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# AUTONOMY AND INFORMED CONSENT IN MEDICAL DECISIONMAKING: TOWARD A NEW SELF- FULFILLING PROPHECY

CATHY J. JONES\*

## I. INTRODUCTION

Our society has long valued privacy, personal autonomy, and free will in decisionmaking. This commitment has been reflected in the works of philosophers, scholars, and writers in many fields,<sup>1</sup> and in the everyday beliefs and actions of individuals.<sup>2</sup> Our system of laws also has reflected

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1. See, e.g., J.S. MILL, ON LIBERTY 203, 212, 282-83 (C. Eliot ed. 1909) in 25 HARVARD CLASSICS; Angell, *Euthanasia*, 319 N. ENG. J. MED. 1348, 1350 (1988). See also *Olmstead v. United States*, 277 U.S. 438, 478 (1928) (Brandeis, J., dissenting) (discussing search and seizure issue in telephone wiretap case):

The makers of our Constitution undertook to secure conditions favorable to the pursuit of happiness. They recognized the significance of man's spiritual nature, of his feelings and of his intellect. They knew that only a part of the pain, pleasure and satisfactions of life are to be found in material things. They sought to protect Americans in their beliefs, their thoughts, their emotions and their sensations. They conferred, as against the Government, the right to be let alone—the most comprehensive of rights and the right most valued by civilized men.

*Id.* Natanson v. Kline, 186 Kan. 393, 406, 350 P.2d 1093, 1104 (1960) (medical malpractice case; "Anglo-American law starts with the premise of thorough-going self determination"); *Schloendorff v. Society of New York Hospital*, 211 N.Y. 125, 129, 105 N.E. 92, 93 (1914) (medical malpractice case, "Every human being of adult years and sound mind has a right to determine what shall be done with his own body").

These examples and the material *infra* notes 2-3 and accompanying text reflect standard liberal theory on the subject of individualism. Not all agree that the classical liberal position on autonomy and self-determination is the only—or the best—basis for protecting individualism. See Nedelsky, *Reconceiving Autonomy: Sources, Thoughts and Possibilities*, 1 YALE J. L. & FEMINISM 7, 7-10 (1989) (arguing that "Feminism requires a new conception of autonomy[.]" criticizing traditional views of autonomy, and redefining autonomy from a feminist perspective throughout the article); Handler, *Dependent People, the State, and the Modern/Postmodern Search for the Dialogic Community*, 35 UCLA L. REV. 999, 1034-49 (1988) (reviewing various schools' of thought criticism of classical liberal legal model).

2. It was not unusual when the attempts to pass legislation mandating the wearing of seatbelts or motorcycle helmets was at its peak to have opponents base their arguments on claims of personal freedom and autonomy. The latest version of such expressed autonomy—"I have the right to live my life as I choose"—seems to be that raised against legislation intended to regulate the so-called sport of "dwarf tossing." Butler, *Dwarf-Tossing Contest in Final Night Despite Uproar*, Reuters News Service, July 14, 1989 (Grand Rapids, Mich.).

those values. While the law does not permit all persons to live their lives as they choose without restriction,<sup>3</sup> it does, in many instances, not only protect but also facilitate individual autonomy and decisionmaking. For example, if individuals have the right to be autonomous and to make decisions freely and voluntarily, whether in buying consumer goods, pleading guilty to a criminal charge, relinquishing a child for adoption, or choosing what type of medical treatment to undergo, they need certain information about alternative decisions they might make and about the consequences inherent in any of those alternatives. In many instances, our laws mandate that such information be provided to persons making such crucial decisions.<sup>4</sup>

Once that information has been provided, however, the law's support—and encouragement—for actual individual decisionmaking frequently becomes ambivalent. In some instances, individuals are given information on which to base decisions, and then, left relatively on their own to decide, are held responsible for those decisions in unambiguous terms. In the consumer protection context, for example, once information has been provided to consumers, generally in writing, and they acknowledge receiving such information, the consumers make decisions that then bind them. While it is true that a statutorily mandated time period sometimes exists during which consumers may rescind their decisions,<sup>5</sup> once that time period has

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3. Obviously, many activities are proscribed by criminal law or by civil sanction. Even those actions which are legal—for example, a competent adult's right to refuse medical treatment—may be restricted or prohibited because of overriding, compelling state interests. *See, e.g.,* Satz v. Perlmutter, 362 So. 2d 160, 162 (Fla. Dist. Ct. App. 1978) (compelling state interests which may override individual's decision to refuse medical treatment include preserving life, protecting innocent third parties, preventing suicide, and maintaining ethical integrity of medical profession); Superintendent of Belchertown v. Saikewicz, 373 Mass. 728, 741, 370 N.E.2d 417, 425 (1977) (same). Even Mill, who believed that society should not interfere with the decisions of competent adults to protect them from themselves, thought that society could interfere with those same decisions in order to protect others or to protect those incapable of exercising free will. Mill, *supra* note 1, at 212, 281-82, 309-10.

