been recently developed in the case law without legislative restrictions. Until 1979, all the patient-oriented standards incorporated the material risk, reasonable person language of *Canterbury v. Spence*.[225] Two jurisdictions that joined the debate late extended the doctrine by setting "patient perspective" disclosure standards.[226] The courts in Oklahoma and West Virginia dropped the requirement of a "reasonable person" screen to determine materiality.[227] Under their subjective standard, the provider must satisfy the particular patient's needs to know enough to make an intelligent choice based on the patient's own set of values. This standard recognizes the idiosyncratic interests and values that individuals might have.[228]

The obligation placed on the professional is to ascertain a significant amount of information about the person, besides the information usually collected to form a diagnosis. The judicial evolution of the doctrine away from professional standards might have carried over into more states had their legislatures not stopped the debate in the mid-1970's.[229]

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224. The Louisiana Medical Disclosure Panel was created by 1990 LA. ACTS 1093, § 1. The panel is charged with:

> . . . prepar[ing] separate lists of those medical treatments and surgical procedures that do and do not require disclosure and for those treatments and procedures that do require disclosure [the panel] shall establish the degree of disclosure required and the form in which the disclosure will be made.

LA. REV. STAT. ANN. § 40:1299.40(E)(4)(b). *See also* HAW. REV. STAT. ANN. § 671-3; TEX. REV. CIV. STAT. ANN., art. 4590i, § 6.03(a).

225. 464 F.2d 772 (D.C. Cir. 1972).

226. Scott v. Bradford, 606 P.2d 554 (Okla. 1979); Cross v. Trapp, 294 S.E.2d 446 (W. Va. 1982).

227. *Scott*, 606 P.2d at 559; *Cross*, 294 S.E.2d at 452 (citing Canterbury v. Spence, 464 F.2d at 786 & 787).

228. This choice is clearly related to the concerns of autonomy:

> The very foundation of the doctrine [of informed consent] is every man's right to forego treatment or even cure if it entails what *for him* are intolerable consequences or risks, however warped or perverted his sense of values may be in the eyes of the medical profession, or even of the community, so long as any distortion falls short of what the law regards as incompetency. Individual freedom here is guaranteed only if people are given the right to make choices which would generally be regarded as foolish ones.

2 FOWLER HARPER & FLEMING JAMES, JR., THE LAW OF TORTS 61 (Supp. 1968).

229. *Compare* ME. REV. STAT. tit. 24, § 2905(1)(A) *with* Downer v. Veilleux, 322 A.2d 82 (1974); *and* NEB. REV. STAT. § 44-2816 *with* Ecceleston v. Chait, 492 N.W.2d 860 (1992) *and* N.Y. PUB. HEALTH LAW § 2805-d *with* Fogal v. Genesee Hosp., 344 N.Y.S.2d 552 (N.Y.A.D. 1973); VT. STAT. ANN. tit. 12, § 1909(a)(1) *with* Small v. Gifford Mem. Hosp., 349 A.2d 703 (1975). *See also* Rook v. Trout, 747 P.2d 61 (Idaho 1987) *and* LePelley v. Grefenson, 614 P.2d 962 (Idaho 1980) establishing a material risk/reasonable person standard for cases

There are notable limitations on a jurisdictional head count. The standards became more complicated with the diversification of disclosure procedures by the state legislatures. As an example, the common law standard of disclosure in Louisiana has been, and remains, strongly supportive of the patient's perspective.[230] However, the Louisiana statute provides a presumption of effectiveness for a written consent form that discloses "in general terms" the risks "of death, brain damage, quadriplegia, paraplegia, the loss or loss of function of any organ or limb, or disfiguring scars" and which states the provider has satisfactorily answered all questions.[231] Only evidence of misrepresentation can be introduced to modify or limit that authorization.[232] Where oral consent is used, the statutory list of risks must be presented and "an opportunity shall be afforded for asking questions . . . which shall be answered in a satisfactory manner."[233]

The statute provides a third approach to disclosure: "[A]s an alternative, a physician or other health care provider may choose to avail himself of the lists established by the Louisiana Medical Disclosure Panel pursuant to the provisions of this Subsection as another method by which to evidence a patient's consent to medical treatment."[234] The Panel's mandate is to "prepare separate lists of those medical treatments and surgical procedures that do and do not require disclosure" and to establish the degree and form of disclosure for the treatments and procedures that require disclosure.[235] The lists can be introduced at trial to evidence compliance or noncompliance with the requirements of disclosure.[236] For the medical professional to have the benefit of the statutory risks, they must also disclose alternatives, additional risks specific to a patient, and provide an opportunity for

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arising prior to the effective date of IDAHO CODE § 39.4301, .4304-.4306. *Rook* retained that standard for post-statutory cases until it was overruled by Sherwood v. Carter, 805 P.2d 452, 462 (1991). A Delaware intermediate appellate court has held that Delaware's common law standard is that of the reasonable patient. Molnar v. Rafetto, (Del. Super. 1990), *interlocutory review denied*, 586 A.2d 1202 (Del. 1990). The decision was not controlled by the professional standards in the Delaware statute because it involved a dentist, and dentistry was not included in the definitions of the informed consent statute. *Id.*

230. *See* Percle v. St. Paul Fire and Marine Ins. Co., 349 So. 2d. 1289, (La. Ct. App. 1977), *cert. denied*, 350 So. 2d 1218 (1977); *see also* Hondroulis v. Schuhmacher, 553 So. 2d 398 (La. 1988).

231. LA. REV. STAT. ANN. § 40:1299.40(A)(a) & (b) (West 1992).

232. *Id.* at § 40:1299.40(A)(c).

233. *Id.* at § 40:1299.40(C).

234. *Id.* at § 40:1299.40(E)(2)(b). The Louisiana lists are developed by an eleven member panel consisting of six licensed physicians, four lawyers, and one dentist. *Id.* at §40:1299.40(E)(3)(a). Three of the attorneys are chosen from a list submitted by the Louisiana Trial Lawyers Association and one is chosen from a list submitted by the Louisiana Defense Counsel Association. *Id.*

235. LA. REV. STAT. ANN. § 40:1299.40(E)(4)(b).

236. *Id.* at § 40:1299.40(E)(4)(c).

any questions.[237] As a final twist on the possibilities, the Louisiana Supreme Court relied on a state constitutional privacy right to limit the therapeutic exception to the doctrine of informed consent.[238] Other states present similarly difficult problems of categorization.[239]

Another problem with jurisdiction counting is that it can distort the human impact of the rules. With respect to informed consent, the

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237. *Id.* § 40:1299.40(E)(7)(c).

238. Hondroulis v. Schumacher, 553 So. 2d 398, 415 (La. 1988).

239. The Texas Medical Disclosure Panel is made up of six physicians and three lawyers. TEX. REV. CIV. STAT. art. 4590i, § 6.03(C) (Supp. 1994). It has a charge identical to the Louisiana panel as to what the lists should contain. *Id.* at § 6.04(b). The Texas statute, however, does not include the added disclosure elements on alternatives, individualized risks and patient questions. The Texas Medical Disclosure Panel has promulgated List A, procedures that require disclosure, with the risks or hazards to be revealed, and List B procedures that require no disclosure. The Panel has also developed a standard consent form that satisfies the disclosure requirements and incorporates by reference the lists promulgated under TEX. REV. CIV. STAT. art. 4590i, § 6.04(b). *See* TEX. ADMIN. CODE tit. 25, §§ 601.01-.4. The statute provides that for procedures not listed, the provider "is under the duty otherwise imposed by law." TEX. REV. CIV. STAT. art. 4590i, § 6.07(b). The Texas Supreme Court has held that language to mean the material risk/reasonable person standard. Peterson v. Shields, 652 S.W.2d 929, 931 (1983).

Hawaii also provides authority for developing a risk list that satisfies disclosure requirements for included procedures. *See* HAW. REV. STAT. § 671-3 (1985). The Hawaii standards, if they include provisions designed to "reasonably inform a patient" of the "recognized possible alternative[s]" and "recognized serious possible risks, complications, and anticipated benefits" are "admissible as evidence of the [required] standard of [disclosure]." *Id.* at § 671.3(b). However, neither the statute nor the case law makes clear the standard for unlisted procedures or treatments.

Georgia's new informed consent statute is more restrictive than a customary professional practice standard. GA. CODE ANN. § 31-9-6.1(a) (1991). Only patients who undergo surgery with general, spinal or major regional anesthesia; or amniocentesis; or have an intravenous or intraductal injection of a contrast material as part of a diagnostic procedure are entitled to disclosure. *Id.* at § 31-9-6.1(a) (1991). This roster of patients needs to be told "in general terms" of only the material risks of the procedure found on the statutory list. *Id.* Any patient or procedure outside the coverage of the new statute has no informed consent cause of action. *See* Young v. Yarn, 222 S.E.2d 113 (Ga. Ct. App. 1975).

Oregon's statute creates a two step process. *See* OR. REV. STAT. § 677.097 (1993). The first step is for the physician to explain "in general terms" the procedure or treatment, and whether there are risks and/or alternatives. *Id.* at § 677.097(1)(a). The physician then must ask if the patient wants a more detailed explanation. *Id.* at 677.097(2). A positive response then requires disclosures, "in substantial detail" of the three topics. *Id.* Failure to ask leaves the disclosure to be measured against the common law backdrop of the material risk disclosure standard. This process reflects a compromise between the legislative goals of the Oregon Trial Lawyers and the Oregon Medical Society. *See* Zacher v. Petty, 982 P.2d 619 (Or. 1992).

The informed consent statute in Utah provides that the "substantial and significant risks" of medical care need to be disclosed but neither the text nor the case law provide an answer to the question of whether this is measured from the patient's perspective or that of the profession. *See* UTAH CODE ANN. § 78-14-5(1) (1992).

In North Dakota, the Medical Malpractice Act with its professionally oriented disclosure standard was held unconstitutional by the North Dakota Supreme Court. Arneson v. Olson, 270 N.W.2d 125 (1978). Subsequently, the act was repealed. N.D. CENT. CODE § 26-40.1-05 (repealed 1983). The case law has not addressed the specific issue of which disclosure perspective controls.

states with the most protective professional standards are mainly states with large rural areas and a relatively low physician to population ratio.[240] Fifty-three percent of the nation's physicians serving fifty-one percent of the population are in jurisdictions with non-professional disclosure standards.[241]

While all jurisdictions have an informed consent doctrine in place, their direct impact on clinical medicine is limited. The origins in litigation, and the narrow focus on spectacularly bad results of invasive procedures, restrict the doctrines. Litigation provides a general deterrent to substandard consent practices through the threat of damages for egregious violations. However, the small number of cases brought on this theory, and the arbitrary process of identifying victims, restricts the monitoring role of litigation. The selection process of malpractice cases for litigation overlooks most cases that merit damages and proceeds with many that lack merit.[242]

Prosecution of informed consent cases is difficult because the critical evidence includes the oral representations made by the medical professional and, often, a written general consent. Compounding the proof problems, the lack of informed consent is actionable only when it causes a bad outcome leaving the patient with a significant disability.[243] This, in turn, limits the medical procedures or interventions that are subject to possible informed consent lawsuits.[244] Some informed consent statutes explicitly restrict their application to invasive procedures.[245]

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240. As discussed *infra*, there is a range of professional standards recognized in malpractice cases. The customary or ordinary practice is a narrowly defined locality and was adopted to protect rural practitioners from being held to an unobtainable standard.

241. *See* STATISTICAL ABSTRACT OF THE UNITED STATES, T. 173, at 119 (1993) (based on U.S. Bureau of Census estimates as of July 1, 1989).

242. PATIENTS, DOCTORS, AND LAWYERS: MEDICAL INJURY, MALPRACTICE LITIGATION, AND PATIENT COMPENSATION IN NEW YORK, THE REPORT OF THE HARVARD MEDICAL PRACTICE STUDY TO THE STATE OF NEW YORK 6 (1990).

243. As a consequence of the way that lawyers conduct their business, there is an informal but real dollar threshold used to screen out cases with "small" damages potential. The amount varies between jurisdictions, but the most commonly cited figure for recent years has been $50,000.

A state medical board can investigate and impose sanctions for ethical or practice violations even in the absence of specific damages being suffered by patients. The number of disciplinary proceedings that are undertaken in any state might suggest that this distinction is primarily theoretical. Similarly, institutional quality assurance and risk management committees monitor performance to varying degrees, even without specific complaints being filed.

244. There have been a few cases that have gone beyond invasive procedures. *See, e.g.*, Fuller v. Starnes, 597 S.W.2d 88 (Ark. 1980) (drug prescription); Keel v. St. Elizabeth Med. Ctr., 842 S.W.2d 860 (Ky. 1992) (CT Scan); Truman v. Thomas, 611 P.2d 902 (Cal. 1980) (failure to inform patient of risk of not having a pap smear).

245. *See, e.g.*, N.Y. PUB. HEALTH LAW § 2805-d(2)(b) (McKinney 1993).

The informed consent cases focus on one segment of medical care services, surgery. In this and other areas of medicine, the presenting of alternative approaches to a medical problem can be a more far-reaching requirement than is risk-disclosure. It fosters more interaction between patient and provider and requires more input and understanding from the patients. Some state doctrines have focused exclusively on risk disclosure and ignored the disclosure of alternatives.[246]

IV. NEARING THE END OF THE ERA OF INFORMED CONSENT

Medical practitioners had to face a hard truth during the Era of Informed Consent. Even with the favorable legislative treatment given the medical profession in informed consent laws, lawyers, judges, legislators, and academics were now defining acceptable medical conduct. As summarized by David Rothman,

> [O]utsiders now framed the normative principles that were to guide the doctor-patient relationship. The critical pronouncements no longer originated in medical texts but in judicial decisions, bioethical treatises, and legislative resolutions. Outsiders, not doctors, defined the moral codes that were to guide physician behavior.[247]

Starting in 1980, the AMA and other national medical societies reacted by addressing the patient relationship in their ethical codes. To regain control over a critical element of professionalism, they aligned their interests with the patient's right of self-decision. Organized medicine's redefinition of the standard of interaction with patients is consistent with its later participation in developing practice guidelines and a national fee schedule for physicians.[248] These steps can be seen as efforts to retain professional control over medical decision-making. As one health law scholar has said of the AMA's cooperation on practice guidelines,

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246. *See, e.g.*, ARK. CODE ANN. § 16-114-206(b) (Michie 1987); DEL. CODE ANN. tit. 18, § 6852(b)(3) (1989); IDAHO CODE §§ 39.4301-.4306 (1993); ME. REV. STAT. ANN. tit. 24, § 2905; N.H. REV. STAT. ANN. §507-C:2(II)(b) (1983); N.C. GEN. STAT. § 90-21.13(a)(2) (1993).

247. DAVID J. ROTHMAN, STRANGERS AT THE BEDSIDE: A HISTORY OF HOW LAW AND BIOETHICS TRANSFORMED MEDICAL DECISION MAKING 4 (1991).

248. The AMA cooperated in the Harvard study that developed the relative values used in the Resource-Based-Relative-Value-System (RBRVS). The RBRVS was developed as a method to deal with payments to physicians for services under Medicare's Part B. See David Blumenthal & Arnold M. Epstein, *Physician-Payment Reform—Unfinished Business*, 326 NEW ENG. J. MED. 1330 (1992).

The AMA has developed criteria and procedures to assist researchers and medical specialty groups with developing practice parameters. *See* Edward Hirshfeld, *Medically Unnecessary Denials: Where the Standards Come From and How Physicians Can Participate*, 262 JAMA 3187, 3193-94 (1989) (Hirshfeld is Associate General Counsel of the AMA).

> Indeed, physicians appear to hope that by voluntarily supplying better professional standards, they will be able to prevent this collapse of their preferred paradigm of medical care, under which they are held accountable only under norms and standards that they themselves develop.[249]

It is reasonable for those in organized medicine to hope their codes will shape the law. The courts are willing to defer to professional medical standards, where they exist. Reported court decisions frequently have cited the AMA *Code* and, occasionally, other codes as well.[250] The codes have been relied upon in defining such legal issues as physician-patient confidentiality[251] and the propriety of discontinuing medical treatment.[252] Now that the profession has acknowledged the importance of informed consent, the courts will likely resume the role they performed after the era of consent ended - serving as one mode of enforcing a standard of care developed within the profession.[253]

As the Era of Informed Consent nears an end, there is consensus at the policy level that the medical decision making process must include the patient as an informed participant. However, there is considerable uncertainty over the appropriate allocation of responsibility and power between the medical provider and the patient. Various models have been proposed, but none have reached the level of a normative standard.[254] Different views of the attributes of the sick role lead commentators to opposite results. Defenders of paternalism have emerged as have proponents of increased patient involvement.[255]

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249. Clark C. Havighurst, *Practice Guidelines as Legal Standards Governing Physician Liability*, 54 LAW & CONTEMP. PROBLS. 87, 90 (1991).

250. A Westlaw search conducted on September 20, 1993, in the "Allstates" database produced a citation list of 100 cases for the search query - "American Medical Association" or AMA /s principles or ethics.

251. *See, e.g.*, Tarasoff v. Regents of Univ. of Calif., 551 P.2d 334, (Cal. 1976); Perreira v. State, 768 P.2d 1198 (Colo. 1989); Crist v. Moffatt, 389 S.E.2d 41 (N.C. 1990); Pearce v. Ollie, 826 P.2d 888 (Idaho 1992); Brandt v. Medical Defense Assoc., 856 S.W.2d 667 (Mo. 1993). *But see* Bryson v. Tillinghast, 749 P.2d at 114 (Okla. 1988) (ethical standards are "aspirational" and not enforceable).

