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# Informed Consent: The Law's Uneasy Compromise with Ethical Theory

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# Informed Consent: The Law's Uneasy Compromise With Ethical Theory<sup>†</sup>

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This article grows out of my work as Assistant Director for Legal Studies with the President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research. I am indebted to a superb group of Commission colleagues, including project co-director Marian Osterweis, legal scholars Alexander M. Capron and Alan Meisel, physician Joanne Lynn, philosophers Daniel Wikler and Allen Buchanan, and particularly to philosopher Dan Brock, with whom I spent many hours in stimulating discussion and debate concerning these issues. I am also pleased to acknowledge my continuing intellectual and personal indebtedness to my teacher and friend, Jay Katz of Yale Law School. Professor Katz's towering contributions on informed consent have made us all his students; the influence of his seminal work on the ideas developed here will be evident.

† Editor's Note: In recent years, both philosophers and legal scholars have written extensively on the topic of informed consent to medical therapy. Much of this literature proceeds from the assumption that the moral ideal and legal doctrine of informed consent are, or should be, substantially the same. In this article, addressed to philosophers, physicians and patients as well as to a legal audience, Professor Weisbard seeks to identify several major disparities between the philosophical and legal conceptions of informed consent, to explain why the "law in action" has departed from the philosophical ideal, and to explore whether, and how, the moral and legal norms for the physician-patient relationship can be restated and brought into closer correspondence.

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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.

*Schloendorff v. Society of New York Hospital* (1914)<sup>1</sup>

Anglo-American law starts with the premise of thorough-going self determination. It follows that each man is considered to be master of his own body . . . .

*Natanson v. Kline* (1960)<sup>2</sup>

[I]t is the prerogative of the patient, not the physician, to determine for himself the direction in which he believes his interests lie.

*Cobbs v. Grant* (1972)<sup>3</sup>

[T]he patient's right of self-decision shapes the boundaries of the duty to reveal. That right can be effectively exercised only if the patient possesses enough information to enable an intelligent choice. The scope of the physician's communications to the patient, then, must be measured by the patient's need . . . . And to safeguard the patient's interest in achieving his own determination on treatment, the law must itself set the standard for adequate disclosure.

*Canterbury v. Spence* (1972)<sup>4</sup>

## I. INTRODUCTION

Philosophers have created an enormous literature addressing the themes of personal autonomy, self-determination, and, in recent years, informed consent.<sup>5</sup> As these quotations from landmark legal decisions make clear, this moral vision of informed consent is by no means foreign to the literature of American law.<sup>6</sup> Justice Cardozo's classic statement of the right of bodily self-determination, articulated so

1. 211 N.Y. 125, 129-30, 105 N.E. 92, 93 (1914).

2. 186 Kan. 393, 406, 350 P.2d 1093, 1104 (1960).

3. 8 Cal. 3d 229, 242, 502 P.2d 1, 10, 104 Cal. Rptr. 505, 514 (1972).

4. 464 F.2d 772, 786-87 (D.C. Cir. 1972).

5. Perhaps the *locus classicus* is J.S. Mill's celebrated essay, ON LIBERTY (1859). An important recent statement is I. BERLIN, *Two Concepts of Liberty*, in FOUR ESSAYS ON LIBERTY 118 (1969). The contemporary bioethical literature is vast; see generally T. BEAUCHAMP & J. CHILDRESS, PRINCIPLES OF BIOMEDICAL ETHICS (2d ed. 1983); R. VEATCH, A THEORY OF MEDICAL ETHICS (1981); R. FADEN & T. BEAUCHAMP, A HISTORY AND THEORY OF INFORMED CONSENT (1986).

6. This article is conceived as a lawyer's response to one particularly elegant recent articulation of the moral foundations of informed consent; see D. Brock, *Informed Consent*, in HEALTH CARE ETHICS: INTRODUCTION (D. VanDeVeer & T. Regan, eds., Temple Univ. Press, forthcoming 1987). For a sophisticated philosophical critique of recent bioethical writings on informed consent, see Shatz, *Autonomy, Beneficence and Informed Consent: Rethinking the Connections*, Part I, 4 CANCER INVESTIGATION 257 (1986); Part II, 4 CANCER INVESTIGATION — (forthcoming).

forcefully in the celebrated *Schloendorff* case, has lived on over the ensuing decades to influence generations of judicial decisionmakers, as well as authors of philosophical essays. His language has become so familiar that today it is easy to forget that poor Ms. Schloendorff lost her case.

Similarly, neither Mr. Cobbs nor Mr. Canterbury, the plaintiffs in the best-known informed consent cases of more recent times, collected damages for his injuries. In this crucial respect, the *Schloendorff*, *Canterbury* and *Cobbs* cases typify the development of the law of informed consent. Simply stated, the law has been far richer in its rhetorical devotion to the ideal of patient self-determination than in its provision of effective legal redress to victimized patients. If the law is to be judged by its success in implementing the moral vision articulated by the philosophers—that is, in providing the competent patient with a meaningful opportunity to participate in medical decisionmaking on a voluntary, informed, and understanding basis—then the law has substantially failed.<sup>7</sup>

How and why has the law fallen short of its own rhetorical promises, to say nothing of its underlying philosophical premises? In this article, I shall argue, first, that in its attempt to translate the moral ideal of informed consent into a set of workable legal rules adapted to the technical requirements of the litigation process, the law has transformed that ideal into little more than a legal “duty to warn” of risks of medical treatment. This duty is measured not by the actual informational needs of the individual patient, but by the hypothetical needs of “reasonable patients” or by the prevailing norms of disclosure of the medical community. While purporting to assure respect for individual self-determination, the inaptly named law of informed consent has done little to “inform” the unique and sometimes idiosyncratic needs, concerns, and fears of individual patients on whose “consent” so much is said to rest. Indeed, one can plausibly maintain that the legal doctrine has done more to teach physicians how to practice medicine “defensively” (so as to minimize legal liability) than it has to foster physician-patient relationships that permit and encourage patients to participate actively and knowledgeably in decisions concerning their care.<sup>8</sup>

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7. For useful empirical reviews of how informed consent operates in practice, see Meisel & Roth, *Toward an Informed Discussion of Informed Consent: A Review and Critique of the Empirical Studies*, 25 ARIZ. L. REV. 265 (1983); and the empirical studies by C. Lidz & A. Meisel and by P. Appelbaum & L. Roth in 2 MAKING HEALTH CARE DECISIONS (1982).
  8. In this respect, my argument bears a family resemblance to Robert Rabin's argument that early tort law is better understood as a regime of “no liability” than as a struggle between competing principles of negligence and strict liability. Rabin, *The Historical Development of the Fault Principle: A Reinterpretation*, 15 GA. L. REV. 925 (1981).

