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**Values**

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# Informed Consent as Active, Shared Decisionmaking

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The complexities of modern life make it difficult for individuals to be masters of their own fate. Perhaps in no sphere of everyday activity is this more acute than in health care. This often frustrating lack of control can be traced to several recent developments: the increasing reliance on advanced technology, the high degree of specialization, the consequent segmentation of care among an imposing array of health care professionals who are often strangers to the patient. But these latter-day developments have only magnified the sense of awe people have always felt when confronted with the mysteries of life, illness, and death that are health care's most basic concerns.

Traditionally, many cultures, including this one, have responded by according healers a unique deference and authority in their relationships with patients.<sup>1</sup> Yet this authori-

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<sup>1</sup> Historically, the law of informed consent developed in the context of claims by patients against physicians. The rationale of existing law would, however, support the application of informed consent requirements to nonphysician practitioners who function as independent providers of health care. As nurses and other nonphysician health professionals move into such roles, these legal requirements will become incumbent upon them as well. The law has thus far had little occasion to address in any detail the distinctive legal obligations regarding informed consent, if any, of nurses and other nonphysician health care professionals in their myriad other professional roles and functions.

Insofar as this Report addresses the distinctively ethical as well as legal requirements of informed consent, the Commission wishes to make clear that its discussion is directed to all health care professionals, including those who work as members of health care teams rather

ty is not, and has not been, absolute. Ancient writings indicate limits on the authority of the physician.<sup>2</sup> Within the Anglo-American tradition, the law has for centuries recognized the obligation of physicians to seek the consent of their patients prior to initiating treatment,<sup>3</sup> And in the past quarter-century, American courts, supported by legal and ethical commentary, have articulated a legal doctrine of “informed consent” that requires health care practitioners not simply to seek the consent of their patients, but also, through a process of disclosure and discussion between practitioners and patients, to make such consents “informed.”<sup>4</sup> Thus, the law requiring informed consent has become an important means by which society regulates relationships between patients and health care professionals.

To what degree does this legal requirement of informed consent advance the ability of patients to maintain control of and be responsible for decisions regarding their lives and their health? How closely does the practice of informed consent in day-to-day health care accord with the theory? Can public policy promote a system in which patients can cope more successfully with the complexities of modern medicine? And quite apart from legal requirements, how can health care providers be encouraged to recognize and to satisfy their distinctive moral obligations to their patients?

Current requirements for informed consent owe much to the legal system, but the values underlying these requirements

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than primarily as independent practitioners. While they may not currently have the same legal duties as independent practitioners, they are subject to ethical obligations to respect and serve the interests of their patients. In this Report, therefore, such individuals are encompassed within the meaning of the terms “professionals”, “providers,” and “practitioners,” which are used here interchangeably except where specifically modified. Some of the informed consent statutes specifically indicate the types of health care providers to whom they apply, such as physician’s assistants, nurses, podiatrists, etc. See Alan Meisel and Lisa D. Kabnick, *Informed Consent to Medical Treatment: An Analysis of Recent Legislation*, 41 U. PITT. L. REV. 407, 410-11 n.12 (1980).

<sup>2</sup> Laurence B. McCullough, *Historical Perspectives on the Ethical Dimensions of the Patient-Physician Relationship: The Medical Ethics of Dr. John Gregory*, 5 ETHICS IN SCI. AND MED. 47-53 (1978).

<sup>3</sup> The earliest reported case dealing with consent to medical treatment is generally acknowledged to be *Slater v. Baker & Stapleton*, 95 Eng. Rep. 860 (K.B. 1767). However, nonconsensual medical treatment involves either a harmful or offensive touching of the person and has therefore long been remediable, at least in theory, under the writ of trespass. See generally Fowler Harper and Fleming James, *THE LAW OF TORTS*, Little, Brown, & Co., Boston (1956) §§ 3.1-3.3 at 211-20.

<sup>4</sup> Alan Meisel, *The Expansion of Liability for Medical Accidents: From Negligence to Strict Liability by Way of Informed Consent*, 56 NEB. L. REV. 51, 79-80 (1977).

are not merely legal artifacts. Rather, they are deeply embedded in American culture and the American character; they transcend partisan ideologies and the politics of the moment. Fundamentally, informed consent is based on respect for the individual, and, in particular, for each individual's capacity and right both to define his or her own goals and to make choices designed to achieve those goals.<sup>5</sup> But in defining informed consent (and its exceptions) the law has tempered this right of self-determination with respect for other values, such as promotion of well-being in the context of an expert-layperson relationship.<sup>6</sup>

The values underlying informed consent are widely shared by people in all segments of American society. Regardless of race, income, education, age, or gender, the vast majority of people surveyed by the Commission felt that patients have a right to information and ought to participate in decisions regarding their health care. Furthermore—despite vastly different views held by many foreign cultures and subcultures within the United States regarding the etiology of illness and the roles of healers and patients—a desire for information, therapeutic choice, and respectful communication appears to be common in all groups.<sup>7</sup>

Despite this consensus on the values underlying informed consent, the doctrine itself is only dimly perceived—and perhaps even misunderstood—by many people. In the Commission's survey, physicians and the public were asked in an open-ended format: "What does the term informed consent mean to you?" (Each portion of every answer was coded separately to see which particular elements of the informed consent doctrine were mentioned; the percentages that follow add up, therefore, to more than 100.) Among the public, 21% said they did not know what informed consent meant; those who gave a substantive answer said:

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<sup>5</sup> Jay Katz, with the assistance of A. M. Capron and Eleanor S. Glass, *EXPERIMENTATION WITH HUMAN BEINGS*, Russell Sage Foundation, New York (1972) at 540-88; Jay Katz and A.M. Capron, *CATASTROPHIC DISEASES: WHO DECIDES WHAT?*, Russell Sage Foundation, New York (1975) at 82-85, 90; George J. Annas, Leonard H. Glantz, and Barbara F. Katz, *INFORMED CONSENT TO HUMAN EXPERIMENTATION: THE SUBJECT'S DILEMMA*, Ballinger Publishing Co., Cambridge (1977) at 33-38; A.M. Capron, *Informed Consent in Catastrophic Disease Research and Treatment*, 123 U. PA. L. REV. 340, 364-76 (1974).

<sup>6</sup> Alan Meisel, *The "Exceptions" to the Informed Consent Doctrine: Striking a Balance Between Competing Values in Medical Decisionmaking*, 1979 WIS. L. REV. 413, 417-29 *passim*.

<sup>7</sup> Robert A. Hahn, *Culture and Informed Consent: An Anthropological Perspective* (1982), Appendix F, in Volume Three of this Report. The nature of communication and decisionmaking are analyzed in several cultures, including "core" American, Navajo, Italian-American, Vietnamese refugee, and mainland Puerto Rican.

- it meant the patient was informed (44%, although only 10% mentioned risks and less than 1% mentioned alternatives);
- it meant that the patient agreed to treatment, often adding that it meant letting the doctor do whatever was “necessary,” “best,” or “whatever he sees fit” (44%);
- it meant that the patients made a treatment decision, such as “to give someone consent to do whatever I wish” (19%);
- it involved patient understanding (11%);
- it was a form (7%); and
- it was consent to termination of treatment, such as “giving a person permission to kill you,” or “legally put in writing patient request not to be put on life support” (6%).

The most frequent responses given by physicians were:

- generally informing patient about condition and treatment (59%);
- disclosing treatment risks to patient (47%);
- patient understanding his or her condition and treatment (34%);
- patient giving permission for treatment (26%); and
- patient understanding treatment risks (23%).