252. *See, e.g.*, *In re* Estate of Longeway, 549 N.E.2d 292 (Ill. 1989); Guardianship of Doe, 584 N.E.2d 1263 (Mass. 1992); Cruzan by Cruzan v. Harmon, 760 S.W.2d 408 (Mo. 1988), *aff'd sub nom.* Cruzan by Cruzan v. Director, Mo. Dep't of Health, 497 U.S. 261 (1990); Matter of Farrell, 529 A.2d 404 (N.J. 1987); Couture v. Couture, 549 N.E.2d 571 (Ohio Ct. App. 1989).

253. See Culbertson v. Mernitz, 602 N.E.2d 98 (Ind. 1992).

254. *See, e.g.*, Ezekiel J. Emanuel & Linda L. Emanuel, *Four Models of the Physician—Patient Relationship*, 267 JAMA 2221 (1992). The authors offer the following models: paternalistic, informative, interpretive, and deliberative (and perhaps a fifth, the instrumental model). *Id.* at 2221-22.

255. *See, e.g.*, Thomas P. Duffy, *Agamemnon's Fate and the Medical Profession*, 9 W. NEW ENG. L. REV. 21 (1987). "Paternalism exists in medicine, not as some evil perpetrated by

A. The New Professional Ethics - Redefining Quality of Care

In the decade of the 1980's, the patient-physician relationship was prominently inserted into medical ethical codes. Organized medicine now explicitly recognizes the patient's right to be informed and to control the choices on care.[256] Written ethics reject paternalism as the basis for the patient-physician relationship. These codes articulate the indigenous medical tradition of truth-telling and consent-seeking suggested by Martin Pernick.[257]

The AMA's *Code of Ethics* has evolved into three integrated components: the *Principles of Medical Ethics*, the *Current Opinions of the Council on Ethical and Judicial Affairs*, and the *Reports of the Council on Ethical and Judicial Affairs*.[258] Each part of the Code serves a different purpose. The *Principles* have been pared down to seven sentences broadly defining the parameters of ethical conduct for physicians. They were revised in 1980 to "seek a proper and reasonable balance between professional standards and contemporary legal standards in our changing society."[259] To the extent that they are relevant here, the new *Principles* state that

> I. A physician shall be dedicated to providing competent medical service with compassion and respect for human dignity.
> II. A physician shall deal honestly with patients . . .
> III. A physician shall respect the law . . .
> IV. A physician shall respect the rights of patients . . .
> V. A physician shall continue to study, apply and advance scientific knowledge, make relevant information available to patients, colleagues, and the public, obtain consultation, and use the talents of other health professionals when indicated.[260]

The AMA Council on Ethical and Judicial Affairs provides the official interpretation of the AMA's *Principles of Medical Ethics* in its publication, *Current Opinions*.[261] Immediately after the 1980 re-

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the profession upon the patient, but rather to fulfill a need created by illness." *Id.* at 27. *See also* Roger C. Sider and Colleen D. Clements, *The New Medical Ethics: A Second Opinion*, 145 ARCH. INTERN. MED. 2169-71 (1985) (supporting paternalism). For a contrary view, *see* Stanley J. Reiser, *The Era of Patient, Using the Experience of Illness in Shaping the Missions of Health Care*, 269 JAMA 1012 (1993).

256. See CURRENT OPINIONS-1992 § 8.08.

257. See PERNICK, *supra* note 41, vol. 3, at 3.

258. AMERICAN MEDICAL ASS'N, REPORTS OF THE COUNCIL ON ETHICAL & JUDICIAL AFFAIRS-(1984-90), *Introduction*, at 3 (1992).

259. CURRENT OPINIONS-1981, at viii.

260. See CURRENT OPINIONS-1981, at ix.

261. The Council (formerly the Judicial Council) is the judicial authority of the AMA. It is composed of seven physician/members of the AMA, one resident physician and one medical student. Council members are nominated by the President of the AMA and elected by the House of Delegates, the AMA's representative assembly. Their published opinions on the Principles appear in CURRENT OPINIONS. *See* AMERICAN MEDICAL ASS'N, CONSTITUTION AND BYLAWS, *reprinted in* ANNOTATED CURRENT OPINIONS, 86 (1992).

vision of the *Principles*, the Council explained one of the recognized rights of patients as follows:

> The patient's right of self decision can be effectively exercised only if the patient possesses enough information to enable an intelligent choice. The patient should make his own determination on treatment. Informed consent is a basic social policy for which exceptions are permitted (1) where the patient is unconscious or otherwise incapable of consenting and harm from failure to treat is imminent; or (2) when risk-disclosure poses such a serious psychological threat of detriment to the patient as to be medically contraindicated. Social policy does not accept the paternalistic view that the physician may remain silent because divulgence might prompt the patient to forego needed therapy.[262]

The AMA Code is also noteworthy for its respect for the individual's choice once the proper disclosure has been made. The *Current Opinions* makes special mention of the variable values found in the patient population: "Rational, informed patients should not be expected to act uniformly, even under similar circumstances, in agreeing to or refusing treatment."[263]

Further elaboration of the *Principles* and their application to specific ethical issues in the practice of medicine are found in the *Reports*. That is where, in 1990, the Council published the *Fundamental Elements of the Patient-Physician Relationship*.[264] The description is of a "collaborative effort" and "mutually respectful alliance."[265]

The AMA Code is the most cited, but not the only, statement of ethical principles for medical professionals.[266] The American Col-

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262. CURRENT OPINIONS-1981 § 8.07. This opinion has been expanded to acknowledge the physician's obligation to accurately present medical facts, make recommendations based on good medical practice, and help the client make choices. CURRENT OPINIONS-1992 § 8.08. The 1992 CURRENT OPINIONS also strongly support patient self-determination when life-sustaining treatments are at issue. CURRENT OPINIONS-1992 § 8.08.

263. CURRENT OPINIONS-1981 § 8.07.

264. REPORTS 1992 No. 26, *Fundamental Elements of the Patient-Physician Relationship*, (issued June 1990).

> 1. The patient has the right to receive information from physicians and to discuss the benefits, risks, and costs of appropriate treatment alternatives. Patients should receive guidance from their physicians as to the optimal course of action.
>
> 2. The patient has the right to make decisions regarding the health care that is recommended by his or her physician. Accordingly, patients may accept or refuse any recommended medical treatment.

Id.

265. *Id.*

266. *See, e.g.*, AMERICAN DENTAL ASS'N, PRINCIPLES OF ETHICS § 1; *and* ADA, CODE OF PROFESSIONAL CONDUCT 1-L. *See also Informed Consent & Refusal, in* DENTAL ETHICS (Weinstein ed., 1993).

Respect for autonomy has only recently become an ethical standard for treatment

lege of Physicians (ACP), a national organization of internal medicine practitioners formed in 1914, published the first edition of its *Ethics Manual* in 1984.[267] The narrative description of the physician-patient relationship states,

> The patient must be well informed to make health-care decisions and work intelligently in partnership with the physician. . . .Information that the patient needs for decision-making should be given in terms the patient can understand. The physician should heed cues from the patient in setting the pace of disclosure, particularly when the illness is grave. . . .Disclosure should never be a mechanical or perfunctory process. Distressing news and information should be presented to the patient in a way that minimizes despair. . . .In general, full disclosure is a fundamental ethical requirement. . . .The doctrine of informed consent goes beyond the question of whether consent was given for a particular treatment. Rather, it focuses on the content of that consent: specifically, on whether the patient knew enough about the nature of the treatment, the alternative methods of treatment, and what would happen in the absence of treatment to make an informed decision. . . .Given the imbalance in knowledge and expertise between the physician and the patient, the physician must provide the patient with enough knowledge to allow the patient to make an informed judgment as to how to proceed. The physician's presentation should be understandable and unbiased; the patient's or surrogate's concurrence must be obtained without coercion; the physician must not take advantage of a situation in which he or she may hold psychological dominance. Truly informed consent is most apt to be achieved through effective communication between patient and physician; it is not achieved by the perfunctory signing of a "legal" consent form. . . .Using language that can be understood, the physician endeavors to present the patient with a basic understanding of the problems they face together and makes it clear that the patient has the right to make the final choice in accepting or rejecting the proposed plan of diagnosis and treatment.[268]

It is difficult to measure the clinical impact of the new ethics. However, patient participation is being widely discussed in medical journals and other forums.[269] In addition to having an impact on the

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decisions. Dentists had long appealed only to the principle of beneficence and, in so doing, often acted paternalistically. This chapter identifies several forces that influenced dentistry's recent adoption of the informed consent doctrine.

Id. at 65.

267. ACP, AMERICAN COLLEGE OF PHYSICIANS ETHICS MANUAL *reprinted in* 101 ANN. INTERN. MED., 129, 263 (1984). A second edition was published in 111 ANN. INTERN. MED. 245, 327 (1989). The third edition appears in 117 ANN. INTERN. MED., 947 (1992).

268. ACP ETHICS MANUAL, *supra* note 268, at 949-50.

269. *See, e.g.*, John M. Lee *Screening and Informed Consent*, 328 NEW. ENG. J. MED. 438 (1993); Emanuel & Emanuel, *supra* note 254, 267 JAMA 2221; Reiser, *supra* note 255, 269 JAMA 1012.

professional culture, the professional codes can be directly enforced by the national organization.[270] The codes have been incorporated into state medical licensing and review board standards,[271] state and local medical societies' bylaws,[272] and the medical staff bylaws of hospitals.[273]

The medical ethics codes have an impact on medical education. Most medical schools in the United States include a medical ethics course in their curricula.[274] The Association of American Medical Colleges, one of the accrediting bodies for medical schools in the United States, has stressed the importance of such courses.[275] The educational response is broader than including ethical codes as required reading. There has been renewed attention to developing the interpersonal skills (IPS) of physicians and medical students. The AAMC has set improvements in this area as a goal for medical schools.[276] A recent study found that some progress has been made:

> In the last two decades, there have been major advances in the theory and technology of teaching of medical interviewing and IPS

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270. The AMA Council has identified three categories of ethics: Moral principles or practices, customs and usages of the medical profession, and matters of policy not necessarily involving issues of morality in the practice of medicine. CURRENT OPINIONS-1981, § 1.01. Each carries with it a different professional response if violated.

> Unethical conduct involving moral principles, values and duties calls for disciplinary action such as censure, suspension, or expulsion from medical society membership . . . . Failure to conform to the customs and usages of the medical profession may call for disciplinary action depending upon the particular circumstances involved, local attitudes, and how the conduct in question may reflect upon the dignity of and respect for the medical profession . . . . In matters strictly of a policy nature, a physician who disagrees with the position of the American Medical Association is entitled to freedom and protection of his point of view.

Id. The inclusion of patient participation in the AMA Code would appear to move it from the category of custom and usages to that of moral principles or practices.

271. *See, e.g.*, Falcon v. Alaska Pub. Offices Comm'n, 570 P.2d 469 (Alaska 1977); Webb v. Jarvis, 575 N.E.2d 992 (Ind. 1991) (Indiana Medical Licensing Board); Petition of Sprague, 564 A.2d 829 (N.H. 1989); Pons v. Ohio State Medical Bd., 614 N.E.2d 748 (Ohio 1993) (Ohio Revised Code § 4731.22(B)(18) specifically refers to the codes of national professional organizations including the AMA as the measure of unethical behavior).

272. *See, e.g.*, 76 J. IND. ST. MED. ASS'N 93 (1983) (incorporating revised AMA Code into bylaws); Kirk v. Jefferson Co. Medical Soc'y, 577 S.W.2d 419 (Ky. Ct. App. 1978); State ex rel. Stufflebam v. Appelguist, 694 S.W.2d 882 (Mo. Ct. App. 1985) (Missouri State Medical Ass'n), *overruled on other grounds*, 776 S.W.2d 389; Guidry v. Harris County Medical Soc'y, 618 S.W.2d 884 (Tex. Civ. App. 1981).

273. *See, e.g.*, Volpicelli v. Jared Sydney Torrance Mem. Hosp., 109 Cal. App. 3d 242 (1980); Gianetti v. Norwalk Hosp., 557 A.2d 1249 (Conn. 1989); Ham v. Holy Rosary Hosp., 529 P.2d 361 (Mont. 1974).

274. *See* Albert P. Jonsen, *Leadership in Meeting Ethical Challenges*, 62 J. MED. EDUC., 95, 96 (1987).

275. Howe, *Medical Students' Evaluation of Different Levels of Medical Ethics Teaching: Implications for Curricula* 21 J. MED. EDUC. 340-49 (1987).

276. *See* ASSOCIATION OF AMERICAN MEDICAL COLLEGES, PHYSICIANS FOR THE TWENTY-FIRST CENTURY: THE GREP REPORT (1984).

> . . . . Studies have demonstrated that history taking and IPS can be effectively taught. There is agreement about the essential elements of effective courses, and successful medical student courses that incorporate these elements have been described.[277]

Virtually all medical schools report that they offer courses on interviewing and IPS.[278] However, the study found that problems remain:

> While these advances are encouraging, our survey data suggest a wide variability in quality and intensity of medical interviewing and IPS teaching among US medical schools. Many teaching programs appear to need substantial improvement . . . . There is a paucity of educators who design, implement, and coordinate this teaching. It appears that, as in 1977, there is little coordination or sequencing of IPS teaching throughout the 4 years in most medical schools.[279]

This system of medical education does not reach the practicing physicians whose disclosure practices often fail to meet the information needs of their patients. One medical educator notes,

> In theory, informed consent has been accepted as an essential component of the doctor-patient relationship; in actuality, physicians frequently fail to communicate elements essential for informed participation by patients. There are several reasons physicians may be reluctant to disclose appropriate information to patients. However, although many physicians favor a relatively non-informative, paternalistic approach to the doctor-patient relationship, studies reveal that most patients desire more relevant information about their conditions, including specific facts regarding their diagnoses.[280]

The concept of the dependent patient relying on the physician to be the beneficent healer is resilient.[281] Percival's *Code* lingers in the professional work ethic, as can be seen in the following quote from the recently retired editor of the *New England Journal of Medicine*,

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277. Dennis H. Novack et al., *Medical Interviewing and Interpersonal Skills Teaching in U.S. Medical Schools, Progress, Problems, and Promise* 269 JAMA 2101, 2101 (1993) (footnotes omitted).

278. *Id.*

279. *Id.* at 2104.

280. Johnson et al., *Teaching the Process of Obtaining Informed Consent to Medical Students*, 67 ACAD. MED. 598 (Sept. 1992).

281. *See, e.g.*, MEISEL, *supra* note 9, § 2.7, at 24. PRESIDENT'S COMMISSION, *supra* note 3, at 80, 85-93; Ruth R. Faden et al., *Disclosure of Information to Patients in Medical Care*, MEDICAL CARE July 1981, 718, 730; Elizabeth G. Patterson, *The Therapeutic Justification for Withholding Medical Information: What You Don't Know Can't Hurt You, Or Can It?* 64 NEB. L. REV. 721, 752 (1985); *see also* Jay Katz, *Informed Consent—A Fairy Tale*, 39 U. PITT L. REV. 137 (1977).

> Unlike the independent shoppers envisioned by market theory, sick and worried patients cannot adequately look after their own interests, nor do they usually want to . . . . If he does not trust the judgment and competence of the first surgeon he consults, he may seek the opinion of another, but he will very shortly have to trust someone to act as his beneficent counselor, and he will surely want the best care available, regardless of how much or how little his insurance will pay the doctor.[282]

When the patient is presumed to be unable or uninterested in contributing to the decision making, there is little opportunity for a cooperative venture to develop. While undoubtedly objecting to the characterization on how it occurred, many practitioners appear to agree with the conclusions of Ivan Illich that individuals are disabled with respect to making their own health care decisions.[283]

In their reform efforts, policy makers have especially targeted physicians' central role in prescribing medical care. After noting that physicians' services make up less than 25 percent of Medicare spending, but that physicians' decisions influence more than 70 percent, the Harvard research team developing the basis for Medicare's new physician reimbursement system concluded that "It is the physicians who are the 'captains of the medical ship,' . . . . The patient's wishes and preferences may be important, but it is the physician who is the key decision maker in health care."[284]

There are a range of opinions as to why practicing physicians have not embraced the idea of medical treatment as a cooperative venture. One legal scholar suggests it is merely indifference to the concept:

> In actual clinical practice, the opposition to informed consent manifested in medical writing is not as apparent as is disinterest. Unless one equates the signing of consent forms with genuine informed consent, it is safe to say that informed consent is largely absent from clinical practice, it is almost exclusively a creature of law.[285]

Others suggest that the educational process attracts those least likely to be able to communicate well with patients:

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282. Arnold S. Relman, *What Market Values are Doing to Medicine*, THE ATLANTIC, March 1992, 99, at 100.

283. *See* IVAN ILLICH, MEDICAL NEMESIS: THE EXPROPRIATION OF HEALTH 40-47 (1975). Illich used the term "expropriation" to denote his conclusion that the medicalization of health under the pressure of the profession deprived individuals of their capacity to suffer and heal.

284. HARVARD SCHOOL OF PUBLIC HEALTH, A NATIONAL STUDY OF RESOURCE-BASED RELATIVE VALUE SCALES FOR PHYSICIAN SERVICES: PHASE II, FINAL REPORT, 29 (1990).