I also shall contend that the technical legal requirements that constitute the current state of the law of informed consent do not provide an adequate justification for the law's failures and do not pose insuperable obstacles to its reform. Rather, the law's failure to implement a thoroughgoing commitment to patient self-determination reflects not a failure of legal technique but a failure of will, rooted in a deep-seated ambivalence among both legal and medical professionals toward the reallocation of decisionmaking authority in the professional-patient relationship. In closing, I will offer some tentative thoughts on the implications of this analysis.<sup>9</sup>

## II. THE LAW AND ITS DEVELOPMENT

Current American law derives from a number of sources, both state and federal: constitutions, statutes, regulations, and, perhaps least familiar to non-lawyers, the large corpus of judge-made decisional law known as the "common law," which has evolved from the decisions of English and American courts over the centuries. At least until the past decade,<sup>10</sup> the law of informed consent had been almost

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9. Limitations of space necessarily constrain the scope of this discussion and require a certain amount of simplification of complex legal issues. For fuller treatment of the themes addressed herein, see J. KATZ, *THE SILENT WORLD OF DOCTOR AND PATIENT* (1984), a compelling book-length analysis of the historical, moral, legal and psychological foundations of informed consent and the physician-patient relationship. See also J. KATZ & A.M. CAPRON, *CATASTROPHIC DISEASES: WHO DECIDES WHAT?* (1975); R. BURT, *TAKING CARE OF STRANGERS* (1979). Among the many outstanding articles in the extensive legal literature are: Capron, *Informed Consent in Catastrophic Disease Research and Treatment*, 123 U. PA. L. REV. 340 (1974); Goldstein, *For Harold Lasswell: Some Reflections on Human Dignity, Entrapment, Informed Consent, and the Plea Bargain*, 84 YALE L.J. 683 (1975); Katz, *Informed Consent—A Fairy Tale? Law's Vision*, 39 U. PITT. L. REV. 137 (1977) [hereinafter cited as Katz, *Law's Vision*] (an account strongly influential on the views presented here); Meisel, *The Expansion of Liability for Medical Accidents: From Negligence to Strict Liability by Way of Informed Consent*, 56 NEB. L. REV. 51 (1977); Meisel, *The "Exceptions" to the Informed Consent Doctrine: Striking a Balance Between Competing Values in Medical Decisionmaking*, 1979 WIS. L. REV. 413. The classic article by Waltz & Scheuneman, *Informed Consent to Therapy*, 64 NW. U.L. REV. 628 (1970), played an influential role in shaping several of the judicial decisions discussed herein and deserves close attention. See also the three volume report of the President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research, *MAKING HEALTH CARE DECISIONS* (1982), and the many additional sources cited therein. Two additional major studies appeared following the completion of this article: R. FADEN & T. BEAUCHAMP, *A HISTORY AND THEORY OF INFORMED CONSENT* (1986); Shultz, *From Informed Consent to Patient Choice: A New Protected Interest*, 95 YALE L.J. 219 (1985).
10. In recent years, as a few courts have expanded the potential scope of physician liability for failure to secure informed consent, several state legislatures (often acting at the behest of medical societies) have enacted legislation to define (and usually to restrict) such liability. See 3 *MAKING HEALTH CARE DECISIONS*, *supra* note 9, at app. L.

entirely a creature of this common law process. In order to understand the historical development and current status of the law of informed consent, it is necessary to explore, albeit briefly, certain characteristics of this process.

#### A. The Common Law Context

As Tocqueville keenly observed a century and a half ago, judicial power in the United States "pronounces on special cases, and not upon general principles."<sup>11</sup> That is, judges are not philosopher-kings for the American Republic, granted roving commissions to pronounce upon all matters of general concern. Rather, the judicial office is confined to the resolution of concrete cases and controversies between individual litigants with tangible stakes in the outcome of the litigation. In deciding the particular cases that come before them, common law judges articulate the applicable legal principles (derived primarily from precedents established in prior cases, as well as from applicable statutes and regulations) and apply them to the facts of the particular case. Such applications of law to facts give greater specificity to the governing principles and create new precedents applicable to future cases. It is through this process that the law continually clarifies and refines legal rules of conduct.

In contrast to philosophical arguments, which may proceed in logical fashion from initial principles to a comprehensive and internally consistent theory, the law progresses in fits and starts, depending on the nature of the questions presented by individual cases and, perhaps, even on the order in which cases arise. The current law of informed consent strongly reflects the influence of this process.

#### B. Characteristics of Informed Consent Cases

Consider the factors that influence whether a dispute will go to court for resolution. Litigation is enormously expensive in terms of money, time and energy. Few potential plaintiffs, and perhaps even fewer plaintiffs' lawyers, are prepared to invest substantial resources purely over "a matter of principle," for example, to win judicial recognition that a given physician has infringed upon the patient's right of self-determination. The harm, which lawyers refer to as a dignitary injury, is generally too abstract and intangible to result in a damage award large enough to justify the lawsuit.<sup>12</sup> Enthusiasm for going to

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11. 1 A. DETOCQUEVILLE, *DEMOCRACY IN AMERICA* 99 (P. Bradley, ed. 1946) (orig. trans. H. Reeve, New York 1838).