Only 14% of physicians mentioned treatment alternatives and only 9% indicated that informed consent had something to do with the patient making a choice or stating a preference about his or her treatment. Furthermore, 4% mentioned consent forms, 3% said it was a legal doctrine, and 3% said it was meaningless.

In this Report, the Commission focuses primarily on the ethical and practical dimensions of informed consent, and in particular on the source and extent of professional obligations of health care practitioners to respect and enhance their patients’ capacities for wise exercise of their autonomy. The focus is not particularly on the law, and the Report recommends few changes in existing legal or regulatory norms. Yet because informed consent arose as a distinctively legal doctrine, and because many misunderstandings and misapprehensions concerning informed consent derive from the doctrine’s origins in the law, it is useful to begin by tracing the legal evolution of informed consent requirements.

## **Legal Background**

**Development of the Law.** The precursors of the modern doctrine of informed consent are found in the venerable English common law regarding battery, which forbade harmful

or offensive nonconsensual touching, however benign in motive or physical effect.<sup>8</sup> No special exceptions were made for medical care, except in emergency situations.<sup>9</sup> Thus, under the common law, a medical intervention in which the practitioner touched the body of the patient would constitute a technical battery unless the patient consented to the intervention.<sup>10</sup>

The nature of the consent required to avoid liability for battery was not especially exacting. It could be given explicitly in words, manifested by actions, or, in some instances, implied from the circumstances.<sup>11</sup> The law was not overly concerned with the quality of the patient's understanding of what was being consented to, nor did it impose any strenuous obligations on the physician to disclose what was involved, beyond perhaps the name or cursory description of the procedure.<sup>12</sup> Although the law imposed no affirmative obligation to go beyond that simple disclosure, the practitioner was expected to refrain from fraudulent or deceptive statements, because they could invalidate the patient's consent and subject the physician to potential liability.<sup>13</sup>

Few of the early cases concerning nonconsensual medical procedures (including American cases in the first decades of this century) gave much explicit attention to disclosure by the physician.<sup>14</sup> Rather, they focused on unauthorized procedures,<sup>15</sup>

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<sup>8</sup> William L. Prosser, *HANDBOOK OF THE LAW OF TORTS* (4th ed.), West Publishing Company, St. Paul, Minn. (1971) § 10 at 36, § 32 at 165.

<sup>9</sup> *Id.*, § 18 at 103.

<sup>10</sup> *Id.*, § 18 at 102, § 32 at 165.

<sup>11</sup> *See generally* Annotation, 76 A.L.R. 562, 566-70 (1932) (collecting cases) and 139 A.L.R. 1370, 1374-75 (1942) (collecting cases).

<sup>12</sup> *See* Meisel, *supra* note 4, at 80-81. Prior to the promulgation of the informed consent requirement in 1957, ordinary consent was required for medical treatment. The term consent denotes that the person giving consent understands the nature of the "touching" that will occur. *See* Marcus L. Plant, *An Analysis of Informed Consent*, 36 *FORDHAM L. REV.* 639 (1968); *RESTATEMENT (SECOND) OF TORTS*, American Law Institute Publishers, St. Paul, Minn. (1979) at § 892(1).

<sup>13</sup> *See, e.g.*, *Wall v. Brim*, 138 F.2d 478, 479 n.7 (5th Cir. 1943); *Hunt v. Bradshaw*, 242 N.C. 517, 88 S.E.2d 762 (1955); *Waynick v. Reardon*, 236 N.C. 116, 72 S.E.2d 4 (1952); *Paulsen v. Gundersen*, 218 Wis. 578, 260 N.W. 448 (1935).

<sup>14</sup> There are a few cases before the first modern informed consent case in 1957 that paid some attention to doctors making disclosure to patients. The earliest, and perhaps the most important, is *Hunter v. Burroughs*, 123 Va. 113, 96 S.E. 360 (1918), in which the court spoke of the doctor's duty to warn a patient of the danger of possible bad consequences of using a remedy. *See also* *Wall v. Brim*, 138 F.2d 478 (5th Cir. 1943); *Pratt v. Davis*, 224 Ill. 300, 79 N.E. 562 (1906), *aff'd* 118 Ill. App. 161 (1905).

<sup>15</sup> *See generally* Annotation, 56 A.L.R.2d 695, 704-07, 716-17 (1957) (collecting cases); Annotation, 139 A.L.R. 1370, 1370-71 (1942) (collecting cases); Annotation, 123 A.L.R. 1115, 1148 (1939) (collecting cases);

instances in which the provider (usually a surgeon) exceeded the agreed scope of the operation<sup>16</sup> or transgressed a specific prohibition made by a patient,<sup>17</sup> This period gave birth to the most well known judicial expression of a patient's right of self-determination, proclaimed in 1914 by Judge Cardozo in the *Schloendorff* case: "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."<sup>18</sup> Two aspects of this celebrated case are worth noting. First, it was not concerned with the question of the information a patient needs to exercise this right to self-determination. Second, the ringing judicial affirmation of the patient's right to consent came in a decision denying recovery of damages.

Not until the latter half of this century did the courts begin to marry the provider's traditional duty to secure consent with a new affirmative obligation of disclosure, perhaps best understood as a "duty to warn," resulting in a new legal doctrine of "informed consent."<sup>19</sup> This magical phrase was first

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Annotation, 76 A.L.R. 562, 562-66 (1932) (collecting cases).

<sup>16</sup> See generally Annotation, 56 A.L.R.2d 695, 709-16 (1957) (collecting cases);

Annotation, 76 A.L.R. 562, 564-66 (1932) (collecting cases).

<sup>17</sup> Corn v. French, 71 Nev. 280, 289 P.2d 173 (1955); Meek v. City of Loveland, 85 Colo. 346, 276 P. 30 (1929); Throne v. Wandell, 176 Wis. 97, 186 N.W. 146 (1922); Markart v. Zeimer, 67 Cal. App. 363, 227 P. 683 (Ct. App. 1924).

<sup>18</sup> *Schloendorff v. Society of New York Hosp.*, 211 N.Y. 125, 105 N.E. 92, 95 (1914).

<sup>19</sup> This judicial development was presaged by the articulation of consent requirements in the context of research with human subjects following the revelations of Nazi atrocities during World War II. See, e.g., the Nuremberg Code (1946-49), which provides in part that the "voluntary consent of the human subject is absolutely essential" and that the "person involved...should have sufficient knowledge and comprehension of the elements of the subject matter involved as to enable him to make an understanding and enlightened decision." The Code specifies that these elements include "the nature, duration, and purpose of the experiment; the method and means by which it is to be conducted; all inconveniences and hazards reasonably to be expected; and the effects upon his health or person which may possibly come from his participation in the experiments." Several of these elements have been incorporated in informed consent requirements regarding nonexperimental health care. See also the "Principles for Those in Research and Experimentation" adopted by the General Assembly of the World Medical Association in 1954, which requires that "each person who submits to experimentation be informed of the nature of, the reason for, and risk of the proposed experiment" and that written consent be obtained. Some slight recognition of these principles existed prior to the Nuremberg trials. See Hubert Winston Smith, *Antecedent Grounds of Liability in the Practice of Surgery*, 14 ROCKY MOUNTAIN L. REV. 233, 263-65, 286-93 (1946): "The surgeon should make



invoked in a 1957 California decision, *Salgo v. Leland Stanford, Jr., University Board of Trustees*,<sup>20</sup> and was further elaborated in two opinions by the Kansas Supreme Court in *Natanson v. Kline*.<sup>21</sup>

Since the Natanson landmark in 1960, claims alleging lack of informed consent have been raised before the highest courts of most states.<sup>22</sup> These courts have adopted various definitions of the legal prerequisites for recovery. Today, most states view failure to secure informed consent as a variety of medical malpractice, subject to the norms governing negligence law.