285. MEISEL, *supra* note 9, § 2.7, at 24.

> Some medical educators have recognized that a selection process which rewards expertise in the natural sciences and an aptitude for performing well on standardized examinations is not necessarily one which will produce physicians inclined to listen closely, talk openly and admit their limits and their ignorance when they exist. It may be necessary to change not only what is taught in medical school, as Katz suggests, but who is there to learn in order to assure more conversation on the part of medical professions.[286]

The limited involvement of patients in decision making reflects and revitalizes these normative assumptions. The tendency of patients to take a passive role in the diagnostic and treatment process is well documented. As one scholar suggests,

> Patients have allowed silence to substitute for conversation as a result of conviction, shared and reinforced by their doctors, that healing can be brought about only when the patient exemplifies the virtues of trust, obedience, and compliance. Medical uncertainty and ignorance have long been seen as the primary threats to patient hope, and thus to the efficacy of medical interventions, not just by physicians but by their patients as well.[287]

This raises a profoundly important question - to what extent can individuals handle the responsibility of deciding their own medical care? Studies show that patients can handle this task better than medical practitioners believe.[288] There are, however, limitations on the amount, and form, of information that a patient can absorb.[289]

The 1980 AMA *Principles* defining the patient-physician relationship coincided with the publication of a newly formulated definition of quality in medical care.[290] Avedis Donabedian defined the interaction between practitioners and patients as the "process of care," divided into the technical and interpersonal domains. Thus,

> Technical care is the application of the science and technology of medicine, and of the other health sciences, to the management of a personal health problem. Its accompaniment is the management of the social and psychological interaction between client and practi-

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286. Arthur Caplan, *Can We Talk? A Review of Jay Katz, 'The Silent World of Doctor and Patient'*, 9 W. NEW ENG. L. REV. 43, 48 (1987) [hereinafter Caplan] *citing generally* APPLYING THE HUMANITIES (Daniel Callahan et al., eds., 1985) *and* ERIC J. CASSELL, THE PLACE OF THE HUMANITIES IN MEDICINE (1984), *and* Edmund D. Pelligrino, *Educating the Humanistic Physician*, 235 JAMA 1288 (1974).

287. Caplan, *supra* note 286, at 45.

288. Faden, et al., *supra* note 281, at 728. *See also* Patterson, *supra* note 281, at 736-47.

289. *See* Jon F. Merz & Baruch Fischhoff, *Informed Consent Does Not Mean Rational Consent: Cognitive Limitations on Decision-making*, 11 J. LEG. MED. 343-46 (1990).

290. 1 AVEDIS DONABEDIAN, THE DEFINITION OF QUALITY AND APPROACHES TO ITS ASSESSMENT (1980).

> tioner. The first of these is called the science of medicine and the second its art . . . .[291]

Regarding technical management of the patient,

> [T]his relationship is revealed in the work of the leading exponents of that science and technology; through their published research, their teachings, and their own practice these leaders define, explicitly or implicitly, the technical norms of good care.
> . . . .
> . . . What constitutes goodness in the interpersonal process is more difficult to summarize. The management of the interpersonal relationship must meet socially defined values and norms that govern the interaction of individuals in general and in particular situations. These norms are reinforced in part by the ethical dicta of health professions, and by the expectations and aspirations of individual patients. It follows that the degree of quality in the management of the interpersonal relationship is measured by the extent of conformity to these values, norms, expectations and aspirations . . . .[292]

The important work of developing measures of the quality of the provider-patient relationship is still in its early stages. As is discussed in Part V below, practice guidelines and the emergent concepts and processes of quality assurance have the potential to define more fully, and then enforce, a new standard of interaction.[293]

B. Revising the Legal Doctrine of Informed Consent

In an informed consent lawsuit, the plaintiff has the burden of proving the existence and likelihood of occurrence of the complication produced by the medical intervention. These facts may be established through the testimony of an expert witness or an admission by the defendants.[294] The duty to disclose is set as a matter of law and

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291. *Id.* at 4.
292. *Id.* at 5.
293. *See* text *infra* Part V(B) & (C) and accompanying footnotes.
294. This information is developed through medical research studies and reported in medical journals or practice guidelines. Without the testimony of the researchers, this information could be excluded from the trial as hearsay (i.e., a statement other than one made by the declarant while testifying, offered in evidence to prove the truth of the matter asserted). *See, e.g.*, FED. R. EVID. 801(c). A statement from a "learned treatise," a published book or periodical established as a reliable authority by an expert witness or by judicial notice, is admissible as an exception to the hearsay rule. *See, e.g.*, FED. R. EVID. 803(18).

The proliferation of practice guidelines and the statutorily mandated risk lists, for example, those developed in Texas, Louisiana and Hawaii, eventually could provide the specific risks to be disclosed regarding a procedure or treatment. There are experiments underway to use practice guidelines in medical malpractice trials without the need for expert testimony. *See* UNITED STATES GENERAL ACCOUNTING OFFICE, MEDICAL MALPRACTICE: MAINE'S USE OF PRACTICE GUIDELINES TO REDUCE COSTS HRD-94-8 (October 1993) [hereinafter MEDICAL MALPRACTICE].

applied to these facts. The material risk/reasonable patient standard can be applied without further assistance from an expert medical witness. The professional standard requires more evidence before it can be applied. Again, this may be provided by expert medical testimony.[295] The rationale for expert testimony stems from the belief that only an expert could know what a reasonably prudent physician would or would not disclose under the circumstances of the case.

Nearly one half of the jurisdictions in the United States rely on the medical profession's standards to establish the duty to disclose in their informed consent cause of action.[296] These established doctrines of informed consent may be revised to reflect the values in the new medical ethics and in the process publicize the new professional norm on the physician-patient relationship. To the extent that the national professional codes establish the perspective for measuring disclosures in informed consent cases, there no longer will be a significant discrepancy between the jurisdictions using the professional and reasonable person standards.[297]

The AMA ethical code and other professional codes provide national standards for patient participation, a subset of which is disclosure of risks and alternatives. At a minimum, the new medical ethics seem to announce that organized medicine will no longer support restricted interactions with patients regarding care choices. This is a major reversal of the position advocated by the AMA five years before the revision of the *Principles*.[298] The AMA's proposed model law on informed consent had sought to limit the information about medical risks given to a patient to assure valid consent and treated written consents as strong evidence of informed decision-making.[299]

The AMA *Principles* and the ACP ethics manual only begin to define the disclosure obligation. They were not written to supply a disclosure standard for informed consent cases.[300] While the codes are

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295. Some state statutes specify that expert medical testimony must be adduced as to the insufficiency of the consent. *See, e.g.*, N.Y. CIV. PRAC. L. & R. § 4401-a (McKinney 1992).

296. *See* discussion *supra* Part III(F).

297. The AMA PRINCIPLES OF MEDICAL ETHICS supports the minority subjective patient standard on causation. Its concluding sentence under § 8.07, *Informed Consent*, reads: "Rational, informed patients should not be expected to act uniformly, even under similar circumstances, in agreeing to or refusing treatment." CURRENT OPINIONS-1981, § 8.07. The objective "reasonable person" standard is less accepting of idiosyncracies. *See* FADEN & BEAUCHAMP, *supra* note 1, at 31-34 for a discussion of the different standards.

298. See MODEL INFORMED CONSENT LAW, Section XXX, *supra* note 183, at 1011.

299. *Id.*

300. However, both the AMA code and the ACP manual define the therapeutic exception narrowly. This should provide guidance to courts when they are faced with arguments on that exception.

not laws but "standards of conduct,"[301] they do relate to legal obligations: "Ethical standards of professional conduct and responsibility may exceed but are never less than, nor contrary to, those required by law."[302] The codes do not rely on the customary or usual practice but clearly define the disclosure obligation as one to be measured by the information needs of the patient.[303]

Introduction of the codes to help set the disclosure standard in an informed consent case will decrease or eliminate the need for an expert. The codes provide evidence of varying weight in the twenty-five jurisdictions that have chosen the professional perspective. The disclosure requirements range from the customary practice in a defined locality to the accepted standard of disclosure or the practice of a reasonable and prudent practitioner.[304] Dissatisfied with the rigors and justifications of the locality standard, all states, except Idaho, have abandoned the use of narrowly defined geographic areas.[305]

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301. CURRENT OPINIONS-1981, AMA Principles of Medical Ethics, pmbl., at ix.

302. CURRENT OPINIONS-1981 § 1.02.

303. Under the ethical codes the therapeutic exception to disclosure is significantly limited. Informed consent is a basic social policy for which exceptions are permitted (1) where the patient is unconscious or otherwise incapable of consenting and harm from failure to treat is imminent; or (2) when risk-disclosure poses such a serious psychological threat of detriment to the patient as to be medically contraindicated. Social policy does not accept the paternalistic view that the physician may remain silent because divulgence might prompt the patient to forego needed therapy.
CURRENT OPINIONS-1992 § 8.08.

304. Under the strict locality rule the customary or ordinary practice of the medical community in a defined area has the force of law. To prevail the plaintiff must identify and prove the local custom. If very limited disclosure is the practice, compliance is set at that level. Procedural consequences stem from the need to secure a medical expert familiar with the local custom who is willing to testify against a fellow physician. See Robinson, *supra* note 156, at 180 (discussing the "conspiracy of silence").

305. The Idaho Code defines both the general medical malpractice standard and the specific informed consent standard as the care ordinarily given in the same community. IDAHO CODE § 6-1012 (medical malpractice), § 39.4301 to .4306 (informed consent). The statutes further define "the same community" as the geographic area served by the nearest general hospital. *See* IDAHO CODE § 6-1012 (general medical malpractice) *and* IDAHO CODE § 39.4304 (informed consent). Idaho has the lowest ratio of physicians to population in the United States, with 125 physicians per 100,000 residents, compared to the national ratio of 216 per 100,000. STATISTICAL ABSTRACT OF THE UNITED STATES, T. 173, at 119 (1993) (based on U.S. Bureau of Census estimates as of July 1, 1989).

The treatment of the locality rule by the courts of one rural state will illustrate the changes. Montana's common law malpractice standard of care moved from the care and skill usually exercised in the same locality to a statewide standard of care, Tallbull v. Whitney, 564 P.2d 162 (Mont. 1977); then to a national standard for board certified specialists, Aasheim v. Humberger, 695 P.2d 824 (Mont. 1985); and finally, a national standard for non-board certified general practitioners, taking into account any legitimate local factors. Chapel v. Allison, 785 P.2d 204, 210 (1990).

Courts have been able to move away from the locality rule, where the standard a physician is expected to exercise is that skill and knowledge normally possessed by members of that profession in good standing in "the same or similar communities." The comment below, taken

Most states providing a statutory informed consent cause of action based on a professional standard adopted either the "accepted standard of disclosure" in the medical community[306] or the practice expected of a "reasonable and prudent" practitioner.[307] These are not based on the customary practice in the locality but have been held to incorporate national standards of practice or disclosure.[308]

Medical specialists, the target of most informed consent law suits, are held to applicable national standards even under the strictest locality rule.[309] The existence of national certification standards has led to reliance on them as proof of the specialist's standard of care.[310]

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from the RESTATEMENT (SECOND) OF TORTS § 299A helps explain the significance of using the "similar community" phrase.

> Type of community. Allowance must be made also for the type of community in which the actor carries on his practice. A country doctor cannot be expected to have the equipment, facilities, experience, knowledge or opportunity to obtain it, afforded him by a large city. The standard is not, however, that of the particular locality. If there are only three physicians in a small town, and all three are highly incompetent, they cannot be permitted to set a standard of utter inferiority for a fourth who comes to town. The standard is rather that of persons engaged in similar practice in similar localities, considering geographical location, size, and the character of the community in general.

RESTATEMENT (SECOND) OF TORTS § 299A cmt. g (1965).

The "same general neighborhood" in Code of Alabama, § 6-5-484 imposes a national standard. *See* Bradford v. McGee, 534 So. 2d 1076 (Ala. 1988) *and* Zills v. Brown, 382 So. 2d 528 (Ala. 1980). For other states, *see* Gambill v. Stroud, 531 S.W.2d 945 (Ark. 1976); Bloskas v. Murray, 646 P.2d 907 (Colo. 1982) (an informed consent case); Purtill v. Hess, 489 N.E.2d 867 (Ill. 1986) (if uniform national standards exist they can be used to establish standard of care in same or similar community); Blair v. Eblen, 461 S.W.2d 370 (Ky. 1970) (rejecting locality rule); Roybal v. Bell, 778 P.2d 108 (Wyo. 1989) (informed consent standard must recognize movement to use of same or similar community standard in general medical malpractice); Kortus v. Jensen, 237 N.W.2d 845 (Neb. 1976).

306. FLA. STAT. ANN. § 766.103 (West 1993); KY. REV. STAT. ANN. § 304.40-320 (Michie 1988); ME. REV. STAT. ANN. tit. 24, § 2905 (Supp. 1993); N.C. GEN. STAT. § 90-21-13 (1993); TENN. CODE ANN. § 29-26-118 (1980). All, except the Tennessee statute, add the provision that for disclosure to be adequate, a reasonable person would need to be able to understand the information as it was presented.

307. ARIZ. REV. STAT. ANN. § 12-561(2), 563 (1992); N.Y. PUB. HEALTH LAW § 2805-d (McKinney 1993); VT. STAT. ANN. tit. 12, § 1909 (Supp. 1993).

308. *See, e.g.*, Logan v. Greenwich Hosp. Ass'n, 465 A.2d 294 (Conn. 1983); Guebard v. Jabaay, 452 N.E.2d 751 (Ill. Ct. App. 1983); Cross v. Trapp, 294 S.E.2d 446 (W. Va. 1982).

309. Buck v. St. Clair, 702 P.2d 781 (Idaho 1985).

310. See Dewitt v. Brown, 669 F.2d 516 (8th Cir. 1982) (applying Arkansas law if a national standard exists, it can be introduced to show the level of care expected in the locality or similar locality); Robbins v. Footer, 553 F.2d 123 (D.C. Cir. 1977); Bahr v. Harper-Grace Hosps., 497 N.W.2d 526 (Mich. 1993), *appeal granted*, 445 Mich. 861 (1994); Thomas v. McPherson Community Health Ctr., 400 N.W.2d 629 (Mich. 1986); Melville v. Southward, 791 P.2d 383 (Colo. 1990); Farrow v. Health Servs. Corp., 604 P.2d 474 (Utah 1979); *but see* Bly v. Rhoads, 222 S.E.2d 783 (Va. 1976) (declining to adopt national standard about legislative enactment.

Other courts have held that the existence of nationally uniform standards for particular conditions can be relied upon to establish the standard in the same or similar community. Smock v. Hale, 555 N.E.2d 74 (Ill. App. Ct.), *reh'g denied* 561 N.E. 708 (1990) (national standard for treatment of Crohn's Disease applied to general practitioners); Swan v. Lamb, 584 P.2d 814 (Utah 1978).

Board certified specialists are seen as holding themselves out as having greater skill than other physicians, thereby justifying the application of a more rigorous minimum standard.

The potential impact of the AMA patient participation ethic in defining the clinical conduct expected of a medical professional can be glimpsed in *Culbertson v. Mernitz*, the first informed consent case to cite the AMA revisions.[311] In *Culbertson*, the physician had not advised a patient of a possible surgical complication that materialized.[312] A medical review panel, used in Indiana to screen malpractice cases, read the proposed complaint, took evidence, and concluded that "such non-disclosure does not constitute a failure to comply with the appropriate standard of care, as such complication is not considered a risk of such surgery requiring disclosure to the patient."[313] The standard of disclosure the Medical Review Panel used was not identified, but the Indiana lower courts had been using the lay standard.[314] After the *Culbertson* lawsuit was commenced, the defendant moved for summary judgment.[315] The plaintiffs' attorneys argued that the "prudent patient" standard was the disclosure standard in Indiana, and thus, no expert testimony was required in response to the motion.[316] They did not provide any evidence on the risk, its chance of occurrence, or the professional practice on disclosure.[317] The trial court granted the summary judgment motion, but the court of appeals accepted plaintiffs' argument and reversed.[318]

The Indiana Supreme Court framed the question on appeal as follows "the issue squarely presented in this petition is whether expert medical testimony is required to establish the standard of care of

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311. 602 N.E.2d 98, 103-04 (Ind. 1992).

312. *Id.* at 99. The plaintiff's underlying condition, urinary stress incontinence, is the subject of a federally sponsored Clinical Practice Guideline. AGENCY FOR HEALTH CARE POLICY AND RESEARCH, PUBLIC HEALTH SERVICE, U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES, URINARY INCONTINENCE IN ADULTS: CLINICAL PRACTICE GUIDELINE, AHCPR No. 92-0038, (1992).

The etiology of the plaintiff's condition, primary anatomic obstruction, was described as being "extremely rare" and appropriate for surgery. *Culbertson*, 602 N.E.2d at 99. The possible risks from surgical treatment are not specifically listed in the guideline. CLINICAL PRACTICE GUIDELINE, *supra* at 48.

313. *Culbertson*, 602 N.E.2d at 99.

314. See Griffith v. Jones, 577 N.E.2d 258 (Ind. 1991), *vacated*, 602 N.E.2d 107 (1992); Payne v. Marion Gen. Hosp., 549 N.E.2d 1043 (Ind. 1990); Revord v. Russell, 401 N.E.2d 763 (Ind. 1980); Joy v. Chau, 377 N.E.2d 670 (Ind. 1980).