12. Indeed, in malpractice actions, the plaintiff's inability to prove "real" damages—beyond a dignitary harm—will generally result in dismissal of the lawsuit (except, perhaps, in certain cases of intentional or negligent infliction of emotional distress). While proof of damage is generally not required in battery actions as a

court tends to be keener when the smell of money is in the air, such as when the plaintiff has suffered serious physical injury and a jury may be inclined to provide the injured patient (and the patient's lawyer)<sup>13</sup> with a large financial recovery.

For these pragmatic (if not morally uplifting) reasons, almost all cases arising from medical mishaps are brought by patients who have sustained serious medical injuries and are seeking substantial damages. The law does not permit recovery merely on the basis that the injury occurred and the patient is thought "deserving" of compensation. Physicians are not required to "act at their peril," assuming legal and financial responsibility for every failure to achieve optimal results. Rather, a specific basis for the physician's liability must be established.<sup>14</sup> Recovery is generally precluded when the risk of harm is

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matter of legal theory, in practice such actions are rarely brought, for the reasons elaborated in the text. See *infra* note 14.

13. Under the contingency fee system generally in effect in medical malpractice litigation, the plaintiff's lawyer is compensated with a percentage of the plaintiff's recovery. The larger the recovery, the larger the lawyer's fee. If the plaintiff receives a small award or loses, the lawyer receives little or no compensation for his or her services. As might be expected, this system does not encourage lawyers to undertake cases over matters of principle, unless fees can be paid on some other basis or from some other source. See *infra* note 33.
14. Although a few commentators have favored the adoption of non-fault-based compensation for medical injuries, and a few judges have made very tentative steps in this direction (see, e.g., *Helling v. Carey*, 83 Wash. 2d 514, 519 P.2d 981 (1974) (Utter, J., concurring); *Clark v. Gibbons*, 58 Cal. Rptr. 125, 426 P.2d 525, 535 (1967) (Tobriner, J., concurring); cf. *Hoven v. Kelble*, 79 Wis. 2d 444, 256 N.W.2d 379 (1977)), the legal system to date requires an injured patient to prove "fault" by the physician to justify a recovery. Fault may encompass either intentional or negligent misconduct. Depending on the jurisdiction, a medical procedure performed without the patient's informed consent (absent emergency circumstances or certain other excuses or justifications) may be classed as either a battery (an unconsented touching) or an instance of negligent malpractice.

A number of important practical consequences may flow from this distinction between legal theories. As previously observed, the requirement that physical injury be proved as a prerequisite to recovery applies to negligence but not to battery actions. See *supra* note 12. There may also be important differences in the applicable statutes of limitations. And there may be differences in the types of medical procedures to which the theories apply. In a surprising decision, at least one jurisdiction following the battery approach has limited the scope of informed consent to procedures involving direct physical touching (e.g., surgery), thereby excluding such medical procedures as drug therapy or psychoanalysis. See *Malloy v. Shanahan*, 280 Pa. Super. 440, 421 A.2d 803 (Pa. Super. Ct. 1980); see also *Boyer v. Smith*, 345 Pa. Super. 66, 497 A.2d 646 (Pa. Super. Ct. 1985).

A full discussion of the tangled relationship between battery and malpractice theories of informed consent is beyond the scope of this article. For a more extended treatment, see Capron, *supra* note 9 at 404 (arguing, *inter alia*, for the creation of a "hybrid of negligence and battery theories that is controlled by its own logic and is not confined by the rules which attach to either of its parent causes of action") and 1 MAKING HEALTH CARE DECISIONS, *supra* note 9, at 21-22 and the sources cited therein.

inherent in the medical treatment, the treatment is skillfully administered, and the patient was apprised of the risks and consented to the treatment.

Traditional medical malpractice claims focus on the question of whether diagnosis and treatment were skillfully performed. If plaintiff can prove that the physician was negligent and that this negligence actually and proximately caused the plaintiff's injury, there may be a basis for recovery. But these claims, even if well-founded, are often difficult to prove, due not least to the difficulty some plaintiffs have encountered in enlisting expert medical witnesses to testify against their medical colleagues (the "conspiracy of silence"). For this reason informed consent claims are often "tacked on" to malpractice cases; if the plaintiff cannot persuade the jury that the physician was negligent in treatment, perhaps the case can be redeemed by proving that the physician failed to warn the patient of the risk of injury.

### C. The Centrality of Disclosure of Risks

For the reasons just discussed, the brute fact of a serious injury typically looms over the trial of an informed consent case. Whatever the theoretical legal basis for the claim, attention is riveted on the particular risk that did materialize in injury. At trial, several fundamental questions are presented. First, *should* the risk have been disclosed? However remote a given risk appeared in prospect, hindsight demonstrates that it was sufficiently "real" that it could result in serious injury—as it did in the very case. It is harder to focus at such moments on whether other, comparable risks (which did not eventuate in injury in the particular case) should also have been disclosed, or on the implications of "complete" disclosure, both positive and negative, for the overall medical decisionmaking process. Second, *was* the risk disclosed? The patient may testify that it was not, but is this a sufficient basis for holding the physician liable, particularly if the physician asserts that he or she customarily discloses risks of this type? What evidence will be required? And third, if non-disclosure is established, did the non-disclosure of the particular risk *cause* the patient to consent to a medical intervention, which then resulted in injury, or might the patient have gone forward with the procedure even if the risk had been disclosed? Again, what is a sufficient basis for such a finding? Each of these questions illustrates the centrality of disclosures of risk to informed consent cases as they are actually litigated.