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a full disclosure of material facts to the patient including risks and alternative treatments, and obtain his enlightened consent before applying any novel or experimental treatment, or administering unproven remedies, or drugs now held in question because of toxic reactions or threat of tissue damage.” *Id.* at 265.

Informed consent in the context of research with human subjects is now subject to extensive government regulation as well as professional codes; *see generally* Chapter Two of the Commission’s study, COMPENSATING FOR RESEARCH INJURIES, Government Printing Office, Washington (1982). Remarkably, none of the seminal judicial decisions rely on, or even cite, statements in the Nuremberg or other research codes. Nonetheless, although they developed along separate, parallel tracks the two areas—informed consent for research and for therapy—are today basically the same, and commentators and federal regulators draw on the extensive case law from therapeutic settings in elaborating the rules that are appropriate for disclosure and consent in research settings. For a thorough analysis of the role of informed consent in medical research, see Robert J. Levine, ETHICS AND REGULATION OF CLINICAL RESEARCH, Urban & Schwarzenberg, Baltimore (1981) at 69-116.

20 *Salgo v. Leland Stanford Jr. Univ. Bd. of Trustees*, 154 Cal. App. 2d 560, 317 P.2d 170 (1957).

21 186 Kan. 393, 350 P.2d 1093, *opinion on denial of motion for rehearing*, 187 Kan. 186, 354 P.2d 670 (1960).

22 As of 1982, 37 states had recognized a legal right of recovery for lack of informed consent. *See* Appendix L in Volume Three of this Report. The number of successful claims (awarding damages to injured patients for not obtaining their informed consent) appears to be relatively small. As to the proportion of malpractice suits involving informed consent, the HEW medical malpractice commission reported that as of 1971 there had been only 90 American appellate decisions in which consent was a major issue. Sylvia Law and Steven Polan, PAIN AND PROFIT: THE POLITICS OF MALPRACTICE, Harper & Row Publishers, New York, (1978) at 112. Law and Polan also cite a study undertaken by the National Association of Insurance Commissioners that reported that, in a survey of claims resolved over a 12-month period in 1975-76, informed consent was raised as an issue in only 3% of the cases. *Id.* at 113. Further, in no reported case have damages been awarded to a plaintiff solely for dignitary harm in the absence of accompanying physical injury. *But see* note 35 *infra*.

Although a few states will no longer allow health professionals to be sued in battery for failure to obtain consent,<sup>23</sup> many more keep the battery action as a partner to suits for negligent nondisclosure.<sup>24</sup> In these states, when no consent at all was obtained or when the procedure actually performed differed substantially from the procedure consented to, the appropriate suit is in battery; when consent to the performed procedure was obtained but disclosure was deficient, the appropriate suit is in negligence.

States have also differed in whether the applicable “standard of care” regarding what must be disclosed is based on professional custom (which typically requires that the patient produce expert testimony on such a standard) or on some notion of the “materiality” of the information to be disclosed (which allows a case to go to the jury without the patient needing to prove professional custom through expert testimony, a standard decidedly more favorable to the injured patient in most circumstances.)<sup>25</sup> Some of the cases suggest that a legal hybrid has been created, drawing on the law of battery, of negligence, and of fiduciary obligations.<sup>26</sup>

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<sup>23</sup> In many states, abolition of battery as the appropriate cause of action for informed consent actions has been achieved judicially. *See, e.g.*, Trogun v. Fruchtmann, 58 Wis.2d 596, 207 N.W.2d 297 (1973). In one state, the change has been legislatively mandated. *See* ARIZ. REV. STAT. ANN. § 12-562(B)(1976). This change has not escaped scholarly criticism. *See, e.g.*, Capron, *supra* note 5, at 403-29, 348-49; Joseph Goldstein, *For Harold Lasswell: Some Reflections on Dignity, Entrapment, Informed Consent, and the Plea Bargain*, 84 YALE L.J. 683 (1975); Plant, *supra* note 12; Marcus L. Plant, *The Decline of “Informed Consent,”* 35 WASH. & LEE L. REV. 91 (1978); Leonard L. Riskin, *Informed Consent: Looking for the Action*, 1975 U. ILL. L. F. 580, 585-92.

<sup>24</sup> *See, e.g.*, Cornfeldt v. Tongen, 262 N.W.2d 684 (Minn. 1977).

<sup>25</sup> Comment, *Informed Consent in Medical Malpractice*, 55 CALIF. L. REV. 1396, 1405-06, 1410 (1967); Note, *Restructuring Informed Consent: Legal Therapy for the Doctor-Patient Relationship*, 79 YALE L.J. 1533, 1572-76 (1970). One of the strongest objections to the “professional” standard is that it is unclear that there is any custom in the medical profession to disclose the kind of information envisioned by the informed consent doctrine to patients. *Canterbury v. Spence*, 464 F.2d 772, 783 (D.C.Cir. 1972), and that there are strong biases in medical practice and training against making disclosure. Theodore J. Schneyer, *Informed Consent and the Danger of Bias in the Formation of Medical Disclosure Practices*, 1976 WIS. L. REV. 124.

<sup>26</sup> *See, e.g.*, Hales v. Pittman, 118 Ariz. 305, 576 P.2d 493, 497 (1973). *See generally* Capron, *supra* note 5, at 404-29; Allan H. McCoid, *A Reappraisal of Liability for Unauthorized Medical Treatment*, 41 MINN. L. REV. 381, 434 (1957); Plant, *supra* note 12, at 650-56; Riskin, *supra* note 23, at 600-04.

A trilogy of major cases decided in 1972 in the Federal appellate court of the District of Columbia<sup>27</sup> and the state supreme courts of California<sup>28</sup> and Rhode Island<sup>29</sup> made it appear that the traditional professional custom standard of care might soon be supplanted by the materiality or patient-based approach. However, since then this trend has slowed and perhaps been reversed.<sup>30</sup> Indeed, a number of state legislatures have incorporated the professional custom standard in legislation, usually at the urging of state and local medical societies.<sup>31</sup> This development was particularly prevalent during the so-called malpractice insurance crisis of the mid-1970s. Although a detailed review of the current state of the law would be a diversion from the Commission's central concerns,<sup>32</sup> a discussion of some of the major influences on its development will help assess how well the current legal doctrine of informed consent accords with both the ethical justifications for the doctrine and the day-to-day realities of health care.

**The Influence of the Litigation Process.** The distinctive role and function of the courts in American society have been major influences in shaping informed consent. Courts do not

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

28 *Cobbs v. Grant*, 8 Cal.3d 229, 104 Cal. Rptr. 505, 502 P.2d 1 (1972).