315. Culbertson v. Mernitz, 591 N.E.2d 1040 (Ind. Ct. App. 3d 1992).

316. *Id.* at 1042.

317. *Id.* at 1043.

318. *Id.* at 1040, 1043.

health care providers on the issue of informed consent."[319] The court saw the answer to this question as being dependent on the disclosure standard: "Resolution of the issue of the necessity of expert medical testimony in informed consent cases depends on whether the issue is viewed through the eyes of the physician or the patient."[320] The court, in a 3-2 decision, adopted the standard of a reasonably prudent physician and held that expert medical testimony was needed to present an issue of material fact in light of the review panel's findings.[321]

The majority dismissed the concerns that the professional disclosure standard dishonors the patient's right of self-decision and places the decision under the exclusive domain of the medical profession: "While this viewpoint may or may not have been justified in 1972 when *Canterbury*, and *Cobbs*, were decided, a review of medical ethics standards of care in 1992 should assuage this fear."[322] The court then quoted with approval AMA *Current Opinion* section 8.08 on patient participation.[323]

The *Culbertson* decision gives new meaning to the "reasonable medical professional."[324] Surprisingly, to the extent that a "reasonable physician" is one who adheres to medical ethics, the professional standard of disclosure will now carry with it much the same responsibility for disclosure as the reasonable patient standard. Watching this interplay of legal standards with the revised professional norms

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319. Culbertson v. Mernitz, 602 N.E.2d 98 (Ind. 1992).

320. *Id.* at 103.

321. *Id.* It is not clear that the court had to choose the disclosure standard to decide this case. Under a material risk standard, the plaintiffs would have needed to present evidence of the existence and likelihood of the risk. They refused to do so, even in light of the finding of the medical review panel.

322. *Id.* (citations omitted).

323. *Id.* at 103-04 *quoting* CURRENT OPINIONS-1992 § 8.08. The majority decided the case based on the need of an expert witness to establish the risk that the complication would occur, not to define the professional standard of disclosure.

> We therefore hold that, except in those cases where deviation from the standard of care is a matter commonly known by lay persons, expert medical testimony is necessary to establish whether a physician has or has not complied with the standard of a reasonably prudent physician. . . .
>
> In the present case we cannot say that the risk of the adherence of the cervix to the vaginal wall is a matter commonly known to lay persons.

Id. at 104.

This analysis also shows one danger of grafting informed consent doctrine onto the stock of medical malpractice. In an informed consent case, if the risk is commonly known to lay persons, there would be no duty to disclose it to the reasonable patient. It is not clear from the opinion whether the risk that materialized for Mrs. Culbertson is one that would need to be disclosed to other Indiana patients.

324. This reliance on national standards is consistent with the evolution of the general malpractice standard in Indiana. Indiana had used the "same or similar community standard." Worster v. Caylor, 110 N.E.2d 337 (1953). The standard was changed to the practice expected of a reasonably careful, skillful and prudent practitioner in similar circumstances. *Ex rel.* Vergara v. Doan, 593 N.E.2d 185 (Ind. 1992).

and the impact on clinical practice of U.S. medical professionals in the United States will be an interesting sociological study. Unfortunately for scholars and policy makers, the social context of medicine continues to change, clouding the causal connections to changes in practice.

V. The Future of the Patient-Provider Relationship in the New World of Health Security

The health care crisis created by limited access and rising costs emerged from the 1992 United States presidential campaign as a leading domestic political issue. A growing number of individuals and families lack the insurance coverage, government program eligibility, or wealth to pay for needed care and, thus, face access restricted to emergency medical care.[325] Many employers have abandoned the tradition of providing medical insurance as an employment benefit.[326] Those continuing to provide coverage are finding ways to limit their exposure.[327] The escalating cost of medical care has limited the ability of government to halt the erosion of access. A number of federal programs, state government, and private initiatives have been undertaken, with mixed results, to provide some categorical relief. Despite these efforts, the cost of individual services, and overall medical care spending, continues to rise faster than the overall inflation rate.[328] Total medical care expenditures have increased to fourteen percent of the gross domestic product, higher than any other major economy in the world.[329]

The origin of this problem lies deep in our economy and traditions of medical practice. The federal government has been reluctant to take the lead in reform efforts despite its growing role as a coverage provider through Medicare and Medicaid. Deference to the medical profession's tradition of self-regulation in matters of clinical judge-

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325. On a given day, approximately 38.0 million Americans are without medical coverage. Adam Clymer, *Health Debate Splinters After Initial Consensus*, N.Y. Times at B8. A portion of this group has chosen to self insure, but many did not have a choice.

326. *Id.*

327. Among the means that have been tried are self-insurance, abandoning community rated insurance plans, limiting the coverage offered and shifting costs to employees. *See, e.g.*, McGann v. H & H Music Co., 946 F.2d 401 (5th Cir. (1991), *cert. denied*, 113 S. Ct. 482 (1991) (eliminating coverage for those in the plan with expensive medical needs). Employee benefit plans are taking advantage of the protective ERISA provisions to refuse to contribute toward the care of those outside the plan. *See, e.g.*, Travelers Ins. Co. v. Cuomo, 813 F. Supp. 996 (S.D.N.Y. 1993).

328. An easy illustration of the rate of medical cost inflation is the annual rise of the Medicare hospital deductible. This payment is calculated at roughly the cost of one day in the hospital. It has steadily risen from $40 in 1966 to $696 for 1994. *See* 58 Fed. Reg. 58554 (Nov. 2, 1993).

329. Clymer, *supra* note 325, at B8.

ment and billing practices is deeply ingrained.[330] Additionally, the federal government, especially Congress, has not wanted to frustrate the rising expectations of providers and patients that the medical care prescribed by the patient's physician will be covered.[331]

A major turning point was reached when the Reagan administration, in response to federal budget concerns, promoted changes in the Medicare program's hospital reimbursement method.[332] The new system is designed to induce hospitals to limit the cost of care they provide. The changes also established a budgetary cap for Medicare spending for hospital care. The Physicians' Medicare Fee Schedule, implemented as of January 1, 1992, has similar goals of changing care patterns and creating at least a "continental budget" for payments to physicians.[333] We are now just into the second decade of this experiment of federal intervention into medical care decision making.[334]

The Clinton Administration's proposed Health Security Act (HSA) served to focus debate on the next round of governmental reform efforts.[335] The proposed act built on the initiatives already underway to expand access, control costs, and switch emphasis to preventive and primary care.[336] Thus, we are becoming familiar with many of the components that will define the next era of health care, even if

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330. The Medicare statute starts with the following provision:

> Nothing in this title . . . shall be construed to authorize any Federal official or employee to exercise any supervision or control over the practice of medicine or the manner in which medical services are provided or over the selection, tenure, or compensation of any officer or employee of any institution, agency, or person providing health services; or to exercise any supervision or control over the administration or operation of any such institution, agency, or person.

42 U.S.C.A. § 1395 (West Supp. 1993).

331. Clymer, *supra* note 325, at B8.

332. Medicare based its original reimbursement formula on the fee for service set by the customary or prevailing rate, a concept borrowed from private insurance policies. *See generally* Gerard F. Anderson & Mark A. Hall, *The Adequacy of Hospital Reimbursement Under Medicaid's Boren Amendment*, 13 J. LEG. MED. 205, 205 (1992)

The Prospective Payment System (PPS), 42 U.S.C.A. § 1395ww (1993), was added by § 101(a)(1) of the Tax Equity and Fiscal Responsibility Act of 1982, Pub. L. No. 97-248, 96 Stat. 324.

333. 42 U.S.C.A. § 1395w-4 (West Supp. 1993).

334. The medical care industry is not a well-understood economic entity. We simply do not yet understand the forces and values that direct the response to a financial intervention.

335. *See supra* note 11, and accompanying text.

336. *See, e.g.*, David R. Olmos, *Strength in Numbers: 11 Firms Join to Get Cuts in Health Insurance Rates*, L.A. TIMES, at D1 (discussing private efforts to control costs); *see also* Washington Health Services Act of 1993, WASH. REV. CODE ANN. § 43.72.005 (West Supp. 1994). The Clinton proposal adds the idea of "managed competition" in the purchasing of insurance coverage. I will not address the major issues of streamlining the billing process and reforming the insurance market. These are the most removed from the point of service issues. Additionally, the lack of experience with health alliances makes analysis very speculative.

their details remain to be worked out. The cost-consciousness being promoted will have a more pervasive impact as federal policy replaces localized initiatives. A global budget with explicit rationing of medical services is possible if spending cuts are not realized through less drastic changes.

Any mandated reform elements will be part of an evolving delivery system. Systemic changes have accelerated in response to the current initiatives and the proposed federal reforms. For example, medical care providers are moving toward integrated networks of medical professionals, institutions, and support personnel with a strong managed care emphasis.[337] The physicians' dominance in prescribing care is eroding as their professional status continues to decline and other providers are substituted when cost effective. The providers of non-hospital special services, such as long term care, will continue to grow because of changing demographics and health patterns, as well as the growing sensitivity to the appropriate services for various patient populations. The one-on-one interaction with an independent practitioner which is the conceptual basis for the informed consent doctrines is no longer representative of most medical care interactions. Patients now have to deal with hospitals that are part of a national chain, physicians in a managed care enterprise, or a home-health-aide supplied by an agency.[338]

The organizational clustering of providers will support the rapid and thorough penetration of two distinctive medical advances of the late twentieth century, comprehensive utilization review and applied outcomes research.[339] New concepts and methods for reviewing medical care are being driven by current theories of production management and evolving capabilities to process massive quantities of data. Reviewers can now analyze a provider's entire range of care in addition to the traditional screening for individual instances of bad care. For the near future, quantitative measures of a practice will dominate the review process.[340]

In addition, qualitative reviews of practice patterns are developing as practice guidelines mature. Care that is based on protocols and evidence-based practice guidelines is replacing care based on expert

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337. *See generally* UNITED STATES GENERAL ACCOUNTING OFFICE, MANAGED HEALTH CARE: EFFECT ON EMPLOYERS' COSTS DIFFICULT TO MEASURE, GAO/HRD-94-3 (1993) [hereinafter MANAGED HEALTH CARE].

338. *Id.*; *see also* STARR, *supra* note 39, at 430-36 (hospitals).

339. See Stephen F. Jencks & Gail R. Wilensky, *The Health Care Quality Improvement Initiative: A New Approach to Quality Assurance in Medicare*, 268 JAMA 900 (1992) (for illustration of these advances to the Medicare areas and Health Care quality improvement).

340. Examples of such measures are a hospital's inpatient mortality rate and the level of resources used by a physician for treating a particular condition. See *infra* Part V.

opinion and customary practice.[341] The content of the guidelines will depend upon the information available from outcomes research and the purpose of the guideline. Guidelines will assist patients and medical professionals in choosing diagnostic approaches and treatment. They also will supply standards for utilization review by peer groups, risk managers, medical care administrators, and paying sources.

The rationalization of the medical care system that the changes achieve will have varying impacts on different phases of care delivery. There will be significant savings in standardizing forms for coverage enrollment and eligibility and claim submission and payment.[342] Developing diagnostic approaches that are comprehensive without being excessive is more challenging. Treatment standards for conditions that have been identified will range from being obvious to those impossible to agree upon and implement.

As the reforms are being put in place, the impact of change on the provider-patient relationship is receiving limited attention, and questions are left unanswered. For example, will the values underlying the informed consent doctrine endure as they conflict with cost-containment policies and the new clinical reality? The driving forces behind reform give cause for concern.[343] The most pressing concern for policy makers is restraining the growth of medical care spending by government and business. The interests of the various medical providers, insurance companies, employers, and state governments are being ably and persistently presented. Thus, their concerns may well reshape the process of care and redefine the patient-provider relationship. The transformation of the financing, provision, and

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341. *See* Deborah S. Garnick et al., *Can Practice Guidelines Reduce the Number of Malpractice Claims?* 266 JAMA 2856 (1991); David M. Eddy, *Practice Policies—What Are They?* 263 JAMA 877 (1990).

342. The Workgroup for Electronic Data Interchange (WEDI) estimates that $42 billion can be saved over the next six years if all payers, providers and participants adopt electronic data interchange standards promulgated by X12, an Accredited Standards Committee of the American National Standards Institute. *See* 2 HEALTH L. REP. (BNA) 46 (December 2, 1993). Uniform electronic claims administration is already being implemented by Medicare and various state Medicaid programs. Florida, Texas, Ohio, California, and Illinois are among some of the states which have imposed such requirements statewide. *See* Elizabeth Gardner, *Ohio Hooks Up Claims System*, MODERN HEALTHCARE, Aug. 26, 1991, at 6.

343. Patient participation did not fare well as a legislative issue during the last flurry of legislative activity responding to a medical care crisis. Organized medicine added the informed consent issue into a larger debate over reforming medical malpractice litigation in the mid-1970's. *See supra* notes 187-88, and accompanying text. The major proponent of patient's rights was the plaintiff's personal injury bar. As noted above, in Section III, the legislatures were most responsive to the physicians. Fourteen of the sixteen states that have made a legislative choice on disclosure use professionally oriented standards. *See supra* note 222, and accompanying text. Where there was not support for the position of organized medicine, little legislation was passed.

review of medical care threaten to overwhelm a principled approach to patient participation in the patient-provider relationship.

Much about the patient-provider relationship of the near future will depend on the details of the evolving system of care. In a more highly regulated medical delivery system, will medical professionals care less if they can decide less? Are patients prepared to accept the challenge of increased responsibility for their own care? The practice guidelines' treatment of the patient's role and the degree to which patient participation is reinforced in utilization review will be two important defining elements. While the patient's role may be enhanced if the issue of patient participation is taken seriously, the reforms have focused on structural elements that are easier to legislate. For example, the Health Security Act directly addressed patient responsibility solely in terms of enrolling in a health plan and making copayments toward services.[344]

There are many reasons for ensuring a fuller role for patient participation in the evolving health care system. The respect for the patient's autonomy and right of self determination are social values that have grown stronger in recent decades and changes in the health care system that fail to reflect these values may be seen as a threat to quality medical care. Further, enhanced patient participation is imperative to an efficient, science-based medical care system for the same reasons it was important in the time of Thomas Percival. Good health is not the product of the providers' efforts alone. For example, no matter how elegant the science behind the treatment, results will be disappointing if the patient does not follow the therapy regimen or decides to stop taking the prescribed medications.[345] Involvement of patients in the process of health care has consistently improved treatment outcomes.[346] The challenge is to encourage, or if necessary

344. Health Security Act, H.R. 3960, 103d Cong., 2d Sess. §§ 1002, 1131-36 (1994).

345. Non-compliance has been found to be in the 25 percent to 50 percent range for outpatients with prescribed drugs. Barry Blackwell, *The Drug Defaulter*, 13 CLINICAL PHARMACOL. 841 (1972). Polypharmacy (multiple medications) is common, especially in the rapidly growing elderly population. Their interaction raises the potential for harmful mistakes by patient and physician. As many as 25 percent of hospital admissions for the elderly are the result of the incorrect use of medication. Joan Morell et al., *Receptivity of Physicians in a Teaching Hospital to a Computerized Drug Interaction Monitoring and Reporting System*, 15 MED. CASE 68 (1977).

346. See Sheldon Greenfield et al., *Expanding Patient Involvement in Care: Effects on Patient Outcomes*, 102 ANN. INTERN. MED. 520 (1985). One study approach was to show patients their own medical records and the treatment algorithm used by the medical professionals. *Id.* at 521. Patients also had a pre-visit review of simple techniques for improving communication with the physician. *Id.* Compared to the control group, these patients had a better understanding of their own situation and they made better use of the face to face meeting with the physician (which averaged 16 minutes). *Id.* at 523. Significantly, they also reported a greater improvement in functional ability than did the more passive control group. *Id.* at 524.

mandate, the labor and time intensive interpersonal work of health care providers in the face of a generalized pressure to reduce care costs.

In Part V, the changing practice of medicine the impact of these changes on the patient-provider relationship will be examined. In Section A, the systemic changes underway will be reviewed. Section B will look at the expansion of the role for utilization review, while section C will provide a view of the outcomes movement and the use of practice guidelines. Section D will present some ideas on how the changes will affect the patient-provider relationship.

A. The Changing Face of United States Medical Care

Responding to social expectations, cost containment efforts, and the changing demands for care, the medical care industry is being restructured. These systemic changes continue the trend toward depersonalized medical care. The patient must deal with providers in the context of, for example, a managed care plan or a home care agency. Many of the important decisions regarding medical care, such as when to refer to a specialist or what diagnostic tests to perform, are being made one step removed from the provider-patient level and without public involvement. Physicians likely will find that their ability to make exceptions to the treatment protocols will decline over time. The non-physician providers will be even less influential than the physicians in such matters. Patients' rights that are defined in relationship to the individual provider, such as informed consent, will reflect the diminished role of those providers.

1. The Decline of the Independent Practitioner

Physicians, perhaps more than other professionals, have had their status challenged over the last twenty years. As Paul Starr has observed, that challenge has redefined the relationship with the client: "Indeed, few other developments so well illustrate the decline of professional sovereignty in the 1970s as the increased tendency of the courts to view the doctor-patient relationship as a partnership in decision making rather than a doctors' monopoly."[347] The relationship of patients to non-physician providers in the medical care system is also changing. For example, nurses, therapists, and pharmacists are being entrusted with greater responsibility for care provision and patient interaction than ever before, but within the context of group protocols.