Probably the most prominent and controversial issue in the evolution of the law of informed consent is the standard for disclosure of risks. The traditional view, still adhered to by a majority of jurisdictions, bases the obligation to disclose on prevailing medical practice. The more modern view rests on a patient-based standard, set by law rather than by medical custom. In either case, the standards articu-



lated by the courts would seem not to require disclosure of commonly appreciated, insubstantial, or very remote risks of injury. Yet, perhaps for the reasons we have seen, physicians have been reluctant to place much credence in these assurances. One physician's lament is illustrative:

The situation is hardly clarified by the remarkably condescending verbiage of *Cobbs v. Grant*. "The patient's interest in information does not extend to a lengthy polysyllabic discourse on all possible complications. A mini-course in medical science is not required . . ." The unspoken corollary to this, of course, is that the physician had better have informed his patient of the complication that actually *did* occur, even if the statistical probabilities were minuscule.<sup>15</sup>

Whether or not this perception is accurate in terms of legal theory or practice, the perception appears to be widespread within the medical community. This apprehension has resulted in some physicians feeling a need to disclose virtually all conceivable risks associated with treatment. These perceived "requirements," in addition to their often criticized burdensome quality to physicians, can lead to a formalistic recitation of a near-endless parade of risks so mind-numbing (and perhaps so frightening) as to overwhelm the patient's capacity to assimilate significant information.<sup>16</sup> The law's concern with risk disclosure, as it is (mis)understood and put into practice, may defeat rather than enhance the patient's capacity to utilize significant information to make sound decisions.

A further consequence of the law's focus on disclosure of risks has been the need to document disclosures. For understandable reasons, courts have been reluctant to encourage swearing contests between physicians and patients regarding what was disclosed, and physicians have come to loathe resting their potential liability on a jury's evaluation of that contest. Hence, the rise of the now ubiquitous "informed consent form." Increasingly, these forms are being commercially prepared and distributed, rather than being individually tailored by the treating physician to the informational needs and educational level of the particular patient. There is growing reason for concern that con-

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15. Laforet, *The Fiction of Informed Consent*, 235 J.A.M.A. 1579, 1580 (1976) (emphasis in original). See also Ingelfinger, *Informed (but Uneducated) Consent*, 287 NEW ENG. J. MED. 465 (1972). But see *Precourt v. Frederick*, 395 Mass. 689, 481 N.E.2d 1144 (1985) (overturning a substantial jury verdict on grounds that even a severe consequence does not "require disclosure if the chance of the consequence occurring was so remote as to be negligible," *id.* at 695, 481 N.E.2d at 1149, and that failure to provide adequate evidence of the likelihood of the risk would preclude submission to the jury, even in a patient materiality jurisdiction). *Precourt's* result, although not all aspects of its relatively skimpy analysis, is favorably reviewed in Curran, *Informed Consent in Malpractice Cases: A Turn Toward Reality*, 314 NEW ENG. J. MED. 429 (1986).

16. See Epstein and Lasagna, *Obtaining Informed Consent: Form and Substance*, 123 ARCH. INT. MED. 682 (1969).

sent forms are becoming substitutes for, rather than documentary evidence of, an ongoing process of disclosure, discussion, and decisionmaking between physician and patient. If physicians come to believe (often incorrectly)<sup>17</sup> that their obligation to obtain the patient's informed consent can be satisfied by securing a signature—even that of a drowsy, drugged, or confused patient on an abstruse, jargon-ridden, and largely unintelligible preprinted consent form—the law's reliance on written documentation may come to pervert its central purpose in requiring informed consent.

A corollary of the law's disproportionate focus on disclosure of particular risks has been its relative indifference to the overall quality of the communicative relationship between physician and patient. This includes the subtle interactions through which the physician may enhance or retard the patient's ability to participate effectively in the process of discussion and decisionmaking. The law has done little or nothing to encourage the physician to talk with, rather than at, the patient; to elicit and respond to the patient's unexpressed fears, concerns, confusions, and questions; or to take positive steps to enhance the patient's ability to participate effectively in the decisionmaking process. The physician who punctiliously recites the litany of potential risks and secures the patient's signature on the proper form, but who fails even to attempt to engage the patient as a person in the decisionmaking process at more than this superficial level, may well be legally protected. One may wonder whether this legal "duty to disclose," although clearly easier to enforce than standards rooted in the patient's level of comprehension or the still more subtle quality of the communications process, bears much resemblance to the professed objectives of patient self-determination that informed consent is said to serve.

#### D. The Law's Technical Requirements

For many generations, lawyers, courts and other observers of the legal system have noted a propensity of jurors, when given the chance, to favor injured plaintiffs over more powerful, richer, and perhaps well-insured defendants. Out of concern for the integrity of their truth-seeking function (and perhaps for other, less salutary reasons), the courts have evolved a number of legal techniques to limit and control the jury's discretion in finding facts and applying (some would argue stretching) the law to cover those facts. Some of these tech-

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17. Under the common law, consent did not need to be written, and written consent did not provide airtight insulation against liability. That is still the case in most jurisdictions. Recent legislation in some states, however, has accorded presumptive validity to signed consents. *See supra* note 10. In such jurisdictions, a patient may overcome the presumption by showing fraud, but might otherwise be bound by a signed consent.

niques can be employed to prevent a claim from reaching the jury; others are reflected in limiting instructions with which the presiding judge charges the jury.

These concerns are amply reflected in the technical legal requirements that an informed consent claim must satisfy to reach the jury for decision. The plaintiff must allege and prove that the physician violated a legally established duty to disclose a particular risk, that the undisclosed risk materialized in a physical injury,<sup>18</sup> and that the failure to disclose "caused" the patient to consent to a procedure which otherwise would have been rejected. These requirements are not unique to informed consent claims; they bear close relationship to the general requirements for other tort actions, particularly including medical malpractice actions. Yet as they have been applied in the informed consent context, these requirements have tended seriously to undercut the law's ability to promote patient self-determination.