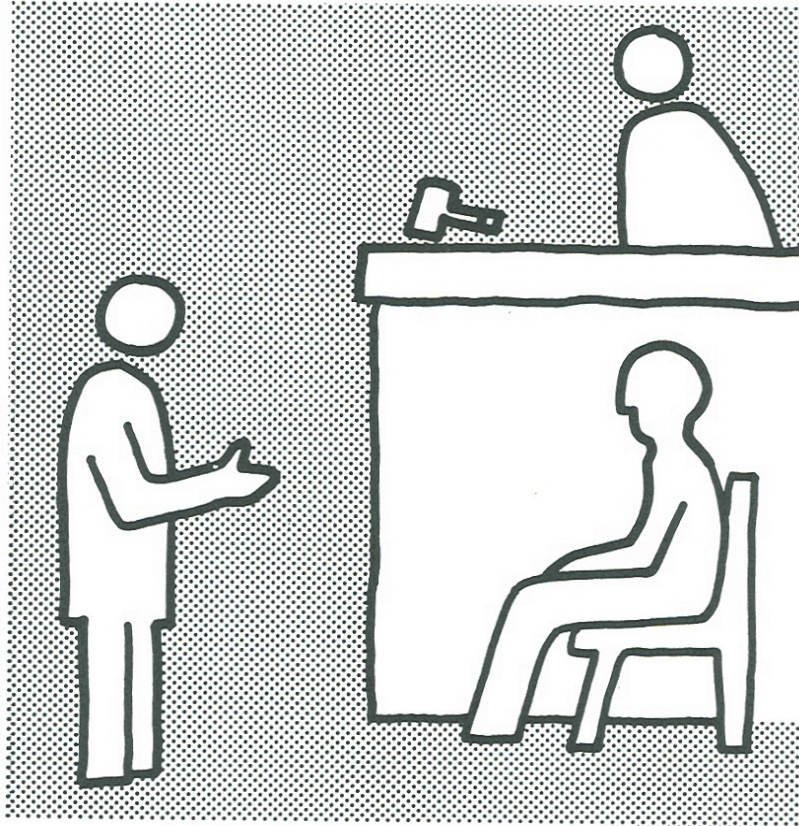
29 *Wilkinson v. Vesey*, 110 R.I. 606, 295 A.2d 676 (1972).

30 This approach had been suggested in scholarly literature prior to these cases. See Jon R. Waltz and Thomas W. Scheuneman, *Informed Consent to Therapy*, 64 Nw. U. L. REV. 628 (1970); Comment, *supra* note 25; Note, *supra* note 25. When the three significant cases were decided in 1972, the intermediate appellate courts of three states had adopted the patient-based approach, though no state supreme courts had. See *Hunter v. Brown*, 4 Wash. App. 899, 484 P.2d 1162, *aff'd*, 81 Wash. 2d 465, 502 P.2d 1194 (1972); *Mason v. Ellsworth*, 3 Wash. App. 298, 474 P.2d 909 (1970); *Cooper v. Roberts*, 220 Pa. Super. 260, 286 A.2d 647 (1971); *Berkey v. Anderson*, 1 Cal. App.3d 790, 82 Cal. Rptr. 67 (1969). Between 1972 and 1978, a total of 10 jurisdictions had adopted the patient-based approach, Annotation, 88 A.L.R.3d 1008, 1034-35 (1978), compared with 17 states that either stayed with or later adopted the standard based on professional custom. *Id.* at 1024-28. However, beginning in the mid-1970s, a number of states enacted statutes changing the standard back to a professional one. Thus as of this writing, 26 states have adopted a professional standard, 9 states have a patient-oriented standard, and 3 states have no law on the subject.

31 Between 1975 and 1977, about half the states enacted legislation relating to requirements for informed consent. See Appendix L in Volume Three of this Report; see also Arnold J. Rosoff, *INFORMED CONSENT: A GUIDE FOR HEALTH CARE PROVIDERS*, Aspen Systems Corp., Rockville, Md. (1981) at 75-186; Meisel and Kabnick, *supra* note 1.

32 The current law of informed consent, including variations among the states, is canvassed in detail in Appendix L in Volume Three of this Report.

exist to reflect philosophically on the state of the world; nor is their role to issue gratuitous, albeit perhaps apt, advice to professionals on how to conduct their relations with patients. Rather, courts are supposed to decide concrete cases, brought by individuals seeking redress for their injuries or enforcement of their rights.



In the context of informed consent, such cases typically involve allegations by an injured patient that a practitioner's improper failure to warn of specific risks led the patient to accept medical procedures that resulted in harm the patient would have avoided if warned. The courts must determine whether such allegations are true and, if so, whether the practitioner should be legally liable to the injured patient. Only by understanding this process and the practical difficulties in carrying it out can the development of the legal doctrine of informed consent be appreciated.

First, the medical malpractice cases that find their way to court invariably involve medical interventions that did not go well.<sup>33</sup> Not only has the patient been physically injured by the intervention, but the patient is sufficiently displeased by the outcome so as to initiate legal action, with its well-known costs and tribulations, which may include the destruction of any positive relationship between patient and professional. When there was a strong preexisting bond between patient and professional, and when the patient was prepared for the possibility of an adverse outcome, litigation is less likely.<sup>34</sup> Thus, the courts' perspective is necessarily shaped by their near-exclusive experience with injured, unhappy patients. The far more numerous instances in which care is provided without serious misadventure do not come before them. This may help explain the sometimes differing perspectives of judges, who see only the bad outcomes, and health care professionals, who see the good as well as the bad.

Second, and more specific to informed consent, courts see only those cases in which particular allegedly undisclosed risks associated with medical procedures have led to actual injuries.<sup>35</sup> This fact, although perhaps obvious in itself, has

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33 This is an almost inevitable consequence of treating actions for lack of informed consent as a species of negligence rather than as battery, *see* note 26 *supra*, since negligence actions traditionally require physical harm to person or property and do not permit an award of damages for dignitary affronts alone. Prosser, *supra* note 8, § 30 at 143. *See also* note 35 *infra*.

34 “[If] patient-physician rapport is high, [the patient] is less likely to sue his doctor in the first instance.” R. Crawford Morris and Alan R. Moritz, DOCTOR AND PATIENT AND THE LAW (5th ed. 1971), quoted in *Wilkinson v. Vesey*, 110 R.I. 606, 295 A.2d 676, 690 (1972).

35 This is referred to as the “materialized risk” requirement, which holds that a patient suffers no legally remediable wrong unless there has been some bodily injury. *See, e.g.*, *Canterbury v. Spence*, 464 F.2d 772, 790 (D.C.Cir. 1972); *Cornfeldt v. Tongen*, 262 N.W.2d 684, 699 (Minn. 1977). This requirement has received severe criticism for failing to “recognize that a citizen can be wronged without being harmed, that his dignity as a human being has been violated and that an assault has taken place the moment the [doctor] commences therapy... even if beneficial...” Goldstein, *supra* note 23, at 691. Occasionally, patients have recovered in lawsuits merely for the dignitary affront involved in nonconsensual treatment. *See, e.g.*, *Lloyd v. Kull*, 329 F.2d 168 (7th Cir. 1964) (\$500 for unauthorized removal of a mole); *Rolater v. Strain*, 39 Okla. 572, 137 P. 96 (1913) (\$1000 for unauthorized removal of a foot bone); *Mohr v. Williams*, 95 Minn. 261, 104 N.W. 12 (1905); *cf. Bailey v. Belinfante*, 218 S.E.2d 289 (Ga. App. 1975) (plaintiff sought damages but did not recover for allegedly nonconsensual treatment by dentist), but none of these cases involved allegations of inadequate disclosure, merely the failure to obtain consent. In the absence of bad results, a patient may only be awarded nominal damages for injury to dignity. *See, e.g.*, *McCandless v. State*, 3 App. Div.2d 600, 606-07, 162 N.Y.S.2d 570, 575-76, *aff'd*, 4 N.Y.2d 785, 149

important consequences for the nature of informed consent litigation. Most significantly, in such cases attention tends to focus almost automatically on the particular procedure employed and on the risk that resulted in injury. The inquiry concerns whether that particular risk was disclosed, rather than whether the overall course of care, and the extended process of disclosure, discussion, and decisionmaking regarding care, were properly respectful of the patient's right of self-determination. Thus, the very nature of the court's task explains the law's oft-remarked preoccupation with the risks of particular procedures,<sup>36</sup> often to the exclusion of other aspects of the medical decisionmaking process.