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347. STARR, *supra* note 39, at 389.

The independent practitioner of medicine is becoming a rarity. For a variety of reasons—increasing practice costs, need for office and collegial support, increased paper work, malpractice concerns, competition for patients—physicians are choosing either to enter a group practice or become an employee.[348] Those self-employed practitioners and those in group practice increasingly have to rely on income from managed care entities.[349] Nearly ninety million people, including more than half of all employees covered under employer-sponsored group health insurance, are enrolled in managed care plans.[350] These forms of financing and delivering care include staff, network, and group model health maintenance organizations (HMOs), independent practice associations (IPAs), preferred provider organizations (PPOs), and several hybrid organizations.[351]

All managed care has internal mechanisms to monitor and authorize care.[352] The roles of insurer and provider are brought closer together or even merged into one business entity. Managed care physicians often serve as "gatekeepers," controlling access to second-

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348. There were an estimated 13,000 physicians in group practice in 1959. This number tripled by 1969, to just over 40,000. ROSEMARY STEVENS, AMERICAN MEDICINE AND THE PUBLIC INTEREST, T.14 at 425 (1972). The number has continued to increase. In 1980, 30 percent of U.S. physicians in an office-based practice were in a group; by 1987, this had increased to almost 50 percent. U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES, 7TH REPORT TO THE PRESIDENT AND CONGRESS ON THE STATUS OF HEALTH PERSONNEL IN THE U.S. (APO 1990). Employed physicians constitute 26 percent of active U.S. physicians.

349. Somewhat surprisingly, the loss of prestige and cost containment efforts have not yet translated into a reduction in income. The average net income for U.S. physicians continued to rise to $170,600 for 1992. AMA, Center for Health Policy Research, SOCIOECONOMIC CHARACTERISTICS OF MEDICAL PRACTICE, 140 (1993).

350. MANAGED HEALTH CARE, *supra* note 337, at 5. As of January 1, 1993, over 40 million people were enrolled in HMOs, twice as many as there were in 1985. INTERSTUDY, *Competitive Edge* (Minn. 1993) and U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES, 6TH ANNUAL REPORT TO THE PRESIDENT AND CONGRESS ON THE STATUS OF HEALTH PERSONNEL IN THE U.S. (June 1988 APO). The number of Medicaid participants in managed care plans doubled between 1990 and 1993, bringing it to a level of 4.8 million. *HHS News*, October 18, 1993. PPOs have grown even faster. MANAGED HEALTH CARE, *supra* note 337, at 6, fig. 2.

351. In a staff model HMO, physicians are employed and work out of an office site owned and operated by the HMO. MANAGED HEALTH CARE, *supra* note 337, at 6. This model has had limited growth with approximately 2.2 million enrollees as of January 1, 1993. MANAGED HEALTH CARE, *supra* note 337, at 6, fig. 2. Group and network models, in which the HMO contracts for physician care with one or more group practices, account for about one-third of the managed care market. *Id.* The largest segment of the HMO market is Independent Practice Associations (IPA), in which private practitioners contract to provide care for some form of capitated payment. *Id.* at 7. There are also mixed models that combine features of the group model and IPA. *Id.* at 7 n.8.

The fastest growing segment of managed care are the PPOs, which combine features of HMOs and traditional indemnity plans. These plans did not exist until the 1980s. Their enrollment now exceeds that of the HMOs. *Id.* at 6, fig. 2.

352. The Health Security Act would have mandated disclosure of the protocols used for health plan utilization and cost control. Health Security Act, H.R. 3960, 103d Cong. 2d Sess. § 1412 (1994).

ary care. The primary care they provide must follow protocols that are, in part, fiscally driven. For participating physicians, these arrangements entail surrendering some clinical independence in return for administrative and professional support, with a steady supply of patients. For the patient, this may mean better access to a medical professional, but less contact with one primary physician.

Medical care administrators are increasingly involved in the areas of medical care decision making and quality review that had been reserved to physicians and their professional self regulation. As an example, hospitals traditionally operated as "doctors' workshops."[353] Today, the interests of the hospital, as an entity, are diverging from the interests of the medical staff.[354] Changes in surgical and anesthetic techniques, revamped reimbursement policies, and changing demographics and care needs are contributing to declining hospital admission rates and shorter average lengths of stay. Fiscal concerns of the hospital have increased the review of physician efficiency and proficiency.[355] Economic credentialing, the evaluation of physicians for appointment or reappointment to a hospital medical staff based on financial performance, is one example of the new merit system for medical staffs.[356]

Another response to the changing environment for medical providers is the development of integrated delivery systems. The systems are designed to ensure a continuum of available care provided in the most appropriate setting based on therapeutic as well as financial considerations. In one form, a hospital becomes the center for a medical care network through mergers, acquisitions, and joint ventures.[357] On the admission end, the hospital purchases primary care practices or affiliates with managed care entities to ensure a steady supply of customers. On the discharge end, there are joint ventures with home health care agencies and nursing homes to ensure that

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353. STARR, *supra* note 39, at 178.

354. For a detailed discussion, *see* John D. Blum, *Hospitals, New Medical Practice Guidelines, CQI, and Potential Liability*, 36 ST. LOUIS U. L.J. 913 (1992).

355. *See, e.g.*, Stephen B. Kritchevsky and Bryan P. Simmons, *Continuous Quality Improvement: Concepts and Applications for Physician Care*, 266 JAMA 1817 (1991).

356. *See generally* John D. Blum, *Economic Credentialing: A New Twist in Hospital Appraisal Processes*, 12 J. LEGAL MED. 427 (1991).

357. *See, e.g.*, Tom Redburn, *Rebounding from Crisis, New York Hospital Changes its Ways*, N.Y. TIMES, Nov. 10, 1993, at B1, 12; *see also* Peters, *Integrated Delivery Can Align Physician and Hospital Plans*, J. HEALTHCARE FIN. MGMT. ASS'N., Dec. 1991, 20; Johnson, *Dynamic Diversification: Hospitals Pursue Physician Alliances, "Seamless" Care*, HOSPITALS, Feb. 5, 1992, 20.

patients can be discharged as soon as possible.[358] The increased complexity of these business relationships require more active and sophisticated hospital administration, counsel, and boards of directors. In this process, there is a shift of responsibility from the medical staff to the administrative staff. Patients have no direct input into the decisions made at the administrative level.

The aging of our population and increased attention to the needs of disabled Americans have driven an expansion of the long term care industry to address chronic medical conditions. The concept of the "least restrictive alternative" for imposed therapy has been adapted to specialized medical services.[359] Nursing homes and home health care agencies have expanded in the last decades to address the need for appropriate long term care.[360] Hospice programs have become a widely accepted means of care for terminally ill patients and their families.[361] Drug, alcohol, and mental health programs have also increased with a strong non-institutional component. Special programs designed for individuals with developmental disabilities or mental retardation are among the most expensive treatments per capita.

These providers depart from the common medical model of a physician assisting an otherwise healthy person through a short term acute care episode. The health problems are long term and often incurable, but proper care can improve the quality of the patients' lives. Although still prescribed under the signature of a physician, most of the medical services are directly provided by others. The patient has contact with physical, occupational, and speech therapists, nurses, counselors, social workers, and dieticians far more often than physicians.

2. *The Rise of Federal Mandates*

The increased involvement of the federal government in health care policy and payment includes mandates directly affecting the provider-patient relationship. Three recent federal enactments impose limited requirements on medical providers to begin to address concerns

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358. *See generally* HCIA & ARTHUR ANDERSON, THE GUIDE TO THE NURSING HOME INDUSTRY (1993).

359. *Id.*

360. Between 1960 and 1993, nursing home expenditures increased from $1 billion to an estimated $76 billion. This represented 3.69% of national health expenditures in 1960 and over 8% estimated for 1993. HCIA AND ARTHUR ANDERSON, THE GUIDE TO THE NURSING HOME INDUSTRY, 1993.

361. There are currently 1,800 hospices serving the United States. *See* Warren L. Wheeler, *Hospice Philosophy: An Alternative to Assisted Suicide*, 20 OHIO N.U. L. REV. 755, 757 (1994).

about access to appropriate care and patient autonomy. First, under the Federal Emergency Care Act of 1986,[362] a person presenting herself to a hospital emergency room while in active labor or in need of emergency medical care must have her labor treated or be stabilized.[363] This care must be provided without regard to her ability to have the care covered.[364] Second, the Patient's Self Determination Act, effective December 1, 1991, requires the hospital, nursing home, hospice program, or home care agency to provide notice to the patient of her state law rights to decide the course of medical care and of the availability of advance directives.[365] Third, concurrent amendments to the Medicare and Medicaid statutes stopped nursing homes from using chemical or physical restraints on residents "for purposes of discipline or convenience."[366] The only restraints allowed are those ordered by a physician for physical safety.[367]

The influence of federal mandates will increase. One dramatic change would be a mandatory participation requirement, as in the Clinton Health Security Act.[368] The current national health care reform debate has been built on strong support for the proposition that access to primary care should be guaranteed for all lawful U.S. residents as a matter of equitable social policy.[369] Access and cost containment are co-dependent because it would be financially difficult and politically impossible to increase access without cost containment. Conversely, participation in the new system of care by most members of the population and most providers is needed or else cost containing initiatives will be substantially weakened.

The federal government's program by program approach to cost containment has achieved limited success as have *ad hoc* steps by other payors. However, all paying sources have discovered that it is often in their interest to shift costs out of their program or policy rather than to identify and cut unnecessary care or to control medical

362. 42 U.S.C. §§ 1395dd (1988).

363. 42 U.S.C. § 1395dd(a) (1988).

364. *Id.* The mandate to provide care regardless of payment is notable because at about the time of the passage of Medicare and Medicaid, the notion of charity care virtually disappeared.

365. 42 U.S.C. § 1395cc(a)(1)(F)(i) (1988) (Medicare participating facilities); 42 U.S.C. § 1396(a)(57) (1988) (Medicaid participating facilities).

366. 42 U.S.C. § 1395i(3)(c)(1)(A)(ii) (1988).

367. 42 U.S.C. § 1396r(c)(1)(A)(ii) (1988) (Medicaid). The need to comply with the law led to a practice guideline developed by the nursing home industry. AMERICAN HEALTH CARE ASSOCIATION, CLINICAL PRACTICE GUIDELINES FOR THE USE OF PHYSICAL RESTRAINTS (1992) (available from the AHCA, 1201 L Street, N.W. Washington, D.C. 20005).

368. Health Security Act, H.R. 3960, 103d Cong., 2d Sess. § 1002(a)(1) (1994).

369. *Id.*

cost increases.[370] Providers have changed the way services are provided to avoid the impact of cost-containment measures. This cost and service shifting has contributed to the large and growing number of individuals without the means to pay for care and steadily increasing medical costs. To deal with this problem, the Clinton administration proposal mandated that all eligible U.S. residents participate in the medical coverage system, and, thus, effectively mandated participation by medical care providers.[371]

Cost containment measures will likely continue to take the form of indirect regulations. Most legislative initiatives avoid directly mandating reductions in current levels of medical care. Politically speaking, the more attractive options are spending caps that put pressure on medical professionals and administrators to reduce spending.[372]

B. The New Role of Utilization Review

New processes and concepts in utilization review will dramatically increase oversight of medical decisions and their outcomes. Medical utilization review is an examination of the care that is provided to a

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370. Medicare has kept the rate of increase of its PPS hospital payments under the rate of medical care inflation. J. Greenleaf, et al., EDUCATING PHYSICIANS RESPONSIBLE FOR POOR MEDICAL CARE: A REVIEW OF THE PEER REVIEW ORGANIZATION'S EFFORTS, OIG Pub. No. OEI-01-89-00020 (1991). Its once generous reimbursement now covers less than 90 percent of the cost of care. *Id.* The shortfall has been made up by higher reimbursements from private insurers. *Id.*

371. Health Security Act, H.R. 3960.

372. An example of such a politically acceptable option was Medicare's Prospective Payment System (PPS) for hospitals. Beginning in 1984, it set payments for each hospital discharge according to the diagnosis related group assigned to that patient. Facilities knew the Medicare payment they could expect from treating any particular diagnosis. David M. Frankford, *The Medicare DRGs: Efficiency and Organizational Rationality*, 10 YALE J. ON REG. 275 (1993). Rather than comparing this income with their costs, and adjusting either the method of treating or the pattern of their admissions, Frankford asserts that the actual response of hospitals "more resembles the use of a blunt instrument . . . rather than fine cutting with a scalpel by DRG." *Id.* at 322. Prior to enactment, there was concern that the PPS would induce hospitals to increase admissions. *Id.* at 306-08. The predetermined payment for each discharge meant that patient volume, rather than extending stays, would be the means to increase revenue. *Id.* The utilization review mechanism was redrafted to better monitor inappropriate admissions and readmissions. *Id.* at 309-10. The reaction of the providers was not as expected. Admissions declined substantially. *Id.* at 309. Much of the decline is attributable to switching many lens procedures, including cataract surgery, to outpatient settings. *Id.* The prospect of increased review prompted the switch for these services that are "relatively simple, generally thought to be overused, and good candidates for outpatient treatment." *Id.* This is even more surprising since reimbursement levels in the first two years of PPS were "overly generous." See Robert F. Coulam & Gary L. Gaumer, *Medicare's Prospective Payment System: A Critical Appraisal*, HEALTH CARE FIN. REV., 1991 Annual Supp. 45, at 53.

PPS has had a limited impact on hospital efficiency and specialization, but may have had a positive effect on patient outcomes by diverting some services to outpatient settings and shortening hospital stays. *See* LOUISE RUSSELL, MEDICARE'S NEW HOSPITAL PAYMENT SYSTEM: IS IT WORKING? 24-46 (1989).

patient, conducted by someone other than the medical professionals directly involved in the case.[373] The review can be done by colleagues, such as the quality assurance committee of a hospital medical staff, or by reviewers outside the medical staff, such as contract agencies working for paying sources.[374] Utilization review by outside reviewers, never popular among providers, will almost certainly surpass medical malpractice litigation as the most noticeable critique of the provision of medical care.

The Medicare law mandates utilization review to cut unnecessary services and improve the quality of care.[375] The current mechanisms for conducting this review are Peer Review Organizations (PROs). Until recently, the PROs have focused on screening for specific instances of bad care.[376] Medicare's utilization review, as a means of quality improvement or fiscal monitoring, has a disappointing history due to professional resistance, questionable standards of review, and weak enforcement mechanisms.[377]

The Health Care Financing Administration, overseer of the Medicare program, has undertaken a new utilization review strategy which is embodied in the Health Care Quality Improvement Initiative (HCQII).[378] This initiative substantially alters the utilization review tasks performed by the Peer Review Organizations (PROs):[379]

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373. *See generally* KATHLEEN R. CICCONE & JONATHON T. LORD, IQA-2 CONTINUOUS PERFORMANCE IMPROVEMENT THROUGH INTEGRATED QUALITY ASSESSMENT (1993). Currently between 300 and 400 organizations provide utilization review services to medical paying sources. Reviewer's application of uniform screening and evaluation standards do vary. Thirty states and the District of Columbia have begun to regulate this industry. However, most of the legislation has been enacted since 1990 and a number of states do not yet have implementing regulations.

374. *Id.*

375. 42 U.S.C. § 1395y(a)(1)(A) (1988). The Medicare payments are restricted to medical services that meet the statutory standard of being "reasonable and necessary." *Id.* See J. Greenleaf, et al, *Educating Physicians Responsible for Poor Medical Care: A Review of the Peer Review Organizations' Efforts* (OIG Pub. No. OEI-01-89-00020) (1991). Physician sponsored PRO's are eligible to obtain contracts under Medicare. 42 C.F.R. § 462.101 (1991). A "physician-sponsored organization," defined as a group comprised of at least 10% of the area's practicing physicians "who are representative of the physicians practicing in the area" is awarded extra credit in bidding for the contract. 42 § C.F.R. 462.102 (1991). The Secretary extends contracts to perform this function in a given geographical area for two year periods. 42 § C.F.R. 462.107(d) (1991).

376. For example, one study concluded that the PRO's detected only the most egregious quality failures. *See* Hoya Rubin et al., *Watching the Doctor-Watchers: How Well Do Peer Review Organization Methods Detect Hospital Care Quality Problems?*, 267 JAMA 2349, 2353 (1992).

377. See RUSSELL, *supra* note 372, at 64-65.

378. The Health Care Financing Administration has identified the four important forces driving the HCQII:

> Variations research: Research has revealed a substantial variation in patterns and outcomes of care from hospital to hospital, and geographical area to area. Accu-

> Central to the HCQII is a fundamental change in the PRO program from its emphasis on individual (and often isolated) clinical errors to an increased emphasis on general improvements in medical care. Under the HCQII, PROs will use statistical quality control to examine variations in both the processes and the outcomes of care. . . . The Initiative is intended to move mainstream medical care toward best available practices, in contrast with a previous emphasis that focused on correcting unusually bad care.[380]

With evolving information technology, reviewers now have access to patient specific data as well as aggregated data showing a provider's practice patterns. Quantitative measures of an individual's practice can be compared to national or regional averages, thus attracting attention to practices outside the mainstream.[381] Profiling is rapidly spreading.[382] A 1992 AMA survey found that almost half of the physicians responding were subject to clinical or economic profiling.[383] The Health Care Financing Administration has taken the next step by publishing profiles of individual U.S. hospitals.[384]

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mulated evidence indicates that variations in risk-adjusted outcomes reflect variations in appropriateness and quality of care.