While a full review of these issues is outside the scope of this article, an analysis of the closely related legal requirements of materiality and causation will illustrate the problem. These requirements call for determinations, first, of what facts would have been important to the patient's decisionmaking regarding treatment, and second, of whether, if particular disclosures had been made, they would have affected or changed the patient's decision to consent to the medical procedure. Obviously, these are matters as to which the patient possesses special, and perhaps unique, knowledge and insight. On the other hand, in the trial setting, the patient is necessarily called upon to provide speculative answers to counter-factual hypothetical questions.

For example, the plaintiff might be asked, "if this risk had been explained to you at the time, which it was not, and if you knew that by consenting to the procedure you might be seriously injured, as in fact you have been, would you still have consented to the procedure?" Answers to such speculative questions might well tend to be self-serving, particularly when the potential for substantial financial recovery rides on the answer. Not surprisingly, courts have shown a certain

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18. This "materialized risk requirement" has been subjected to powerful criticism, not least for its failure to "recognize that a citizen can be wronged without being 'harmed,' that his dignity as a human being has been violated . . ." Goldstein, *supra* note 9, at 691. The requirement also fails to recognize that an incomplete disclosure may decisively and adversely affect a patient's choice among alternatives, even when the particular risk that eventuates in injury has been disclosed. For example, failure to disclose other risks (or other treatment characteristics) which do *not* materialize can skew the patient's comparative assessment of alternative courses of action, thus resulting in an injury that would have been avoided if full disclosure had been made and another alternative pursued. The law's failure to permit recovery in such cases further demonstrates that its primary focus is on the physician's duty to disclose risks, rather than on any duty to facilitate informed patient choice among alternative courses of action. This point has not always been sufficiently appreciated.

reluctance to rest important legal determinations on such speculative testimony.

The law's treatment of these difficult issues is best examined in the context of a particular case. Since *Canterbury v. Spence*<sup>19</sup> is widely and correctly regarded as the leading case in favor of a more patient-oriented approach to informed consent, its equivocations provide an especially telling example of the ambivalence at the root of the law's commitment to patient self-determination.

The *Canterbury* court, through much of its opinion, emphasized the critical objective of assuring patient self-determination. The court stressed that the informational needs of the patient should be determinative of the mandated scope of disclosure: "To be sure, the objective of risk-disclosure is preservation of the patient's interest in intelligent self-choice on proposed treatment, a matter the patient is free to decide for any reason that appeals to him."<sup>20</sup> And in an earlier passage: "Optimally for the patient, exposure of a risk would be mandatory whenever the patient would deem it significant to his decision, either singly or in combination with other risks."<sup>21</sup> In these passages, the court seems to focus on the informational needs of the *particular* patient. Those needs may be highly personal and perhaps idiosyncratic. That focus is fully consistent with a philosophical conception of informed consent predicated on respect for the autonomy of the individual. Yet a few paragraphs later, the court restates the applicable legal standard as one which is "not subjective as to either the physician or the patient; it remains objective . . ." <sup>22</sup> That is, the risk is "material" and must be disclosed only "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 . . . in deciding whether or not to forego the proposed therapy."<sup>23</sup>

The *Canterbury* court follows a similar approach in its discussion of causation. The court recognized that the "purpose of the disclosure rule is to protect *the patient* against consequences which, if known, *he* would have avoided by foregoing the treatment,"<sup>24</sup> thus articulating a personal or subjective standard. Ironically, the court then resolved the causality issue according to an objective standard: "in terms of

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19. 464 F.2d 772 (D.C. Cir. 1972). A very similar analysis might be made of *Canterbury's* California twin, *Cobbs v. Grant*, 8 Cal. 3d 229, 502 P.2d 1, 104 Cal. Rptr. 505 (1972). Both decisions closely followed the analysis set forth by Waltz & Scheuneman in their classic 1970 article, *supra* note 9. For the seminal discussion of *Canterbury*, strongly influential on the analysis suggested here, see Katz, *Law's Vision*, *supra* note 9.

20. *Canterbury v. Spence*, 464 F.2d 772, 790 (D.C. Cir. 1972).

21. *Id.* at 787.

22. *Id.*

23. *Id.* (quoting Waltz & Scheuneman, *supra* note 9) (emphasis added).

24. *Canterbury v. Spence*, 464 F.2d 772, 790 (D.C. Cir. 1972) (emphasis added).

what a *prudent person* in the patient's position would have decided if suitably informed."<sup>25</sup>

The impact of adopting these objective standards of materiality and causation is to replace an approach based on the needs and values of the particular patient, however odd or idiosyncratic, with the needs of hypothetical reasonable or prudent patients. This approach rejects the centrality of the individual patient, in all his or her particularity, and implicitly accepts the view that in any medical choice-making situation, there can be only one "correct" decision—not a range of possible decisions, each potentially appropriate depending on the tastes, values, and trade offs among conflicting values of the individual patient. Thus, while removing the standard of what to disclose from the exclusive confines of the medical profession, and focusing its analysis on the informational needs of most reasonable or prudent patients, the *Canterbury* decision nonetheless fails to require disclosure to be calibrated to any special informational needs of the particular patient. Nor does the decision encourage the physician to determine what those special needs are, or whether they even exist.<sup>26</sup>

Why this retreat from the implications of the court's professed commitment to patient self-determination? The court provides a candid response. It rejects a legal standard predicated on whether the "factfinder believes the patient's testimony that he would not have agreed to the treatment if he had known of the danger which later ripened into injury."<sup>27</sup> In the court's view, such an approach "places the factfinder in the position of deciding whether a speculative answer to a hypothetical question is to be credited . . . [based] solely on testimony of a patient-witness shadowed by the occurrence of the undisclosed risk."<sup>28</sup> It "places the physician in jeopardy of the patient's hindsight and bitterness."<sup>29</sup> This the court simply cannot abide.

Therefore, even in the decision regarded as signalling the high-water mark for judicial respect for patient autonomy, the court's commitment to self-determination is insufficient to overcome its resistance to letting the finder of fact (typically, the jury) listen to the patient's testimony and decide what *that patient* wanted to know and would have decided if provided with appropriate information. The decision is a step forward for those patients whose needs and values are

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25. *Id.* at 791 (emphasis added).