Third, courts must grapple with difficulties posed by the impact of hindsight on the litigation process. Such problems arise in a number of contexts, and if not resolved satisfactorily may endanger the integrity of the courts' truth-seeking function.

Two closely related instances of such difficulties involve the centrally important determinations of whether information that was not disclosed was "material" to the patient (that is, "when a reasonable person in what the physician knows or should know to be the patient's position, would be likely to attach significance to the risk or cluster of risks in deciding whether or not to undergo the proposed therapy"<sup>37</sup>) and whether the provider's failure to disclose this information "caused" the patient to undertake the course of action that resulted in injury. In both instances, the patient's own testimony about what would have been important to know and how that information would have affected his or her decision may be colored by hindsight, as well as by the patient's recognition that different reconstructions of hypothetical past decisions may help determine whether the case is won or lost. Thus, while injured patients will possess unique insight into their own values and choices, the courts have understandably tried to limit the impact of possibly speculative and potentially self-serving testimony.<sup>38</sup>

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N.E.2d 530, 173 N.Y.S.2d 30 (1957), in which a patient in a state mental hospital was awarded \$10,000 for an unauthorized abortion performed on her. The damages were, however, reduced by the appellate court in light of testimony that her condition was improved by this termination of pregnancy.

<sup>36</sup> See, e.g., Jay Katz, *Informed Consent—A Fairy Tale?: Law's Vision*, 39 U. PITT. L. REV. 137, 172 (1977).

<sup>37</sup> This formulation was originally put forth by Professor Jon Waltz and Thomas Scheuneman in their classic article on informed consent and adopted, more or less verbatim, in the seminal informed consent case of *Canterbury v. Spence*, 464 F.2d 772, 788 (D.C.Cir. 1972). See Waltz and Scheuneman, *supra* note 30, at 640.

<sup>38</sup> See *Canterbury v. Spence*, 464 F.2d 772, 791 (D.C.Cir. 1972).

Accordingly, for both determinations of the materiality of information concerning risks and the existence of proximate cause, most courts have been drawn to what is known as an “objective standard.” This requires juries to consider the issues as if they were an “average, reasonable person” in the position of the particular patient.<sup>39</sup> To the degree that the decision of the average, reasonable patient would differ from the perhaps idiosyncratic decision of a particular patient, the law’s objective standard fails to support that particular patient’s right of self-determination.<sup>40</sup> Nevertheless, a more subjective standard, better attuned to the values of each person, could pose serious practical difficulties in litigation.<sup>41</sup>

Although this standard attempts to protect against the dangers of hindsight, the physicians’ burdens may still be increased since it is impossible to control fully the degree to which a jury may actually consider any special circumstances and needs of a particular plaintiff. In assessing whether the particular risk that resulted in injury should have been disclosed, the jury cannot magically forget that the risk in fact materialized. A jury, as the finder-of-fact in the case before it, is not in a position to explore all the practical implications of requiring disclosure of a particular risk to future patients facing comparable decisions. Consequently, the judgments in individual cases may seem to impose overly burdensome disclosure requirements. It would be unfortunate, in the Commission’s

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39 *See, e.g., Canterbury v. Spence*, 464 F.2d 772, 788 (D.C.Cir. 1972); *Sard v. Hardy* 379 A.2d 1014, 1022 (Md. Ct. App., 1977); Rev. Code Wash. Ann. § 7.70.050(c).

40 “In holding that the materiality of information is to be judged by what the law’s mythical ‘reasonable person’ would want to know, these courts retreated from the logic of their own reasoning.” Capron, *supra* note 5, at 407; *see also* Goldstein, *supra* note 23; Joseph King, *In Search of a Standard of Care for the Medical Profession: The “Accepted Practice” Formula*, 28 V AND. L. REV. 1213, 1265 (1975); Riskin, *supra* note 23, at 589.

41 Although acknowledging the practical difficulties attendant upon the use of a subjective test of causation, the North Carolina Supreme Court nevertheless adopted the test because “[t]he detriments of the objective standard are more severe.” The court continued by stating:

In determining liability by whether a reasonable person would have submitted to treatment had he known of the risk that the defendant failed to relate, no consideration is given to the peculiar quirks and idiosyncracies of the individual. His supposedly inviolable right to decide for himself what is to be done with his body is made subject to a standard set by others. The right to base one’s consent on proper information is effectively vitiated for those with fears, apprehensions, religious beliefs, or superstitions outside the mainstream of society.

*McPherson v. Ellis*, No. 147 A81, slip op. at 2-3 (N.C. March 3, 1982).

opinion, if these legal interventions resulted in physicians feeling compelled to recite formally a parade of all risks remotely associated with each alternative treatment. Such recitations can be so overwhelming that patients are unable to distinguish truly significant information and to make sound decisions. A more appropriate course, albeit a more demanding one, would be for the courts to consider the practical implications of requiring disclosure of a particular risk—and of all comparable risks—to all patients facing comparable decisions.

The fourth influence of the litigation process on the evolution of informed consent law is that courts must determine whether required disclosures were in fact made.<sup>42</sup> Here again, reliance on after-the-fact testimony by patient or provider may be less than satisfactory. As in many other legal contexts, written documentation of disclosure and consent can provide useful evidence—hence, the ubiquitous “informed consent form.”<sup>43</sup> Unfortunately, all too often such forms can become a substitute for, rather than merely a record of, a continual process of disclosure, discussion, and consent. If providers come to believe (probably incorrectly<sup>44</sup>) that their obligation to obtain the patient’s informed consent can be satisfied by securing a signature—even if a patient is drowsy, drugged, or confused or the form is abstruse, jargon-ridden, or largely unintelligible—the law’s inclination to rely on written

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42 Informed consent cases almost inevitably lead to “testimonial contests” in which patients claim that they were not warned of the risks that befell them, and doctors claim that warnings were issued. *See, e.g.*, *Bloskas v. Murray*, 618 P.2d 719, 720-21 (Colo. Ct. App. 1980); *Beck v. Lovell*, 361 So.2d 245, 248-49 (La. Ct. App. 1978); *Schroeder v. Lawrence*, 359 N.E.2d 1301, 1302 (Mass. 1977). This problem also arose in older “consent” cases before the development of the informed consent requirement. *See, e.g.*, *Beatty v. Cullingworth*, 44 CENT. L. J. 153 (Q.B. 1896)(unreported).

43 Because consent forms are often conclusorily worded—that is, the patient acknowledges that he has received information or “adequate” information about risks, benefits, alternatives, etc., but the form does not actually recite this information—at best they will protect the physician against a suit for battery, but not for negligent failure to disclose. Note, 44 BROOKLYN L. REV. 241, 260 (1978). Actually providing full information to patients is not always the goal of consent forms; rather, “avoiding this risk [of liability] seems to be a primary concern of those who draft what are strangely called ‘informed consent forms’....” Goldstein, *supra* note 23, at 692.

44 Merely obtaining a patient’s signature on a consent form does not provide airtight insulation against liability. *See, e.g.*, *Demers v. Gerety*, 85 N.M. 641, 515 P.2d 645, 649 (Ct. App. 1973). Although no informed consent statutes require that consent be obtained in writing, some statutes confer a “presumption of validity” on a written consent. It is not clear, however, that such a presumption works any substantial change in the common law. *See Meisel and Kabnick, supra* note 1, at 469-76.



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documentation may pervert its central purpose in requiring informed consent.