Studies of peer review: A growing body of research is raising questions about the reliability of physician review of hospital medical records to determine quality of care.

New models for quality improvement: New approaches to quality improvement that have entered the health care industry from other industries suggest that substandard care generally results from poor process design, inadequate information, and poor training.

Practice guidelines development: The Federal government and professional groups have started a process to develop and publish clinical practice guidelines, which provide potential blueprints for quality improvement efforts in the clinical areas they address.

58 Fed. Reg. 12043 (1993). *See also* Jencks & Wilensky, *supra* note 343. Kathleen N. Lohr, *Medicare: A Strategy for Quality Assurance*, (Institute of Medicine Report), February, 1990.

379. 58 FED. REG. 12043.

380. 57 FED. REG. 26871-01 (1992). As of April 1, 1993, the Peer Review Organizations contracting with Medicare to perform the utilization review function were to devote approximately 50% of their time on HCQII.

381. See John D. Blum, *Hospitals, New Medical Practice Guidelines, CQI, and Potential Liability*, 36 ST. LOUIS U. L.J. 913, 921 (1992) [hereinafter, Blum]; Kent, *Patient Outcomes Profiles Help Hospitals Evaluate Quality, Decide on Reappointment*, 2 REP. ON MED. GUIDELINES & OUTCOMES RES. (Feb. 1, 1991).

382. Blum, *supra* note 381, at 921.

383. AMER. MED. ASS'N, CENTER FOR HEALTH POLICY RESEARCH, SOCIOECONOMIC CHARACTERISTICS OF MEDICAL PRACTICE, 1993. The practice was most prevalent for physicians with a managed care (HMO, IPA, PPO) contract. HMO staff physicians received a higher rate of regular feedback regarding their clinical profile (75%) than did any physicians other than government employees. *Id.*

384. The profiles include basic descriptions such as the number of beds along with performance statistics such as patient mortality rates and average length of stay. HEALTH CARE FINANCING ADMINISTRATION (HCFA), MEDICARE HOSPITAL MORTALITY INFORMATION, 1988-90 (1992); *see also* Larry M. Manheim et al., *Regional Variation in Medicare Hospital Mortality*, 29 Inquiry 55 (1992); Wan, *Hospital Variations in Adverse Patient Outcomes*, 7 QUAL. ASSUR. UTIL. REV. 50 (1992).

Utilization review focusing on patterns and outcomes of care are data-intensive, and new systems for acquiring and analyzing data are critical to their success. This raises several fundamental questions. First, what data is, can be, and should be collected? It is more challenging to translate patient participation into a number than it is with cost or patient mortality. Inaccurate or incomplete data would distort the picture of what is being done.

Second, what standards should be used as the review criteria? The choices reflect a particular balancing of the tension between three values: medical care quality, patient autonomy, and cost containment. The relative weights assigned each value will depend on the role of the standard setter. Review by the medical staff quality assurance committee would be expected to stress professionally defined quality, while a paying source may put greater weight on cost containment and identifying inappropriate care. Risk management review focuses on high risk procedures and seeks to prevent actionable, bad results.[385] Practice guidelines, discussed in the next section, may be adapted for use as review criteria.

Finally, the response of the reviewer and the degree of flexibility of the standards as applied will determine the impact on practice patterns. The Health Care Financing Administration is stressing a cooperative approach under the Health Care Quality Improvement Initiative.[386] This is a significant change from their prior utilization review efforts. For example, until recently, the Health Care Financing Administration refused to disclose the utilization screens and guidelines used in determining whether services are medically necessary and reasonable. This was to avoid "gaming" of the system by physicians.[387]

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385. Eleanor D. Lee & Marilyn M. Kinney, *Medical Standard Setting in the Current Malpractice Environment: Problems and Possibilities*, 22 U.C. DAVIS L. REV. 421, 423 (1989).

386. 58 Fed. Reg. 12042 (1993). The HCFA explains the approach as follows:

> The PROs will systematically and regularly analyze these data to identify trends, changes in trends, and variations from national or peer group patterns. Once significant patterns have been identified, the PROs will, through their feedback and cooperative projects, work with provider administrative and medical staffs, as well as with interested expert groups, to improve the processes and outcomes of care provided to, and experienced by, Medicare beneficiaries. The PROs will also use baseline data to monitor progress toward sustained superior ("benchmark") performance.
>
> The essence of each project is to combine the statistical interpretation of Medicare data (for example, pattern analysis) with feedback to the medical community to improve care and outcomes measurably.

Id.

387. Timothy P. Blanchard, *"Medical Necessity" Denials as a Medicare Part B Cost-containment Strategy: Two Wrongs Don't Make it Right or Rational*, 34 ST. LOUIS U. L.J. 939, 993 (1990).

The new utilization review effort is supported by popular theories of production management, known as Total Quality Management (TQM) or Continuous Quality Improvement.[388] These theories stress the use of statistical data to measure production outcomes.[389] As applied to medical care services, the theories support a central role of management in coordinating work by the patient care team and redirecting resources to address problems and shortcomings.[390] Besides the Health Care Financing Administration, the other important overseer of U.S. medical care delivery is the Joint Commission on Accreditation of Health Organizations (JCAHO).[391] Both have enthusiastically adopted Continuous Quality Improvement and are integrating it into their standards for reviewing care providers.[392] The major revisions of the JCAHO accreditation standards are described by a hospital industry publication as follows:

> The central theme of the proposed 1994 changes is complete organizational commitment to continuously improving the total quality of patient care. This commitment must be built into the hospital's long-range strategic planning process, its allocation of resources, its stated expectations, and its reward structures for employees. Ultimately, hospitals will be expected to have a comprehensive self-assessment system in place to support and promote continuous improvement in the quality of patient care.[393]

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388. *See, e.g.*, W. Edwards Deming, *Quality, Productivity, and Competitive Position* (1980); CICCONE & LORD, *supra* note 373, at 24-26.

389. CICCONE & LORD, *supra* note 373.

390. Mary T. Koska, *New JCAHO Standards Emphasize Continuous Quality Improvement*, HOSPITALS, Aug. 5, 1991, 41; Kritchevsky & Simmons, *supra* note 355, at 1819-22.

391. The Joint Commission on Accreditation of Healthcare Organizations (JCAHO) is the world's largest health care standard and accrediting body. The organization's name and work reflect the changes in providers of care. In 1987 the name was changed from the Joint Commission on Accreditation of Hospitals to reflect its expanding role in surveying and accrediting the many other health care organizations.

392. CICCONE & LORD, *supra* note 373, at 23.

393. *Id.* at 24. The 1992 JCAHO hospital accreditation standards already reflect the increasing administrative responsibility for quality of care.

> The revised standards place greater emphasis on the role of leadership in assessing and improving patient care and further clarifying certain steps in the monitoring and evaluation process. As stated in the preamble, the standards are based on the following principles:
>
> • A hospital can better improve patient care quality and satisfy patients by assessing the process-the governance, managerial, clinical, and support functions-that most affect patient outcomes.
>
> • Some of these processes are carried out by physicians, nurses, or Governing Body members; others are carried out by managers or support staff; and some are carried out jointly. The goal of quality improvement is to coordinate and integrate these processes.
>
> •The role of the hospital's leadership is to help everyone working in these processes to assess and improve them.

Id. at 23 (footnotes omitted) (citing JOINT COMM'N ON ACCREDITATION OF HEALTHCARE ORGANIZATIONS ACCREDITATION MANUAL FOR HOSPITALS, 137-38 (1992)).

In contrast with this approach, prescriptive utilization review standards can be applied to limit beneficial services solely for economic reasons.[394] An example of a standard that overrides patient autonomy and professional discretion is found in New York Medicaid's home care program.[395] Before Medicaid coverage of home care services is authorized, a medical and social assessment is conducted to determine whether home care services are appropriate for the individual.[396] If home care is determined to be appropriate, a care plan specifying the level, frequency, and duration of services is developed and authorized for coverage.[397]

Reacting to concerns about a state budget deficit, the state legislature mandated the additional pre-authorization step of a fiscal assessment.[398] After the care plan is developed, the cost of the services to the Medicaid program is calculated.[399] When home care would cost Medicaid more than institutional care, coverage for home care is denied unless limited exceptions apply.[400] Since the Medicaid program has restrictive financial eligibility criteria, Medicaid participants who are above the cost threshold cap have only two options - accept institutionalization or do without needed care.[401] The authorization

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394. *See* Frances H. Miller, *Denial of Health Care and Informed Consent in English and American Law*, 18 AM. J.L. & MED. 37 (1992). Oregon has been granted a conditional waiver from Medicaid requirements so that it can restrict coverage of certain treatments for certain conditions as part of a plan to increase the number of individuals who have coverage. *See Oregon Request for Medicaid Waiver Approved by HHS with Conditions*, 4 MEDICARE REPORT (BNA) 13 (Mar. 26, 1993). The process of ranking the treatment-condition pairs was, in part, a debate on their relative usefulness. *Id.*

395. *See* N.Y. SOC. SERV. LAW § 365-a(2)(d) & (e) (McKinney 1993).

396. *See, e.g.*, N.Y. SOC. SERV. LAW § 367-o.

397. *See* N.Y. SOC. SERV. LAW § 365-(a)(2)(d) & (e).

398. See N.Y. SOC. SERV. LAW §§ 367-j (home health services) *and* § 367-k (personal care services). Some, but not all, local social services districts began to implement the process in the latter part of 1993.

399. In keeping with the narrow focus on saving money for the Medicaid program, it is the cost to Medicaid, not the total cost of care, that is the relevant figure. The assessing agency must consider all "economies" that could reduce the cost. If, for example, Personal Emergency Response Services can appropriately replace personal care aide hours that change in the care plan must be done. Other economies include shared aide services, Medicare covered home health care, patient managed home care, and adult day health programs. The remaining services are then entered into a worksheet along with the cost of each category of care, e.g. Personal Care Aide Level 1, Personal Care Aide Level 2, Home Health Aide, Physical Therapist, Speech Therapist, Registered Nurse, Licensed Practical nurse, etc. The average monthly cost is then computed. *See id.* § 367.

400. One major exception is that institutionalization is contraindicated e.g. would result in a diminishing of the participant's ability to perform the activities of daily living, such as toileting, eating, transferring or bathing. N.Y. SOC. SERV. LAW § 367-j(1)(e)(iv).

401. N.Y. SOC. SERV. LAW § 366(2)(a)(4) & (7). Clients would be unable to agree to lower levels of care since the Medicaid program must be satisfied that the care plan is adequate and provides for the safety of the individual. *Id.* §§ 367-j(2)(a)(1) and 367-k(2)(a)(1).

Current recipients of Medicaid covered home care who exceed the cost threshold will be reauthorized for home care only until an appropriate placement is available. *Id.* §§ 367-j(1)(f)(ii) and 367-k(1)(e)(ii).

process does not take into account the desirability of allowing the patient to remain at home and retain a degree of independence.

The treating physician's only contribution to the assessment process is the Physician's Order for Personal Care Services.[402] Effective January 1, 1993, New York Medicaid policy is to preclude physicians from prescribing the amount of personal care services for their patients using that form.[403] The New York State Department of Social Services, the administrator of New York's Medicaid program, explained the reason for this policy as follows:

> In recent years, many social services districts have reported increasing difficulty in obtaining required physician orders which accurately describe the recipient's/patient's medical condition and needs. Physicians are under increasing pressure from recipients/patients and their families to order services to meet social and family rather than medical needs.[404]

C. *Redefining Quality in Medical Care Review*

A medical practice guideline is a set of recommendations that lays out one or more acceptable approaches to the provision of medical care for a particular illness or medical problem.[405] The guideline can include both diagnostic and treatment options.[406] The content of practice guidelines depends on the information available and the intentions of the promulgators.[407] The outcomes movement, a renewed effort to carefully assess long term outcomes and analyze effectiveness of treatments, was spurred by research showing significant variations in medical care usage among similar populations.[408] A critical look at

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402. N.Y. COMP. CODES R. & REGS. tit. 18, § 505.14(b)(3)(i).

403. Implementation of this policy has been enjoined by, Kuppersmith v. Perales, 535 N.Y.S.2d 510 (1988) (Table, no. 35297N).

404. New York State Department of Social Services Administrative Directive, 92 ADM-48 (December 1, 1992).

405. Another widely used definition is that practice guidelines are "systematically developed statements [of recommendations for patient management] to assist practitioner and patient decisions about appropriate health care for specific clinical conditions." MARILYN J. FIELD & KATHLEEN N. LOHR, CLINICAL PRACTICE GUIDELINES: DIRECTIONS FOR A NEW PROGRAM 8 (1990). The Institute of Medicine (IOM) defines good practice guidelines as having the following attributes: validity, reliability, clinical applicability, clinical flexibility, clarity, multidisciplinary process of development, scheduled review to determine whether revisions are warranted and documentation. *Id.* at 10.

406. See Blum, *supra* note 354, at 913 n.3.

407. *Id.* at 927-45.

408. *See, e.g.*, John E. Wennberg & A. Gittelsohn, *Small Area Variations in Health Care Delivery*, 182 SCI. 1102 (1983); John E. Wennberg, *Dealing with Medical Practice Variation: A Proposal for Action*, 3 HEALTH AFFAIRS 6 (1984); Mark R. Chassin et al., *Variations in the Use of Medical and Surgical Services by the Medicare Population*, 314 NEW ENG. J. MED. 285 (1986); Payne, *Identifying and Managing Inappropriate Hospital Utilization: A Policy Synthesis*, 22 HEALTH SERVICES RES. 709 (1987).

accepted medical practices found there were few with support of solid outcome studies.[409] Researchers, with increased financial support from the federal government, have undertaken to review the outstanding literature and proceed where needed with new studies.[410]

An essential step in the production of practice guidelines is processing sound medical research results into diagnostic and treatment algorithms useable in clinical situations and in utilization review.[411] The production of high quality practice guidelines is time consuming and expensive. For the greatest potential financial impact, common conditions with widely variable treatment standards are being selected for guideline development, as are the most expensive procedures. For risk management purposes, the selection process focuses on high risk procedures performed by high risk specialists.[412] The Maine Liability Demonstration Project is the leading effort in the use of practice guidelines to reduce malpractice claims.[413]

The influence of the practice guidelines will depend on the content, degree of acceptance by the providers, and the enforcement powers behind the guidelines.[414] The guidelines will have a greater impact the more prescriptive they are and the less they comport with

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409. AGENCY FOR HEALTH CARE POLICY AND RESEARCH, (AHCPR) MEDICAL EFFECTIVENESS RESEARCH DATA METHODS (M. Grady & H. Schwartz eds., 1992) (AHCPR No. 92-0056).

410. *See generally* Jencks & Wilensky, *supra* note 339. The HCQII is a preliminary step toward what could approach one massive outcome study involving all care provided by Medicare.

411. In health care, an algorithm is a defined and prescribed sequential process whereby clinical and diagnostic findings at a particular point in the process determine the next diagnostic, clinical or therapeutic decision or action to be made or taken. URINARY INCONTINENCE IN ADULTS, *supra* note 312, Glossary, at 109.

412. *See, e.g.*, Deborah W. Garnick et al., *Can Practice Guidelines Reduce the Number and Costs of Malpractice Claims*, 266 JAMA 2856 (1991).

413. *See* MEDICAL MALPRACTICE, *supra* note 294. Twenty practice guidelines for four high risk specialties, anesthesiology, emergency medicine, obstetrics and gynecology and radiology, were identified as having the most potential impact on the number of malpractice claims filed in Maine. Guidelines developed by the national medical specialty associations provide most of those used, but some guidelines were developed locally where national standards had not been developed. *Id.* The guidelines were incorporated into the rules of the Maine Board of Registration in Medicine and the Maine Board of Osteopathic Examination and Registration through a rulemaking process. *Id.* Physicians participating in the Project can introduce the guidelines to establish the standard of care in a malpractice action. *Id.* Recent legislation opens the project to any specialty that adopts practice guidelines. *Id.*

Three other states, Florida, Minnesota and Vermont, are developing similar programs. The Health Security Act contained a national demonstration project very similar to Maine's. *See* Health Security Act, § 5312 H.R. 3960, 103 Cong., 2d Session (1994).

414. Another recent effort, development of consensus standards for practice sponsored by the National Institutes of Health, had little impact on practice patterns. *See, e.g.*, Jacqueline Kosecoff et al., *Effects of National Institutes of Health Consensus Development Program on Physician Practice*, 258 JAMA 2708, 2710-13 (1987).

accepted methods of practice.[415] As one commentator has concluded,

> The prescriptiveness of the guideline will depend in part on the extent of the outcomes research literature, but also will depend substantially on the motivations of those developing the guidelines. It is much easier to develop a guideline that encompasses the practices of all but the real deviants than one that asks a substantial minority or even majority to change their practice. Unless those who develop the guideline are committed to making significant changes, the guideline is likely to have little effect on practice.[416]

Given the differing range of information we have on medical outcomes for specific treatments, practice guidelines will range from being completely prescriptive to those allowing considerable discretion.[417] For the widely accepted or well enforced standards, evidence based, national norms of care are replacing individual clinical judgment, expert opinion, and prevailing practice standards.[418] Given the strong incentive for administrators and paying sources to rely on practice guidelines, one noted commentator on practice policies has concluded that "[i]t is not stretching things too far to say that whoever controls practice policies controls medicine."[419]

The federal government has committed substantial resources to developing high quality practice guidelines and improving their acceptance by medical practitioners.[420] In 1989, the Agency for Health Care Policy and Research (AHCPR) was created within the federal Public Health Service.[421] It has a mandate to support the development of clinically relevant guidelines.[422] The AHCPR guidelines must

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415. See Paul B. Ginsburg, *Alternative Approaches to Health Care Cost Containment*, 30 JURIMETRICS J. 447 (1990).