26. The court's unelaborated references to reasonable or prudent persons "in the patient's position" may allow some theoretical leeway for greater individualization within the confines of a formally "objective" test. Thus far, it appears that few if any courts have accepted this invitation, although some have rejected the objective test in favor of an explicitly subjective standard, at least with respect to the causal inquiry. *See infra* note 30.

27. *Id.* at 790.

28. *Id.* at 791.

29. *Id.* at 790-91.

in conformity with those of the court's hypothesized "reasonable patients." This approach, however, does little to promote the choice-making autonomy of patients who might choose to pursue a path distinct from that of the "prudent" majority. The *Cobbs* decision is subject to much the same critique.

Might the law surmount the technical restrictions of *Canterbury* and *Cobbs* to realize more fully the promise of patient self-determination made explicit in the rhetoric of those opinions? A few courts have made tentative steps in that direction, moving beyond *Canterbury* to adopt more individualized tests of materiality and/or causation.<sup>30</sup> It is too early to assess how far those paths will lead and whether they will be beset with the practical problems of litigation that troubled the *Canterbury* and *Cobbs* courts. But with the advent of the so-called medical malpractice crisis of the mid-1970s, the tide of change clearly has been held back and perhaps reversed. While the causes of that alleged "crisis" had little to do with informed consent, massive lobbying efforts by state and local medical societies helped to persuade many state legislatures to enact statutes reinstating pre-*Canterbury* "professional standards" rules for disclosure and, in some cases, according presumptive validity to patient-signed informed consent forms. The legal promise of patient self-determination was not

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30. See, *Scott v. Bradford*, 606 P.2d 554 (Okla. 1979); *McPherson v. Ellis*, 305 N.C. 255, 287 S.E.2d 892 (1982). In *Scott*, the court generally adopts a *Canterbury*-style informed consent analysis but rejects *Canterbury*'s "reasonable man" approach to the causation inquiry as severely limiting the protection granted an injured patient and as "backtracking on its own theory of self-determination." *Scott, supra*, at 559. The court adopts an explicitly subjective standard requiring the jury to resolve the causation problem "by examining the credibility of plaintiff's testimony." *Id.* The court's holding on the scope of required disclosure is somewhat obscure; while stating that "the scope of a physician's communications must be measured by his patient's need to know enough to enable him to make an intelligent choice" and that risk is material and therefore must be disclosed "if it would be likely to affect patient's decisions," *id.* at 558 (emphasis added), thus suggesting at least some element of individuation, the court does not characterize its own holding on this point as either subjective or objective.

The *McPherson* court rejects the objective standard for determining the causation issue, on grounds that "no consideration is given to the peculiar quirks and idiosyncracies of the individual," and that patient's "supposedly inviolable right to decide for himself what is to be done with his body is made subject to a standard set by others." *McPherson, supra*, at 273, 287 S.E.2d at 897. The court adopts a subjective standard for determining causation despite its expressed concern "that the only evidence usually available is the plaintiff's bald assertion, tempered by hindsight, as to what he would have done had he known all the facts." *Id.* at 273, 287 S.E.2d at 896. The cause of action adjudicated in *McPherson* arose prior to the 1976 effective date of state legislation limiting the scope of informed consent claims in North Carolina, thus restricting the precedential impact of the decision even in its own jurisdiction. See *Dixon v. Peters*, 306 S.E.2d 477 (N.C. Ct. App. 1983).

achieved and, with a few exceptions,<sup>31</sup> the law of informed consent has largely stagnated since.

### III. POSSIBILITIES FOR REFORM

To recapitulate our progress thus far: we began with a moral vision of patient self-determination, a vision seemingly accepted by the law and enshrined in its rhetoric. In translating this elevated rhetoric into workable rules of decision, legal "craft" or "technique" transformed the vision into a rather anemic legal duty to disclose certain characteristics of the proposed medical procedure, particularly risks of treatment. As understood by practicing physicians seeking to avoid potential legal liability, these rules of decision were operationalized through the use of informed consent forms, characterized primarily by

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31. See, e.g., *Truman v. Thomas*, 27 Cal. 3d 285, 611 P.2d 902, 165 Cal. Rptr. 308 (1980). In *Truman*, the California Supreme Court creates a cause of action for "informed refusals" of medical care and rejects the contention that duty to disclose under *Cobbs v. Grant* applies only when the patient consents to the recommended procedure. The court imposes obligations on physicians to provide patients with information regarding "all material risks of which a reasonable person would want to be informed before deciding not to undergo the procedure," so that "patients might meaningfully exercise their right to make decisions about their own bodies." *Id.* at 292, 611 P.2d at 906, 165 Cal. Rptr. at 312.

In recent years, the courts have turned their creative focus from informed consent to so-called "right-to-refuse-treatment" cases, often involving decisions to terminate life-sustaining care for incompetent patients. The courts have typically based their analysis in these cases on a constitutional right to privacy, see, e.g., *In re Quinlan*, 70 N.J. 10, 355 A.2d 647 (1976); *Superintendent of Belchertown v. Saikewicz*, 373 Mass. 728, 370 N.E.2d 417 (1977), rather than on the common law roots from which the informed consent doctrine has grown. But see *In re Storar*; *Eichner v. Dillon*, 52 N.Y.2d 363, 420 N.E.2d 64, 438 N.Y.S.2d 266 (1981) (viewing the matter as one of common law and citing *Schloendorff* as a major precedent).