Finally, the structure of lawsuits requires the naming of particular defendants who will bear financial responsibility in the event of an adverse judgment, either individually or, more typically, through their liability insurers. Injured patients may bring claims against all persons associated with their care, but claims are typically directed against parties with “deep pockets,” usually institutions and individual physicians. This pattern does not necessarily reflect the activities of other members of the health care team, particularly nurses, with regard to informing patients and securing their consent.

Thus, the litigation process has shaped the legal doctrine of informed consent. The nature of the cases coming before the courts led to a particular perspective on the character, failings, and potential of relationships between patients and health care providers. The existence of an injury led courts to concentrate on whether there had been disclosure of the particular risks of the medical procedure rather than to an evaluation of the process of patient-professional communication as a whole. The need to avoid giving undue weight to a patient’s after-the-fact, speculative, and potentially self-serving testimony regarding materiality and causation led to an objective standard that can contradict individual patients’ particular values or desires. And the need to identify legal responsibility and potential financial liability led to a particular view of the appropriate roles of members of the health care team. Taken together, these have brought the current law to an uneasy compromise among ethical aspirations, the realities of medical practice, and the exigencies of the litigation process.<sup>45</sup>

**Law, Ethics, and Medical Practice.** The realities of court decisions on informed consent thus fall short of the law’s professed commitment to the value of self-determination. Since “the courts imposed primarily a duty-to-warn on physicians,”

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<sup>45</sup> Several of the major judicial opinions articulating (and broadening) the legal right to informed consent came in appellate decisions reversing judgments at the trial court level, typically on the ground that the district court’s instructions to the jury improperly confined the jury’s ability to find in favor of the plaintiff. Thus, the appellate courts, which are somewhat more removed from the exigencies of trial work, have been more willing to expand the scope of required disclosure. Further, the practical result of these appellate decisions is not the award of damages, but rather the return of the case for retrial under the proper (broadened) legal standard. Thus, the ultimate questions of liability and damages still have to be determined by a jury. Even under the broadened standard the jury may decide that the provider met the obligation of disclosure or that the lack of disclosure did not, in light of the medical indications favoring the procedure, “cause” the patient’s decision to undergo the procedure, thereby resulting in injury.

thereby avoiding a judicial recognition of the proposition that patients have a decisive role to play in the medical decisionmaking process, they have merely reinforced “physicians’ traditional monologue of talking *at* and not *with* patients.”<sup>46</sup> As a result they have missed the opportunity to move toward what is needed: “a new and unaccustomed dialogue between physicians and their patients...in which both, appreciative of their respective inequalities, make a genuine effort to voice and clarify their uncertainties and then to arrive at a mutually satisfactory course of action.”<sup>47</sup>

The Commission, while recognizing the difficulty of the task, believes that “shared decisionmaking” is the appropriate ideal for patient-professional relationships that a sound doctrine of informed consent should support.<sup>48</sup> The Commission doubts that this will occur, however, if primary reliance is placed on the courts. This is not to say that present legal requirements for informed consent should be abandoned or reduced in scope. Current law serves the important purpose of encouraging health care professionals to disclose important facts to patients and not to proceed with medical interventions unless patients have consented. The law also serves a critical moral and educative role in proclaiming (even if not always fully enforcing) the value of self-determination. These functions can and should continue. The Commission’s skepticism relates solely to the likelihood that an expansion of the existing law could control ever more minutely the relationships of patients and health care professionals.

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<sup>46</sup> Jay Katz, *Disclosure and Consent: In Search of Their Roots*, in Aubrey Milunsky and George J. Annas, eds., *GENETICS AND THE LAW II*, Plenum Press, New York (1980) at 122.

<sup>47</sup> *Id.*

<sup>48</sup> *Id.* at 124. Dr. Katz cautions emphatically that translating such a prescription into practice is an inordinately hard task—it is opposed by thousands of years of tradition; it demands unrelenting vigilance, for the propensity to view patient[s]...as children who need to be led, however gently, is ever-present; it calls for a commitment that takes patience and time. Perhaps such a prescription asks for too much, perhaps even patient[s]...may not wish to interact with professionals on that basis.

*Id.* Further, he observes, the required “prescription...[of] nurtur[ing] the patient[s]’ autonomous, adult functioning through a persistent dialogue...goes counter to current practices that exploit the natural regression resulting from illness and stress.” *Id.* at 125-26. Finally, the possibilities of achieving shared decisionmaking based on mutual respect and trust are further undercut by the pervasiveness of uncertainty in medical practice and by physicians’ attitudes toward it: “[T]he prevailing climate of professional conduct is first to pay lip service to uncertainty and then to proceed, while interacting with self and patients, as if uncertainty did not exist.” *Id.* at 126.

The litigation process itself seriously limits the law's ability to reach into an intimate relationship so as to foster a genuine dialogue between health care professionals and their patients.<sup>49</sup> Not only is the Commission doubtful that laws or regulations can fully bring about shared decisionmaking between patient and professional, but it is concerned that efforts to do so may have unintended and deleterious side effects.

Nevertheless the Commission does not believe that the ideal of better informed consent should be abandoned. In subsequent portions of this Report the Commission attempts to define the ideal more precisely and to suggest a number of means in addition to statutes and judicial decisions that could move day-to-day medical practice closer to shared decisionmaking.

### **The Context of Consent**

The Commission believes that an analysis of "the ethical and legal implications of requirements for informed consent to...undergo medical procedures"<sup>50</sup> is best undertaken in the context of a broader examination of relationships between patients and health care professionals in American society. At issue is the definition of the patient-professional relationship, as well as the appropriate role of formal and informal modes of social regulation in shaping it. Clearly, the resolution of these issues requires more than a simple review of the existing law of informed consent. Thus, the remainder of this Report considers patterns of communication between patients and health care professionals and how decisions are made. These inquiries are framed by the Commission's ultimate question about this aspect of its work: how can a fuller, shared understanding by patient and professional of their common enterprise be promoted, so that patients can participate, on an informed basis and to the extent they care to do so, in making decisions about their health care?

**Historical Development.** While the law has proclaimed, if not always given effect to, such propositions as "Anglo-

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<sup>49</sup> Courts may not, in any event, be inclined to enforce truly shared decisionmaking, even if they were able to do so. Law has often been reluctant to intrude on the autonomy of the medical profession, out of deference to medical expertise, respect for the values of life and health served by the medical profession, and perhaps an unspoken recognition that rules created for health professionals may someday be applied to the legal profession as well. The very history of informed consent litigation, as well as other areas of medical malpractice, provides ample (although not unmixed) evidence for these views.

<sup>50</sup> 42 U.S.C. § 300v-1 (a)(1)(A)(1981) the statutory mandate adopted in 1978, under which the Commission examines this issue.

American law starts with the premise of thorough-going self-determination<sup>51</sup> and “each man is considered to be his own master,”<sup>52</sup> recent scholarship has suggested that such sentiments have played little role in traditional health care and are indeed antithetical to the proclaimed norms of the medical profession.<sup>53</sup> Medical skepticism of patients’ capacities for self-determination can be traced to the time of Hippocrates:

Perform [these duties] calmly and adroitly, concealing most things from the patient while you are attending to him. Give necessary orders with cheerfulness and sincerity, turning his attention away from what is being done to him; sometimes reprove sharply and emphatically, and sometimes comfort with solicitude and attention, revealing nothing of the patient’s future or present condition.<sup>54</sup>

These attitudes continued to be reflected both in professional codes of ethics and in influential scholarly writings on medical ethics throughout the nineteenth and early twentieth centuries, and indeed survive to this day.<sup>55</sup> Studies of the records of daily medical practice (rather than normative statements of professional ethics) have found distinct “indigenous medical traditions” of truth-telling and consent-seeking, grounded on the theory that such knowledge “had demonstrably beneficial effects on most patients’ health.”<sup>56</sup> But little evidence exists that such traditions combined in anything like the modern doctrine of informed consent. Nor did they derive from or imply any commitment by the medical profession to patient autonomy. Indeed, when patients’ wishes regarding treatment were respected it was largely because providers recognized their limited therapeutic capabilities and the substantial risks accompanying medical interventions (for example, surgery without antiseptic) as well as the impracticability of forcing treatments on resisting patients.<sup>57</sup>

**Contemporary Trends.** Recent changes in health care practices, as well as broader societal changes in contemporary American life, have led to an intense reexamination of

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51 Natanson v. Kline, 186 Kan.393, 350 P.2d 1093 (1960).