416. *Id.* at 454.

417. For a description of the spectrum from practice standards to options, see David M. Eddy, *Designing a Practice Policy; Standards, Guidelines and Options*, 263 JAMA 3077 (1990).

418. One of the first national practice guidelines, developed to standardize the steps in anesthetizing patients, has been credited with improving quality. *See* AM. SOCIETY OF ANESTHESIOLOGISTS (ASA), STANDARDS FOR BASIC INTRA-OPERATIVE MONITORING (1986).

419. David M. Eddy, *Practice Policies — What Are They?*, 263 JAMA 877, 880 (1990).

420. The federal agency budget for outcomes research and practice guideline development increased from under $2 million in 1988 to $75 million in 1992. For an example of earlier efforts, see REPORT OF THE U.S. PREVENTIVE SERVICES TASK FORCE, GUIDE TO CLINICAL PREVENTIVE SERVICES (1989).

421. Omnibus Budget Reconciliation Act of 1989, § 6103(a), 42 U.S.C. § 299(a) (1993); *amended by* the Agency for Health Care Policy and Research Reauthorization Act of 1992, 1320(b)-12 (Supp. II 1994).

422. 42 U.S.C. § 299b-1(a) (Supp. II 1993). The guidelines' priorities are to:

1. Improve methods for disease prevention,
2. Improve methods of diagnosis, treatment, and clinical management for the benefit of a significant number of individuals,
3. Reduce clinically significant variations among clinicians in the particular services

> 1. be based on the best available research and professional judgment . . .
> 2. be presented in formats appropriate for use by physicians, health care practitioners, medical educators, and medical review organizations and providers, in formats appropriate for use by consumers of health care;
> 3. include treatment-specific or condition-specific practice guidelines for clinical treatments and conditions in forms appropriate for use in clinical practice, for use in educational programs, and for use in reviewing quality and appropriateness of medical care; and
> 4. include information on risks and benefits of alternative strategies for the prevention, diagnosis, treatment, and management of a given disease, disorder, or other health condition; and
> 5. include information on the costs of alternative strategies for the prevention, diagnosis, treatment, and management of a given disease, disorder or other health condition, where cost information is available and reliable.[423]

AHCPR has issued several *Guidelines* and a number are in development.[424] In compliance with the legislative mandate, the *Guidelines* are issued in separate formats for providers and the public.[425]

D. The Future of The Patient-Provider Relationship

Unprecedented changes in the organizational structure and financing of medical care in the United States offer the promise of controlling medical cost inflation while improving access to primary care. The financial stakes of the major organized interests ensure that their concerns will be brought to the attention of the legislators writing the statutes and the administrative agencies that will further develop

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and procedures utilized in making diagnoses and providing treatments and
4. Reduce clinically significant variations in the outcomes of health care services and procedures.

42 U.S.C. § 299b-3(a) (Supp. I 1993).

The AHCPR practice guidelines are developed either by panels convened by the AHCPR or through contracts with non-profit organizations. 42 U.S.C. § 299b-2 (Supp. I 1993).

423. 42 U.S.C. § 299b-1(b) (Supp. I 1993).

424. Among the AHCPR guidelines released are URINARY INCONTINENCE IN ADULTS; MANAGEMENT OF FUNCTIONAL IMPAIRMENT DUE TO CATARACT IN THE ADULT; ACUTE PAIN MANAGEMENT: OPERATIVE OR MEDICAL PROCEDURES AND TRAUMA; DIAGNOSIS AND TREATMENT OF DEPRESSED OUTPATIENTS IN PRIMARY CARE SETTINGS; PRESSURE ULCERS IN ADULTS: PREDICTION AND PREVENTION; SICKLE CELL DISEASE; EARLY EVALUATION AND MANAGEMENT OF HIV INFECTION; AND DIAGNOSIS AND TREATMENT OF OTITIS MEDIA IN CHILDREN.

425. Each AHCPR Guideline set issued includes a Guideline Report, a Quick Reference Guide for Clinicians, a Clinical Practice Guideline and a Patient's Guide. The Guideline Report is the most comprehensive version, designed primarily for use by researchers. The two clinical guides are intended as desk-top references for clinical decision making. They include algorithms for various patient subpopulations. The Patient's Guide is for the public. *See, e.g.*, URINARY INCONTINENCE IN ADULTS, *supra* note 312.

policy and oversee its execution. However, problems that do not translate forcefully into political issues may get crowded off the agenda of what must be addressed. The role of the individual in medical decision making is one of these overlooked issues.

The widespread professional indifference to patient participation means that the service-level practices will be responding to provider self-interest, more so than to patient rights. In turn, provider self-interest will be determined in light of the policy emphasis on cost controls. This makes the future of the patient-provider relationship dependent on the provider's reaction to federal policy aimed at limiting the cost of care.

To date, the development of informed consent doctrines and the broader right of patient self-determination have focused on the patient and physician, with some acknowledgment that other medical professionals may be substituted for the physician in a one-to-one relationship. This has been an inappropriate model for long term care relationships. With the movement toward group practices and prescriptive utilization review standards, the independent medical practitioner model also will miss important new issues and conflicts in primary and secondary short-term care. In long term care, we have experience with cost-conscious, highly regulated, non-physician directed care.[426] This experience can be instructive about the future of the patient-provider relationship.

1. Utilization Review, Practice Guidelines and the Exchange of Information

High quality practice guidelines will help narrow the information gap between patients and medical providers. As an example, when an AHCPR practice guideline is developed, the basic medical information regarding the condition and the alternatives for treatment are processed into a Patient's Guide.[427] This assists the provider in developing fuller patient participation. Even if the provider is aware of the outcome literature and understands the significance of the findings, making the information available to the patient could be a time consuming venture. Because of this, the Patient's Guides are of significant importance.

As with other features of practice guidelines, the treatment of patient participation will vary depending on the source and intended

426. Two such areas are nursing homes and long-term care facilities regulations.
427. See *supra* note 425 and accompanying text.

use of the guidelines. The lay person versions of the AHCPR practice guidelines encourage patient self-education. The Patient's Guides also suggest that the patient make her concerns and preferences known to the provider and ask questions when uncertain about the available choices in care.[428]

The AHCPR clinical guidelines stress the importance of patient communication and provide some guidance to the practitioner in this area.[429] In contrast, the practice guidelines used in the Maine Liability Demonstration Project address informed consent and patient participation only superficially.[430] This is surprising considering the research strongly connects poor patient relationships with high rates of medical malpractice claims.[431]

The preparation of written patient guides is not a complete answer for augmenting patient involvement. Significant portions of the patient population will find such information unhelpful. Furthermore, the important interpersonal work of explaining what the medical information implies for a patient given her particular circumstances cannot be generalized and must be left to the provider.

Practice guidelines will have an educational value to providers if the guidelines are made relevant to clinical practice. Providers are coming to realize that current information and high quality recommendation are a prerequisite to more effective communication with patients. As was noted in a recent medical journal article,

> Before they participate in a screening program, patients must give informed consent. To do so, they need to understand the risk of a false positive result and the invasive procedures that may follow it. Rather than merely transmit expert recommendations, physicians should match the appropriate level of screening with each patient's unique attitude toward the risks of disease and the risks associated with the screening procedures.

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428. *See, e.g.*, URINARY INCONTINENCE IN ADULTS, *supra* note 312.

429. For example, the Practice Guideline on urinary incontinence reminds the reader that:

> Treatment options including their risks, benefits and outcomes should be discussed with the patient so that informed choices can be made. As a general rule, the least invasive and least dangerous procedure that is appropriate for the patient should be the first choice. For many forms of UI, behavioral techniques meet these criteria. However, an informed patient's preference must be respected.

Id. at 27.

430. *See* MEDICAL MALPRACTICE, *supra* note 294, App. IV, V, VI, VII.

431. Irwin Press, *The Predisposition to File Claims: The Patient's Perspective* 12 LAW, MEDICINE, AND HEALTHCARE 53 (1984); *see also* Gerald B. Hickson et al., *Factors That Prompted Families to File Medical Malpractice Claims Following Perinatal Injuries* 267 JAMA 1359 (1992); Marlynn L. May & Daniel B. Stengel, *Who Sues Their Doctors? How Patients Handle Medical Grievances* 24 L. & SOC'Y REV. 105 (1990).

> But to inform patients, physicians themselves must be informed. Strange et al. recently discovered that family physicians are more interventionist in their screening than the U.S. Preventive Services Task Force recommends. The study found correlations between lack of compliance with the recommendations and lack of knowledge (unfamiliarity with the recommendations, lack of residency training, and lack of teaching experience).[432]

Medicine is, and will continue to be, an inexact science. However, the uncertainty in developing a diagnosis, in choosing the most appropriate cause of treatment, and in predicting the patient's response to a treatment or procedure will be reduced as clinical guidelines develop.[433]

Many in the medical profession may welcome this form of continuing medical education. In return, physicians, especially the general and family practitioners, may be quite willing to abide by even the strictest practice standards.[434] The high rate of participation in the Maine Liability Demonstration Project (between 87 percent and 92 percent of the original four specialties involved), and the recent expansion of that project to all Maine specialties suggest that specialists welcome the guidance of explicit, professionally developed standards.[435] The guidelines represent a more responsible approach to "defensive medicine" than ordering extra diagnostic tests.[436] Other medical professionals, such as nurses, have had a long history of complying with practice protocols or guidelines.[437]

As practice guidelines become better accepted, providers may be less tolerant of patients whose treatment preferences fall outside the recommended norms. It is possible that practice guidelines will be written for various philosophies of care. Competing medical groups may well differentiate themselves by selecting, for example, an osteopathic approach as compared to an allopathic approach. In large

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432. John M. Lee, *Screening and Informed Consent*, 328 NEW ENG. J. MED., 438 (1993).

433. *See generally* FIELD & LOHR, *supra* note 405.

434. The primary care providers are under increasing pressure to deal with a large caseload that presents a wide range of symptoms and maladies. To process those individuals, the physician must rely on hundreds of rules they have learned. A newspaper reporter described the work of a pediatrician, Michael Levitas, in a group practice in Cumberland, Maryland. Dr. Levitas sees about 35 patients a day. There is opportunity to slow down, consult, study, but only when absolutely necessary. It is largely a job of remembered knowledge, applied hour after hour. In a day-and-a-half visit, Michael Levitas does not once consult a book. David Brown, *Volume Medicine*, WASH. POST (National Weekly Edition, Sept. 27-Oct. 3, 1992), 10-11.

435. MEDICAL MALPRACTICE, *supra* note 294, at 27.

436. *Id.*

437. *See, e.g.*, Nancy K. Rhoden, *Informed Consent in Obstetrics: Some Special Problems*, 9 W. NEW ENG. L. REV. 67 (1987).

urban areas with a diverse cultural mix, there may be an array of providers targeting various market niches. This would support the care preferences of substantial minorities.

For the population without access to an array of providers, practice guidelines could set up a strict orthodoxy in treatment alternatives. The lack of scientific studies on alternative medicine might translate into its absence from practice guidelines. This may mean that the acupuncturist or chiropractor will not be part of the medical group serving an area and thus, may not be able to stay in business. Practice guidelines might work better than the AMA *Code of Ethics* to discourage professional contact with "cultists."[438] The tolerance for unconventional approaches, with their uncertain potential, will be tested.[439]

Unconventional patients also may be treated poorly in a cost-conscious world of "efficient" care. With providers being reviewed and compared on the outcomes for the patient population they serve, there will be a strong preference for the "good" patients — those who will comply with recommended therapy, appear at follow-up appointments, and take up little provider time with questions, a need for instruction, or complaints.

2. *Monitoring Patient Participation*

Patient participation, as part of quality medical care, can be monitored and enforced . The incorporation of effective measures of patient participation in the utilization review standards is made difficult by the lack of documentation of this aspect of medical care.[440] Without documentation, retrospective review is limited. What is im-

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438. The 1956 AMA PRINCIPLES OF MEDICAL ETHICS contained the following:

> A physician should practice a method of healing founded on a scientific basis; and he should not voluntarily associate professionally with anyone who violates this principle. All voluntarily associated activities with cultists are unethical.

PRINCIPLES OF MEDICAL ETHICS, Section 3, ¶ 1.

> The importance of maintaining the dignity of medicine and of upholding the soundness of the teachings of scientific medicine as opposed to the fallacies of sectarianism must be emphasized. Either the theories and practices of scientific medicine are right and those of the cultists are wrong, or the theories and practices of the cultists are right and those of scientific medicine are wrong. The physician who maintains professional relations with cult practitioners would seem to exhibit a lack of faith in the correctness and efficacy of scientific medicine and to admit that there is merit in the methods of the cult practitioners.

Id. Section 3, ¶ 5. *But See*, AHCPR CLINICAL PRACTICE GUIDELINE, ACUTE LOW BACK PROBLEMS IN ADULTS (acknowledging efficacy of chiropractic care for some cases of lower back pain).

439. A recent survey reported in the New England Journal of Medicine describes the "enormous presence" of unconventional medicine. David M. Eisenberg et al., *Unconventional Medicine in the United States*, 328 NEW ENG. J. MED., 246, 251 (1993).

440. *See generally* Avedis Donabedian, *The Quality of Care—How Can It Be Assessed?* 260 JAMA 1743 (1988).

portant is a monitoring process that prospectively encourages informed participation, rather than relying solely on a retrospective review or litigation. The second major hurdle is setting meaningful review standards.[441] It will be tempting to establish a system of easy and superficial compliance.[442] Merely documenting that brochures were handed out or videos played will not satisfy the professional duty. Measures of patient satisfaction, such as surveys, will shed some light but are only a proxy for the more elusive items of disclosure and sharing of responsibility.[443]

For institutional providers and medical groups, the quality control process for patient participation could resemble that used in research. One function of the Institutional Review Boards (IRB), reducing the risk of each experiment or treatment, is within the jurisdiction of institutional risk management and quality assurance committees.[444] Many institutions also have Institutional Ethics Committees.[445] These committees primarily have dealt with the difficult, but narrow, questions of withholding or withdrawing life-sustaining care.[446] With a broader mandate, they could focus on the form and content of disclosure that needs to be made to a patient, given the patient's particular values and circumstances.[447] The key issue for surgery patients will move from disclosure of known risks to the more challenging discussion of treatment alternatives.[448]

Informed consent lawsuits are another option for monitoring and enforcement. However, since the doctrines are aimed at protecting patients from surgical procedures that would have been rejected by a reasonable person, the essential facts of an informed consent cause of action should rarely arise in a system with high quality practice guidelines and comprehensive utilization review. The more likely concern in a cost conscious system is undertreatment and underinforming. Effective cost-containment could have a negative effect on the willingness of fee for service providers to discuss alternatives that are less

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441. *Patient Judgments of Hospital Quality: Report of a Pilot Study*, 28 MED. CARE S1, S1-S2 (Meterko, Nelson, & Rubin eds., Supp. 1990).

442. One example would be accepting the entrance of the following into the patient's record as proof of compliance: Date: XX Discussed risks and alternatives with patient.

443. *See, e.g.*, Eugene C. Nelson, et al., *The Patient Comment Card: A System to Gather Customer Feedback*, 17 QRB 278 (1991); *Pilot Study*, *supra* note 453.

444. *See* 45 C.F.R. § 46.113 (1993).

445. Gregory A. Jaffe, *Institutional Ethics Committees: Legitimate and Impartial Review of Ethical Health Care Decisions* 10 J. LEG. MED. 393, 393 (1989).

446. *Id.* at 394-95.

447. *See id.* at 403-04.

448. Through practice guidelines and the risk lists developed in Texas, Louisiana and Hawaii, there should be easy access to the material risks of invasive procedures. *See supra* notes 197-99, 224, 231-37, 239 and accompanying text.

favorably reimbursed from the provider's point of view.[449] For cost-conscious managed care providers, the concerns are described in a recent law review article as follows:

> Under managed competition, a doctor's allegiance is divided between her patient and the health plan that employs her. The pressure to limit medical resource consumption may lead the doctor not to mention to her patient possible tests and procedures. In her own mind, the doctor will conduct a cost-benefit analysis and conclude that the potential benefits of certain alternative tests or procedures are not worth the cost. Discussing additional diagnostic or therapeutic options may result in a confrontation with the patient, who may demand the further treatment. Thus, the risk that the doctor may simply say nothing is substantial.
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> . . . .
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> . . . For example, a doctor may be satisfied with a given level of diagnostic clarity or a certain outcome of treatment, or a doctor may decide not to administer any medical treatment at all. Battery doctrine is inapposite in each of these cases where no touching occurs. Informed consent doctrine may not provide any additional protection because the rules governing informed consent are still touch-oriented. Consequently, although each of these situations implicates important autonomy interests, the patient's consent to these decisions may not be required.[450]

Furthermore, the informed consent doctrines are premised on independent physicians, or other providers, substituting their judgment for that of the patient. The choices may be removed from both these parties by administrative choices of care protocols.