Perhaps in time the two streams of "informed consent" and "right to refuse treatment" will rejoin, prompting closer attention to the possible constitutional roots of informed consent doctrine and a fresh analysis of the basis for the law's commitment to autonomy in decisionmaking. An important first step in this direction was taken recently by the New Jersey Supreme Court in *In re Conroy*, 98 N.J. 321, 486 A.2d 1209 (1985). The court there moved beyond the strictly constitutional privacy analysis set forth in its earlier *Quinlan* decision to base its recognition of a patient's right to accept or reject life-sustaining medical treatment explicitly on the common law doctrine of informed consent as well as on the constitutional right to privacy. *Id.* at 346-56, 486 A.2d at 1221-26. In the course of its discussion, the *Conroy* court employed language that may well prove influential in future informed consent litigation. Although the court is addressing a legal context somewhat different from that of traditional informed consent claims by competent patients, the relevance and import of the court's analysis is clear:

The standard we are enunciating is a subjective one, consistent with the notion that the right that we are seeking to effectuate is a very personal right to control one's own life. The question is not what a reasonable or average person would have chosen to do under the circumstances but what the particular patient would have done . . . .

*Id.* at 360-61, 486 A.2d at 1229.

their lengthy recitals of potential risks and by their general unintelligibility to most patients. These forms are typically presented to patients for signature the night before the procedure is to be performed, with limited opportunity for individualized discussion. So the law is served, the physician is protected from legal liability, and patient autonomy is "respected."

Might we have done better? Is this discouraging pattern the ineluctable result of the impersonal and technical requirements of the legal process? Does meaningful, rather than merely formal, protection of patient self-determination simply pose a challenge beyond the law's grasp?

I would argue that such a purely technical explanation for the law's failure is neither sufficient nor satisfying. Particularly during the decades of the 1960s and 1970s, the law demonstrated its potential to be a creative force for change in American society. Many societal institutions once thought intransigent to outside regulation (schools, prisons, mental institutions) as well as other social problems (racial discrimination, environmental pollution, consumer products safety) have been subjected to legal control to a greater or lesser extent and with more or less success by judges and legislators perceptive of the need for reform. Is the physician-patient relationship beyond the realm of such legal creativity?

While this is not the occasion to delineate in full an alternative legal model for informed consent, consider the plausibility of a new legal cause of action, which might be enacted by statute or perhaps recognized by an innovative common law court.<sup>32</sup> This new cause of action would establish a patient's right to participate in medical decisions on an informed, understanding, and voluntary basis. It would impose an affirmative obligation on physicians to facilitate the patient's exercise of this right to the extent reasonably possible. Satisfaction of this obligation would be measured by the needs of the particular patient insofar as those needs could reasonably be determined by the physician, and assessed in light of the entire course of medical care. Damages would be awarded by the tribunal (which could be an administrative or arbitral body rather than a court) for dignitary harms on the basis of a statutory schedule (e.g., \$1000-\$10,000; perhaps more for punitive damages in unusual circumstances) without any requirement that the patient allege or prove physical injury. Provision might be made for losing defendants to pay reasonable legal fees to prevailing plaintiffs' attorneys, to encourage the pursuit of meritorious actions not justified by the prospect of large contingent

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32. This model, while without any clear precedent, is not entirely fashioned from whole cloth. Several of its features find parallels in provisions of California legislation governing medical experimentation. CAL. HEALTH & SAFETY CODE §§ 24170-24179.5 (1978).



fees.<sup>33</sup> (Tribunals might also be authorized to charge defendants' legal fees against plaintiffs in cases of abusive or plainly meritless actions). Finally, successful actions would automatically result in referrals to state licensing authorities for consideration of appropriate disciplinary action against offending physicians on grounds of professional misconduct.

The point here is not necessarily to advocate adoption of this approach as a substitute for, or supplement to, the existing law of informed consent. That would require a far more detailed specification of the proposal and a careful evaluation of its negative as well as positive implications.<sup>34</sup> Rather, the proposal is raised only to suggest that by viewing patient self-determination as a goal independent of the avoidance of physical injury and separate from the legal apparatus of medical malpractice, many of the technical obstacles discussed earlier might be avoided or overcome.<sup>35</sup>

If some such proposal for legal reform has merit, why has it not yet been adopted? Here the law's failure to live up to its own rhetoric seems to reflect not a lack of legal imagination or craft, but a failure of will. That is, the law's commitment to patient self-determination is, at best, ambivalent and equivocal. Those who shape the law are not yet prepared to give full legal effect to their own rhetoric.

What are the sources of this reluctance? While any response is necessarily speculative, one may begin by noting that lawyers and judges, like physicians, are professionals whose own status, economic position, and professional autonomy are rooted in a particular and long-dominant image of the professional-client relationship. The layperson's respect for professional expertise, deference to professional authority, and fear of the unknown are prominent features of the legal as well as the medical landscape. Would it really be surpris-

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33. A provision for fee-shifting would probably require specific statutory authority. See *Alyeska Pipeline Serv. v. Wilderness Soc'y*, 421 U.S. 240 (1975) (upholding the "American Rule" that a prevailing litigant is ordinarily not entitled to collect a reasonable attorney's fee from the loser). For example, Congress has enacted a number of statutory attorney's fees provisions, particularly in such public interest contexts as civil rights and environmental litigation. These have been accepted and applied by the courts.

34. A detailed proposal along these general lines, published after the completion of this article, has been advanced by Shultz, *From Informed Consent to Patient Choice: A New Protected Interest*, 95 YALE L.J. 219 (1985).

35. The reader may wish to consider which obstacles would remain, and how they might be handled under this system. To be sure, the financial recoveries would be relatively modest. However, the set of incentives created for physicians, patients and lawyers might be more conducive to affecting physician behavior in the desired fashion than is the current system. Further, these incentives would provide powerful reinforcement for the law's professed goal of promoting patient self-determination.

ing for lawyers and judges,<sup>36</sup> as well as physicians, to be concerned that a true sharing of authority between professional and layperson, such as might be brought about by more vigorous legal protection of patient/client self-determination, would undermine the foundations of professional authority which have served them so well?<sup>37</sup>

One need not argue that professionals have consciously and cynically manipulated their esoteric crafts to undercut the professed goal, under the camouflage of a fog of rhetoric. A far more subtle process may be at work. These considerations may influence and shape the world views of professionals at a less-than-fully conscious, subterranean level. Legal professionals may thus be predisposed not to resist too strenuously when the technical dynamics of the legal process, dynamics which are well known and comfortable to them and which seemingly operate on their own force, lead them away from effective protection of self-determination. Indeed, the complex interaction of conscious commitment to patient autonomy with subterranean concerns about loss of professional dominance at the individual level may well be reflected in the contradictory, yet parallel pattern of the law, in which professed adherence to the "root premise of thoroughgoing self-determination" is undercut by esoteric legal doctrines which vitiate the force of this commitment.