52 Scott v. Bradford, 606 P.2d 554, 556 (Okla. 1980).

53 See Jay Katz, *Disclosure and Consent in Psychiatric Practice: Mission Impossible?*, in Charles K. Holling, ed., *LAW AND ETHICS IN THE PRACTICE OF PSYCHIATRY*, Brunner/Mazel, Inc., New York (1980) at 91.

54 Hippocrates, *Decorum*, in *HIPPOCRATES*, Harvard University Press, Cambridge, Mass. (W.H.S. Jones trans. 2d ed. 1967), quoted in Katz, *supra* note 46, at 124.

55 See Katz, *supra* note 53, at 91, 97-100.

56 Martin S. Pernick, *The Patient’s Role in Medical Decisionmaking: A Social History of Informed Consent in Medical Therapy* (1981), Appendix E, in Volume Three of this Report.

57 *Id.*

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relationships between patients and health care practitioners. Gradually, a new understanding of the proper levels and limits of health care is emerging; from this flow changes in the relative rights and obligations of patients and professionals concerning matters such as disclosure and consent for medical interventions.

Perhaps the most significant single factor in this process is the emergence of the scientific, technological approach to medical care over the course of the past century. The rapidly evolving technical prowess of medicine has, of course, brought with it improved health, greater quality and length of life, and new sources of hope for the ill. This revolution in the capacities of medicine has also had profound effects on the structure of the health care delivery system and on the nature of the patient-professional relationship.

Several of these changes are particularly relevant to informed consent. First, health care is now provided in a vast array of settings, ranging from home visits by traditional family doctors to clinics, health maintenance organizations, and multispecialty group practices, to nursing homes and other long-term or chronic care facilities, to high-technology tertiary care centers. Care is frequently provided by teams of highly specialized professionals whose individual responsibilities may be defined less by the overall needs of the patient than by particular diseases or organ systems. When this occurs there may be no single professional in effective command of the entire care of the patient, no one who knows the patient well and to whom the patient may turn for information, advice, and comfort. In such instances the health care system's increased capacity and determination to overcome a disease or defect may be accompanied by a diminished capacity and inclination to care for the patient in more human terms.<sup>58</sup>

Such situations pose a far more serious threat to patient well-being and autonomy than any formal disclosure of remote risks on informed consent forms could possibly remedy. Indeed, the Commission believes that serious efforts by health care institutions to ensure that patients have one identifiable and reliable source of information concerning their care would do far more to remedy the current ills of the health care system than would legal prescriptions with which compliance can be neither assumed nor enforced.<sup>59</sup>

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<sup>58</sup> Dissatisfaction by both patients and some professionals with these depersonalizing tendencies of modern medicine is suggested by the renaissance of interest in holistic medicine and the rise of the self-care movement.

<sup>59</sup> The problems of not having one person coordinating care are illustrated in this quote from a patient with leukemia:

I kept fighting through all the fevers and transfusions. I felt I could only survive it by insisting on control. And there would

The expanded potential of medicine has also widened the range of choices about health care. Increasingly, the question is not simply whether to accept a single intervention that is available for a particular condition, but which intervention to choose. Often the alternatives vary markedly in their prospects for success, their intrusiveness, their potential side effects, and their other implications for patients' ability to conduct their lives as they see fit. A determination of what is "indicated" is thus inextricably intertwined with the needs and values of the particular patient.

These changes in medicine have been accompanied by broader trends in American society and culture that have reinforced their impact. Since the early 1960s there has been an extraordinary emphasis on the rights of citizens to direct the course of their lives, from voting rights to consumer rights. This stress on the individual has been coupled with a skepticism toward claims of specialized expertise and a suspicion of powerful institutions and the "establishment." Health care has not escaped its share of criticism in the process.

Some commentators have seen in these trends the basis for a new view of the role of medicine and the nature of the patient-provider relationship:

The traditional paternal model of medicine was premised on trust in the physician's technical competence and moral sensitivity and was characterized by patient dependency and physician control. This model is being replaced gradually by one in which patients are increasingly involved in decisionmaking concerning their own medical care. The rise of consumerism and the associated emergence of "rights" language in medicine has encouraged some individuals to view medicine as a

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be plenty of chances to test my resolve. The personnel assigned to monitor various functions never coordinated their blood sample requirements on a given day, so they'd come two or three times to leech my tender, collapsing veins. I finally put my foot down.

"You're not going to take more blood," I shouted. "You take it once a day. Get together and find out how much you want and for what purpose, and, goddam it, in the absence of an emergency, don't you touch my veins. Also, no one's going to draw blood except the intravenous nurse team," I said, "because that's all they do, and they know how to do it."

I got my way in both instances, thereby saving myself considerable pain.

Morris B. Abram, *THE DAY IS SHORT*, Harcourt Brace Jovanovich, New York (1982) at 209.

“serving” profession and to regard themselves not as patients but as “medical consumers.” Such “medical consumers” sometimes wish to invert the traditional model of medicine and to make the physician a passive agent, a hired technician who practices under the direction and control of his “client.” However, despite these changes which affect some patients and some physicians, many patients and physicians continue to interact in a fairly traditional, paternalistic physician-patient relationship.<sup>50</sup>

The survey done for the Commission lends support to the conclusion that changes are occurring in the relationship between physicians and patients. Compared with previous studies, the current results demonstrate a clear sense of physicians’ responsibilities for making disclosures and reaching mutual decisions.<sup>61</sup> Although the results from the separate surveys of the public and of physicians indicate substantial agreement on these expectations, some lack of congruence remains. Moreover, the observational studies done for the Commission make it apparent that in actual relationships even more divergence occurs between laypeople’s and professionals’ expectations.

The role of the health care professional thus appears to be in a “phase of incomplete redefinition,” as one Commission witness noted.<sup>62</sup> During this time “judgments of conscientious persons have become divergent and perplexed” and societal consensus does not exist.<sup>63</sup> No longer are the proper ends and limits of health care commonly understood and broadly accepted; a new concept of health care, characterized by changing expectations and uncertain understanding between patient and practitioner, is evolving. The need to find an appropriate balance of the rights and responsibilities of patients and health care professionals in this time of change has been called “the critical challenge facing medicine in the coming decades.”<sup>64</sup>

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<sup>60</sup> Mark Siegler, *Searching for Moral Certainty in Medicine: A Proposal for a New Model of the Doctor-Patient Encounter*, 57 BULL. N.Y. ACAD. MED. 56, 60 (1981).

<sup>61</sup> The legal doctrine of informed consent has been severely criticized by medical professionals for going too far in its requirements for disclosure. See note 5 in Chapter Seven *infra*. Such criticism has diminished substantially in recent years. Furthermore, there is considerable evidence that physicians today actually do disclose a great deal more information’ to patients than they did 10-20 years ago. See Chapter Four *infra*.

<sup>62</sup> Siegler, *supra* note 60, at 61.