3. *Expanded Access and the Patient-Provider Relationship*

Expanded access presents a mixed set of consequences. One immediate impact is that informed consent and participation in decision making becomes relevant to millions of individuals. Substituting a primary care office for the emergency room as the entry point for care will offer those newly covered with an opportunity for greater involvement in their own medical care.

Some provider-patient relationships will be entered into under different circumstances with increased access. Currently, a patient

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449. One proposal to counteract this is to identify interaction as a specifically reimbursed service component, much as professional patient liability insurance costs were singled out as a component of the RBRVS.

450. Elaine Lu, *The Potential Effect of Managed Competition in Health Care on Provider Liability and Patient Autonomy*, 30 HARV. J. ON LEGIS. 519, 529 (1993) (footnote omitted) (citing Matthew R. Gregory, *Hard Choices: Patient Autonomy in an Era of Healthcare Cost Containment*, 30 JURIMETRICS J. 483, 493-94 (1990)).

must find a physician who chooses to accept her. Establishing the relationship may be the only way for an individual to receive primary and preventive medical care and it improves the chances of early detection of progressive conditions. The relationship allows for the entrance into a hospital other than through the emergency room. The AMA has jealously guarded the right of the physician to choose her patients. The long campaign against "contract medicine" was motivated by the defense of this right.[451] Even today, the AMA's *Principles* provide, "A physician shall, in the provision of appropriate patient care, except in emergencies, be free to choose whom to serve, with whom to associate, and the environment in which to provide medical services."[452] This ethic has strong backing in the common law and statutes.[453] The principle also has been well recognized on the clinical level. The freedom not to undertake to serve a patient, combined with the importance of receiving care, gives the physician a clear advantage over the patient in establishing that relationship. Competition for patients has shifted this dynamic in favor of the patient. Mandatory participation for providers would make patient acceptance an administrative detail, rather than a professional prerogative, and further neutralize the professional dominance.

In contrast, medical care services that do not have excess capacity, such as nursing homes, will have an increased advantage over patients. This is because more individuals will be competing for a limited resource.[454] Starting with the nursing home admission process, the

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451. *See* American Medical Ass'n v. Federal Trade Comm'n, 638 F.2d 443 (2nd Cir., 1980), *aff'd by an equally divided Court*, 455 U.S. 676 (1982), *reh'g denied*, 456 U.S. 966 (1982) (granting enforcement of an FTC order prohibiting the AMA and local medical societies from engaging in unfair commercial practices such as the use of professional ethical codes to restrict contract practices that limit the patients' choice of a physician); American Medical Ass'n v. United States, 130 F.2d 233 (D.C. Cir. 1942), *aff'd* 317 U.S. 519 (1943) (AMA and local affiliate threatened to expel from medical society those who participated with an early health maintenance organization. Such expulsion would result in loss of staff privileges at local hospitals. Criminal conviction of antitrust laws violation upheld); Group Health Coop. of Puget Sound v. King County Med. Soc'y, 237 P.2d 737 (Sup. Ct. Wash. 1951) (similar actions taken by a local medical society found to violate state anti-trust laws).

452. AMA PRINCIPLES OF MEDICAL ETHICS, Principle VI.

453. *See, e.g.*, 42 U.S.C. § 1395(a) (1988); *see also* 42 U.S.C. § 1396a(a)(23) (Supp. II 1994) (guaranteeing such a free choice for individuals on Medicaid).

The federal statute establishing the Medicare program of government medical insurance for the elderly and disabled describes free choice as follows:

Free Choice by patient guaranteed

Any individual entitled to insurance benefits under this title may obtain health services from any institution, agency, or person qualified to participate under this title *if such institution, agency or person undertakes to provide him such services.*

42 U.S.C. § 1395(a) (Emphasis added).

454. For example, New York State has successfully limited the construction of new nursing home beds. This has been, in large part, a policy choice to encourage the use of non-institutional

patient and her family may feel that they must please the administration and staff. This imbalance in bargaining position allows the nursing home to use admission agreements with terms favorable to the facility. Once admitted, the patient depends on the facility for her food, shelter, and medical care and again may choose not to assert rights for fear of some form of reprisal.

Federal law provides some patient protection. In the area of patient participation, both the Medicaid and Medicare statutes provide that residents possess

> [t]he right to choose a personal attending physician, to be fully informed in advance about care and treatment, to be fully informed in advance of any changes in care or treatment that may affect the resident's well-being and (except with respect to a resident adjudged incompetent) to participate in planning care and treatment or changes in care and treatment.[455]

This supportive language has not been translated in the standard practice of nursing homes, as shown by the later passage of legislation prohibiting the use of physical and chemical restraints for the convenience of the staff or for disciplinary purposes.[456]

A broader range of professionals such as nurses, midwives, and pharmacists are sharing responsibility for patient care and counselling.[457] In a recent law review article, these professionals were portrayed as seasoned veterans in the struggle against physician-dominated medical care:[458]

> Nurses and social workers would appear to be likely sources of informed medical opinion and even encouragement to autonomy in the face of physician power and authority. Both these groups have acquired a fair amount of expertise at how best to preserve autonomy in the face of authority within health care contents.[459]

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care (family, friends and formal home health care providers). One result is a median occupancy rate for all New York nursing homes of over 98 percent. See HCIA, THE GUIDE TO THE NURSING HOME INDUSTRY, 1993, 67 (1993).

455. 42 U.S.C. § 1396r(c)(1)(A)(i) (1988).

456. *See* Omnibus Budget Reconciliation Act of 1987, Pub. L. No. 101-508, § 4711(f)(2)(G), 104 Stat. 1388, 1388-179 (1987).

457. The Health Security Act would have expanded Medicare payment for physicians' assistants, nurse practitioners and clinical nurse specialists. Health Security Act, § 4022 H.R. 3960, 103 Cong., 2d Sess. (1994). It also proposed to override state practice laws that "restrict the practice of any class of health professionals beyond what is justified by the skills and training of such professionals." Health Security Act, § 1161, H.R. 3960, 103 Cong., 2d Sess. (1994).

458. Nancy K. Rhoden, *Informed Consent in Obstetrics: Some Special Problems* 9 W. NEW ENG. L. REV. 67 (1987).

459. *Id.* at 81.

These professionals are closer to their patients, in personal relations as well as class, than are physicians. The movement to patient care teams may diffuse the sense of responsibility to discuss matters with the patient. An unconcerned management can leave individuals without someone to talk to or with insufficient information.

Patient education on the basics of a disease or condition may be done better through means other than a face to face meeting with a physician. Technical advances in word processing and video are leading to a library of patient oriented information that can be tailored to the individual needs and circumstances of each patient.[460] The modifying factors can include a range of patient characteristics, such as educational level and personal health beliefs.[461]

It is not hard to imagine an interactive system that would allow individuals to better assist in the diagnosis process. The programs, available in medical offices, at home, or a central location, would work much like the screening protocols and algorithms used in some health maintenance organizations (HMOs). The branching logic used in medical algorithms fits well with computer processing. The AHCPR has a subcommittee studying the feasibility of developing a computer based system that would help families to integrate a primary care plan into their health management activities.[462]

Once a diagnosis has been reached, basic information about the patient's condition could be available to her in a tailored format. This would include print, video, and audio all in the appropriate language. An information source such as this would avoid the need for repetitious briefings by medical care personnel on basic concepts. Specialists in patient education could personalize the information and help prepare any questions the patient would have to present to the physician. In addition to these efforts, the public will need to be better educated on health issues. The health courses in our schools must prepare students for the expanding role they will be expected to

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460. *See, e.g.*, Cathy D. Meade, et al., *Educating Patients with Limited Literacy Skills: The Effectiveness of Printed and Videotaped Materials about Colon Cancer*, 84 AM. J. PUB. HEALTH 119 (1994); Elaine DeRosa, *Developing an Interactive Video for Patients Suffering from Kidney Disease*, 3 J. MED. EDUC. TECH. 15 (Winter, 1993).

461. *See, e.g.*, Celett S. Skinner, et al., *Physicians' Recommendations for Mammography: Do Tailored Messages Make a Difference?* 84 AM. J. PUB. HEALTH 43 (1994).

462. These may become the modern equivalent of the 19th century home medical guides. *See supra* note 49. The Agency is also studying the creation of uniform health care data bases in order to better assess the impact of health care. AHCPR FACT SHEET (Nov. 1992). This is essentially the resumption of one of Percival's crusades. He sought to improve record keeping of vital statistics as a way of learning more about patient outcomes. In the Age of Information we should be able to do much better.

play in health and medical care.[463] Supplementing this basic education would be specific public health initiatives.[464]

One area of concern regarding expanded access is that more patients with limited experience in medical decision making will be meeting professionals who lack skills and training in interpersonal relations, especially in cross-cultural encounters. Physicians today can rely on the insurance coverage they accept to screen their patient population. For example, if a medical group doesn't participate in Medicaid, the physicians and staff will rarely, if ever, have a low income client. In a world of Health Security, they may not have that option.

Newcomers to a managed care provider will be expected to behave in ways that would have been unnecessary or even inappropriate in other settings. Neither the chaos of an emergency room nor the luxury of unlimited access to specialists prepare patients for the managed care environment. The medical providers facing stricter budgetary controls may not be very tolerant of any perceived non-conformity or demand for "extra" services. The inherent frustrations may severely retard a broader experimentation with and belief in cooperative decision making.

There is the likelihood of increased racial, ethnic, and class tensions with the movement toward increased access. The current system provides high quality care to some patients and low quality care to others.[465] Researchers are only beginning to understand the health impact of such factors as poverty and race on access. At the personal level, the differences in outcome may be linked to variations in how the medical professional interacts and assesses a patient depending on her race and economic status. A medical profession frustrated with the constraints of the evolving system of care may find convenient targets in patients with lower socio-economic status or personal traits that are easy marks for prejudice. On the other hand, more uniform practice guidelines may reduce the bias in diagnosis and treatment.

The increasing role of management, and treatment protocols that are influenced by financial considerations, suggest enterprise liability

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463. The Health Security Act provided for a sequential, age- appropriate, comprehensive school health education program for grades K-12. Health Security Act, Subtitle G, H.R. 3960, 103d Cong. 2d Sess. (1994).

464. Public Health efforts such as New York's Breast Cancer Detection and Education Program show how a coordinated approach might be able to improve the health status of individuals through education and early detection. N.Y. PUB. HEALTH LAW § 2405-8 (McKinney 1993).

465. *See, e.g.*, Jane Perkins, *Race Discrimination in America's Health Care Systems*, 27 CLEARINGHOUSE REV. 371 (Special Issue, 1993).

for many aspects of care, including the information exchange. No cases have yet held the medical enterprise liable for a failure to obtain informed consent. However, it has been held that the hospital has a duty to ensure quality of care.[466] In the future, patient participation may increasingly be viewed as an element of quality medical care.

While the general rule remains that a hospital cannot be held vicariously liable for the negligence of non-employee physicians, recent cases have held the hospital responsible for the negligence of independent contractors employed in the emergency room.[467] The new structures of medical care which increase the role for the medical administration in promoting quality of care, make enterprise liability more appealing. Having hospitals and other medical care corporations as defendants in informed consent cases may change the juries' perception of the claims.[468]

There is already increasing enterprise liability that is administratively enforceable. The Joint Commission on Accreditation of Healthcare Organizations has recognized a general hospital corporate quality mandate and is strengthening it in the revisions to its accreditation standards.[469] Federal mandates have focused on the enterprise in patient autonomy and quality related issues. For example, the Patient Self-Determination Act requires that the providers have policies and procedures in place to advise each admittee of "an individual's rights under State law, (whether statutory or as recognized by the courts of the State) to make decisions concerning . . . medical care, including the right to accept or refuse medical or surgical treatment and the

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466. *See, e.g.*, Insinga v. LaBella, 543 So. 2d 209 (Fla. 1989); Darling v. Charleston Community Mem. Hosp., 211 N.E.2d 253 (Ill. 1964), *cert. denied*, 383 U.S. 946 (1966) (hospital was liable for its failure to provide adequate and competent staff and its failure to require consultation); Moore v. Board of Trustees of Carson-Tahoe Hosp., 495 P.2d 605 (Nev. 1972), *cert. denied*, 409 U.S. 879 (1972); Pedroza v. Bryant, 677 P.2d 166 (Wash. 1984); Johnson v. Misericordia Community Hosp., 301 N.W.3d 156 (Wis. 1981).

467. *See, e.g.*, Jackson v. Power, 743 P.2d 1376 (Alaska 1987); Magana v. Elie, 439 N.E.2d 1319 (Ill. App. Ct. 1982); Hardy v. Brantley, 471 So. 2d 358 (Miss. 1985); Martell v. St. Charles Hosp., 523 N.Y.S.2d 342 (1987).

468. *See* Valerie P. Hans and William S. Lofquist, *Jurors' Judgments of Business Liability in Tort Cases: Implications for the Litigation Explosion Debate*, 26 LAW AND SOC'Y REV. 85 (1992). In a survey of jurors, the authors asked for a response to the statement: A company should be required to tell the public about any possibility, however small, that its products might be unsafe. Eighty-eight percent of the respondents agreed or strongly agreed, with an additional 7 percent neither agreeing nor disagreeing. The authors noted:

> Tort jurors held high standards for business in the abstract, as we saw in their questionnaire responses, yet these standards become more diffused or difficult to apply as jurors approached the concrete task of assessing responsibility and compensation in individual cases.

Id. at 102.

469. JCAHO, ACCREDITATION MANUAL FOR HOSPITALS, 137-38 (1992).

right to formulate advance directives. . . ."[470] Providers also must provide education for the staff and the community on these topics.[471]

VI. CONCLUSION

Patient-provider relationships at the beginning of the century were personal in nature with the participants on relatively equal footing. The open marketplace for medical providers and remedies supported a collaborative care venture. As organized conventional medicine gained prestige and became more scientific in approach, a gap developed between patients and providers, especially surgeons. This proved to be dangerous for some patients who were subjected to invasive procedures and suffered statistically predictable complications. The courts and legislatures developed protective doctrines, first requiring consent for all segments of the procedure, and later, informed consent. In the process, outsiders took a direct role in setting minimum standards in patient relations. In 1980, organized medicine began to reassert its professional prerogative to define the providers' role in patient relations. Revised medical codes of ethics acknowledge the importance of informed consent and the broader patient right of self determination. These changes reflect and support societal values that place an increasing value on patient autonomy.

The medical care structure underlying the patient-provider relationship is undergoing an unprecedented change. Independent practitioners of medicine are giving way to managed care enterprises and integrated delivery systems. More effective utilization review focusing on cost is expanding the oversight of care providers. Accepted medical

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470. 42 U.S.C. § 1395cc(f)(1)(A)(i) and 42 U.S.C. § 1396a(w)(1)(A)(i) (1988). *See also* Interim Final Rule, 57 FED. REG. 8194 (1992).

471. Another example is the National Practitioner Data Bank which was created by the Health Care Quality Improvement Act of 1986, 42 U.S.C. 11101-11152 (Supp. 1994). Many sources are required to report certain information to the Bank. *See, e.g.*, Fiorentino v. Wenger, 227 N.E.2d 296 (1967) (for a holding that would no longer be viable regarding the hospital's liability). The types of information reported includes malpractice claim payments, and adverse actions taken by the hospitals and administrative or professional bodies overseeing the practice of medicine. *Id.* at § 11131(b). Hospitals are expected to request a report on a practitioner at the time they grant privileges, and every two years thereafter. *Id.* at § 11135(a). A failure to request the information creates a presumption that the hospital knew the contents of the report and that presumption may be used in a malpractice action against the hospital.

The National Practitioner Data Bank was created by the Health Care Quality Improvement Act of 1986, P.L. 99-660, and is codified at 42 U.S.C. 11101-11152. It became operational as of September 1, 1990. Those who must report include medical malpractice insurers, hospitals and other medical care entities, state medical and dental boards, peer review boards or committees of professional societies, and self-insured providers.

The Data Bank eliminates the defense that the hospital did not know about an adverse action emanating from outside her own facility. The existence of the Data Bank has also undoubtedly reduced the number of actions taken by hospitals and other reporting providers that fall within the statutory definition of an adverse action.

practices are being challenged and replaced by practice guidelines drawn from outcome studies. The paradigm of the patient-provider relationship for the informed consent doctrines involves a physician with clinical autonomy. Patient care teams, operating under group practice protocols, are replacing the autonomous physician. The responsibility for counselling the patient is being determined by administrative delegation. Government regulation provides the oversight to this system. In short, the new relationships require a new framework for analysis.

Perhaps we have been expecting too much of our physicians. We want them to be the technical masters of their craft and the source of our moral support. We also ask them to educate us on each malady as it comes along in our lives. Some of these functions need to be shared with others in the health care field.

These changes may bode well for increased patient participation in medical decision making. Better medical information and new methods of processing and presenting that information can relieve the individual care provider of some basic medical counselling if it is made an administrative priority. The institutional culture regarding patient rights may be the ultimate barometer of the future of patient involvement. New tensions will surface, and financial incentives may limit the provider's interest in the time consuming interpersonal work of talking with the patient. Nevertheless, the potential for moving forward is there. What is needed is the social commitment to carry it out.