If the law's continuing inability, or unwillingness, to effect a restructuring of the professional-patient relationship is rooted in a pervasive ambivalence toward the practicability and the desirability of the goal, then it may well be time to rethink the appropriate role of law in regulating these relationships. The quest for a legal "quick fix" may indeed be quixotic, doomed to subversion by judges and physicians, and perhaps by ambivalent patients as well. If change is to come on a matter so fundamental, so tied to enduring habits, capacities, and attitudes, it might well be argued that the pace of change must be slower and more evolutionary, and its direction less adversarial. Such

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36. The specter of liability in actions for lack of informed consent brought by clients against their lawyers is already lurking by the door. See, e.g., Spiegel, *Lawyering and Client Decisionmaking: Informed Consent and the Legal Profession*, 128 U. PA. L. REV. 41 (1979); Martyn, *Informed Consent in the Practice of Law*, 48 GEO. WASH. L. REV. 307 (1980); Peck, *A New Tort Liability for Lack of Informed Consent in Legal Matters*, 44 LA. L. REV. 1289 (1984); Weisbard, *Defensive Law: A New Perspective on Informed Consent*, 146 ARCH. INTERN. MED. 860 (1986).

37. One view of what is at stake is exemplified with unusual candor by a Wisconsin judge who, although less given to clouding his deference to professional expertise with the rhetoric of patient self-determination than some of his judicial colleagues, nonetheless gives voice to a rather common underlying sentiment: "The writer has more confidence in the standards of the professional group involved than in court or jury deciding what disclosures need or ought be made to a patient. . . . Children play at the game of being a doctor, but judges and juries ought not." *Scaria v. St. Paul Fire & Marine Ins.*, 68 Wis. 2d 1, 227 N.W.2d 647, 659 (1975) (Hanson, J., dissenting).

change, intended to reshape the professional consciousness of physicians (and perhaps the consciousness and expectations of patients as well), may come best through education, and not from law.

But where is the impetus for such change, and on what grounds may we be confident that this evolutionary process will in fact occur? Particularly with respect to professional education and training, can we depend on medical educators—themselves steeped in the older tradition—to serve as teachers and role-models on the path to this brave new world?

Perhaps the appropriate role for law is found here after all. It is natural to view law as a vehicle for providing relief to the injured and for setting standards to regulate conduct. But law also serves a symbolic or expressive function, giving voice to the norms and aspirations of society. Indeed, as we have seen, the law of informed consent has been rather more successful in this symbolic function than in actually providing monetary damages to injured patients. Yet a cautionary note is in order here: one must consider carefully the continuing vitality of any symbol which becomes completely and permanently divorced from the reality it is said to symbolize. Extreme divergence between symbol and reality, like other species of hypocrisy, ultimately invites contempt and disillusionment. That may not be far from the reality of "informed consent" within the medical community today.

For both law and philosophy, the task of the moment is to articulate a vision of the physician-patient relationship that can serve as a common, shared goal for physicians and patients alike. Neither the traditional model of "medical paternalism," which rests on professional dominance of the relationship, nor the currently fashionable mirror image of that model, "consumer sovereignty," which relegates the professional to the passive role of a "body mechanic" or technician,<sup>38</sup> is likely to serve this purpose. What is needed is a shared vision, attractive to both professionals and laypersons, based on mutual respect exemplified in a shared commitment to define common goals and to work collaboratively to achieve those goals.<sup>39</sup>

I believe such a vision would focus less on the events of disclosure and consent and more on the *process* of promoting effective patient participation in *shared* decisionmaking. In this process, the professional's role would be to engage the patient in a continuing dialogue,

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38. See, e.g., Bayles, *Physicians as Body Mechanics*, in CONTEMPORARY ISSUES IN BIOMEDICAL ETHICS (J. Davis, B. Hoffmaster & S. Shorten, eds. 1978).

39. One such effort is reflected in a challenging series of articles by physician-educator Mark Siegler. See, e.g., 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 (1981); Siegler & Goldblatt, *Clinical Intuition—A Procedure for Balancing the Rights of Patients and Responsibilities of Physicians*, in THE LAW-MEDICINE RELATION: A PHILOSOPHICAL EXPLORATION (S. Spicker, J. Healey & H. T. Engelhardt, eds. 1981).

seeking to elicit through conversation the patient's goals and objectives, fears, hopes and concerns, and then to discuss the alternative courses of action in light of both the patient's goals and concerns *and* the professional's knowledge and experience. In such a dialogue the professional would be no mere technician, but an advisor, confidante, and colleague. Correlatively, the patient could reasonably expect to understand the professional's recommendations and the basis for those recommendations, while retaining the ultimate right of decision (at least so far as rejecting unwanted therapies or procedures).

Whether this vision is best described by the term "informed consent" is doubtful. As we have seen, that label has been applied, often inconsistently and misleadingly, to a philosophical ideal, a legal doctrine, and an only partially (and often grudgingly) realized medical practice. Perhaps the term itself has outlived its usefulness, and survives only for lack of a suitable alternative. But however phrased, the ideal set forth here, of the physician's obligation to facilitate effective patient participation in a process of shared decisionmaking, provides a more compelling vision of the physician-patient relationship than the current legal doctrine or medical reality that goes by the name of "informed consent." It also provides a more promising candidate for transforming that ideal into a reality.