<sup>63</sup> *Id.*

<sup>64</sup> *Id.*

**The Commission's View**

Two models of the patient-professional relationship have dominated the debate surrounding this challenge. For the sake of simplicity, while recognizing the caricatures involved, these may be referred to as “medical paternalism” and “patient sovereignty.” Medical paternalism is based on a traditional view of health professionals—typically physicians—as the dominant, authoritarian figure in the relationship, with both the right and the responsibility to make decisions in the medical best interests of the patient. In reaction to this view, some have sought to take over the physician’s dominant position. Proponents of maximal patient sovereignty assign patients full responsibility for and control over all decisions about their own care. According to this view, practitioners should act as servants of their patients, transmitting medical information and using their technical skills as the patient directs, without seeking to influence the patient’s decisions, much less actually make them.

Both positions attempt to vest exclusive moral agency, ethical wisdom, and decisionmaking authority on one side of the relationship, while assigning the other side a dependent role. In the view of the Commission, neither extreme adequately reflects the current nature and needs of health care. The debate has increasingly become an arid exercise, which the Commission believes should be replaced by a view that reflects the tremendous diversity of health care situations and relationships today. In this Report, the Commission attempts to shift the terms of the discussion toward how to foster a relationship between patients and professionals characterized by mutual participation and respect and by shared decisionmaking. The Commission believes such a shift in focus will do better justice to the realities of health care and to the ethical values underlying the informed consent doctrine.

Although described in a single phrase, the Commission’s view is intended to encompass a multitude of different realities, each one shaped by the particular medical encounter and each one subject to change as the participants move toward accommodation through the process of shared decisionmaking:

The nature of the patient involved—his personality, character, attitude, and values—and the factors which led him to seek a medical encounter with this particular physician are central components of the process. Similarly, the personality, character, attitude, values, and technical skills of the physician affect the accommodation. Further, the quality of the interaction between patient and physician—the chemistry of the interaction—modify the process. Of course, the nature of the medical problem, including its type, acuteness, gravity,



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and its potential for remediation, will be a major determinant of whether a physician-patient accommodation is achieved. For example, the entire process will be modified profoundly and telescoped if the patient is acutely or critically ill and alternative medical resources are unavailable. Finally, other considerations which may affect the achievement of a physician-patient accommodation include the clinical setting, *e.g.*, a hospital, doctor's office, or the patient's home; the organization of the medical service, Health Maintenance Organization, or fee-for-service; and also, occasionally, the claims of relevant third party interests such as those of family, insurers, or the state.<sup>65</sup>

At each point, the patient and physician will arrive at a joint decision in which the physician agrees to care for the patient and the patient agrees to be treated by the physician. The particular resolution of rights and responsibilities reached at a given point of the relationship may change with time and circumstances. The resiliency of the relationship will depend importantly on the extent of trust and confidence exchanged between patient and professional.<sup>66</sup>

Whether society should accept whatever accommodation the parties agree to regarding the communication process and the allocation of decisionmaking authority is a complex issue. It raises the question of whether patient-professional relationships are best seen as purely contractual ones, subject to modification solely on the basis of agreement by the parties, or are instead invested with a certain public interest that justifies the imposition by society of limits on the acceptable range of consensual arrangements. The contractual view has strong roots in American traditions of voluntarism and individual responsibility. Yet for reasons of history, tradition, expectations, and disparities in educational, class, and health status, patients and professionals often start out on substantially unequal footing, raising serious questions about the ability of many patients to have an effective role in shaping the relationship.

Through law, American society has regulated relationships between patients and health care practitioners for almost a century. The control of advertising by doctors (to prevent the deception of unknowing patients) and the licensing of practitioners (to prohibit quackery and establish minimum standards of expertise) are some of the earliest examples. Medical malpractice law and criminal law also establish some limits on the freedom of practitioners in the interests of patients. Informed consent is merely one of the newer ways that society

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<sup>65</sup> *Id.* at 62.

<sup>66</sup> *Id.* at 63.

places some limits on the range of relationships between patients and practitioners.

The Commission concludes that considerable flexibility should be accorded to patients and professionals to define the terms of their own relationships. The resolution favored by the Commission is a presumption that certain fundamental types of information should be made available to patients and that all patients competent to do so have a right to accept or reject medical interventions affecting them. Similarly, a professional who has been as flexible about possible avenues of treatment as his or her beliefs and standards allow is not generally obligated to accede to the patient in a way that violates the bounds of acceptable medical practice or the provider's own deeply held moral beliefs.

Nevertheless, in light of the disparities between the positions of the parties, the interaction should, at a minimum, provide the patient with a basis for effective participation in sound decisionmaking regardless of the particular form of the accommodation. It will usually consist of discussions between professional and patient that bring the knowledge, concerns, and perspective of each to the process of seeking agreement on a course of treatment.<sup>67</sup> Simply put, this means that the physician or other health professional invites the patient to participate in a dialogue in which the professional seeks to help the patient understand the medical situation and available courses of action, and the patient conveys his or her concerns and wishes.<sup>68</sup> This does not involve a mechanical recitation of abstruse medical information, but should include disclosures that give the patient an understanding of his or her condition and an appreciation of its consequences.

The Commission encourages, to perhaps a greater degree than is explicitly recognized by current law, the ability of patients and health care professionals to vary the style and extent of discussion from that mandated by this general presumption. Such variations might take any of several directions: in one relationship, the patient might prefer not to be

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<sup>67</sup> The Commission's focus in this discussion on the process of reaching agreement is quite deliberate. For perhaps understandable reasons, much of the scholarly legal and philosophical literature concentrates on the "hard case," the case in which no agreement can be reached: when it comes to the crunch, who ultimately has the power to decide? Although such questions cannot be ignored, the Commission's effort in this Report is to readjust the balance toward fuller consideration of those less dramatic issues that arise routinely in the day-to-day practice of responsible medicine and nursing but that have received less attention and emphasis.

<sup>68</sup> This image of reaching out to a patient is captured well in the following: "The skillful doctor, metaphorically speaking, throws out a rope to the patient drowning in illness and by encouraging the patient to hold on furthers the healing process." Abram, *supra* note 59, at 116.

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burdened by detailed discussion of risks unlikely to arise or to affect the decision; in another relationship, a patient might request unusually detailed information on unconventional alternative therapies; in a third, a patient with a longstanding and close relationship of trust with a particular physician might ask that physician to proceed as he or she thinks best, choosing the course of therapy and revealing any information that the physician thinks would best serve the interests of the patient. Inherent in allowing such variations is the difficulty of ensuring they are genuinely agreeable to both parties and do not themselves arise out of an imbalance in status or bargaining power.

The health professional's expert knowledge, focused through the particular diagnosis and prognosis for the patient, usually confers on that person the natural role of leader and initiator in building this shared understanding. The patient, on the other hand, is especially well placed to assess the overall effects of the medical condition and possible treatments, in light of his or her own particular goals and values. Thus each party brings to the relationship special knowledge and perspectives that can help to clarify for both parties what is actually at issue in any decision to be reached.

The Commission is aware that its description of mutual participation and shared decisionmaking sets a high ideal. Both professional and patient in this dialogue are liable to misunderstandings and confusions, false hope or despair, unvoiced fears, anxiety, and questions. Even when each is sensitive to the presence of these barriers to full understanding and seeks to surmount them in the interest of agreeing on their common venture—that is, treating the patient successfully—difficulties will persist. Yet it remains a goal worth striving toward. In this Report the Commission not only fills out the contours of the concept sketched here but also explores its roots in basic values and in contemporary opinion and its implications for the education of health professionals, the delivery of care, the attitudes of patients and providers, and the rules of society as expressed through the law.