4. *See, e.g.,* 15 U.S.C.A. § 1638(a) (West 1982) (requiring in other than open-end credit transaction detailed disclosure relating to, *inter alia*, financing of purchase); 18 U.S.C.A. Rule 11 (West 1986 & West Supp. 1989) (detailing information to be provided to and understood by criminal defendants before they may enter plea of guilty or nolo contendere); VT. R. PROB. PROC. 80.4 (Supp. 1988) & VT. R. PROB. PROC. Forms 125, 125A, & 125B all implementing VT. STAT. ANN. tit. 15, § 432(b) (Supp. 1988). Taken together, the Vermont statute, rule, and forms set standards for the relinquishment of a child for adoption by a birth mother. Part of that procedure includes a requirement that the birth mother execute the relinquishment "before the court" unless the court authorizes relinquishment before another court or person. Rule 80.4(a). According to Reporter's Notes to Rule 80.4, in-court relinquishment "is designed to guard against relinquishment executed as a result of ignorance or undue influence." *See also* MINN. STAT. ANN. § 144.651 (9) (West 1989) (sets forth, as part of "Patient Bill of Rights," information patients are entitled to receive before making health care decisions); *infra* notes 28-71 and accompanying text (detailed discussion of disclosure requirements relating to the medical treatment context).

5. *See, e.g.,* 15 U.S.C.A. § 1635(a) (West 1982) (consumer credit transaction in which security interest retained or acquired in principal dwelling of person to whom credit was extended may be rescinded by obligor until midnight of third business day following consum-

expired the decision is final; furthermore, during that period, there is no interference by an intermediary between seller and buyer to determine whether the consumer understands the information provided, whether the consumer is making a free and voluntary decision,<sup>6</sup> or whether the consumer is making the "right" decision.

In other instances, however, the law treats provision and comprehension of information and decisionmaking based on that information very differently. For example, Rule 11 of the Federal Rules of Criminal Procedure requires criminal defendants choosing to plead guilty or nolo contendere to appear in open court to be advised by the judge of the alternatives available to them and the consequences of those various alternatives.<sup>7</sup> Judges, how-

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mation of transaction or delivery of information and rescission forms together with statement containing material disclosures required by 15 U.S.C.A. § 1601 *et seq.* (West 1982 & West Supp. 1989), whichever is later); MASS. GEN. LAWS. ANN. ch. 93, § 48(A) (West 1984) (agreement providing for sale or lease of goods or rendering of services or both, primarily for personal, family, or household purposes in excess of twenty-five dollars, consummated at place other than address of seller or lessor may be cancelled by buyer before midnight of third business day following execution of agreement).

6. The issue of whether the consumer's decision was free and voluntary could be challenged on grounds such as coercion or fraud in an adversarial setting after the parties had entered into the agreement. Barring such grounds, however, the consumer is bound by the terms of the contract. *See, e.g.,* Refrigeration Discount Corp. v. Haskew, 194 Ark. 549, 551, 108 S.W.2d 908, 909 (1937); Hartford-Connecticut Trust Co. v. Clark-Barone Co., 21 Conn. Sup. 367, 370, 154 A.2d 883, 885-86 (1959) (quoting in part United States *ex rel.* and for Benefit of Administrator of Fed. Hous. Admin. v. Troy-Parisian, Inc., 115 F.2d 224, 226 (9th Cir. 1940)); American Buyers Club v. Woolridge, 46 Ill. App. 3d 263, 265, 361 N.E.2d 1378, 1380 (1977).

7. FED. R. CRIM. P. 11 (West Supp. 1989) provides, in pertinent part:

(c) Advice to Defendant. Before accepting a plea of guilty or nolo contendere, the court must address the defendant personally in open court and inform the defendant of, and determine that the defendant understands, the following:

(1) the nature of the charge to which the plea is offered, the mandatory minimum penalty provided by law, if any, and the maximum possible penalty provided by law, including the effect of any special parole term or term of supervised release and, when applicable, that the court may also order the defendant to make restitution to any victim of the offense; and

(2) if the defendant is not represented by an attorney, that the defendant has the right to be represented by an attorney at every stage of the proceeding and, if necessary, one will be appointed to represent the defendant; and

(3) that the defendant has the right to plead not guilty or to persist in that plea if it has already been made, the right to be tried by a jury and at that trial the right to the assistance of counsel, the right to confront and cross-examine adverse witnesses, and the right against compelled self-incrimination; and

(4) that if a plea of guilty or nolo contendere is accepted by the court there will not be a further trial of any kind, so that by pleading guilty or nolo contendere the defendant waives the right to a trial; and

(5) if the court intends to question the defendant under oath, on the record, and in the presence of counsel about the offense to which the defendant has pleaded, that the defendant's answers may later be used against the defendant in a prosecution for perjury or false statement.

(d) Insuring that the Plea is Voluntary. The court shall not accept a plea of guilty

ever, may not stop at providing that information. Rule 11 requires further that the judge address the defendant in open court to determine whether the defendant understands the information provided,<sup>8</sup> and whether the defendant is entering the plea voluntarily and not as a result of force or threats or promises apart from a plea agreement; the court must also determine whether the defendant's willingness to plead guilty or nolo contendere results from prior discussions between the government attorney and the defendant or the defendant's counsel.<sup>9</sup> If judges believe that those decisions to plead are not knowing or voluntary, they cannot accept the pleas.<sup>10</sup>

Similarly, in the family law context, some jurisdictions, by statute or rule, regulate the procedures relating to relinquishment of a child for adoption in order to ensure that the relinquishing parties understand the alternatives and consequences of their decisions to relinquish. In Vermont, for example, a birth mother relinquishing a child for adoption to a private individual must execute the relinquishment "before a judge of probate."<sup>11</sup> The relinquishment form itself states

After due consideration and believing that the best interests of my said child will be promoted by being placed in a foster home for adoption, I do hereby *voluntarily and unconditionally* surrender the said child to \_\_\_\_ for the purpose of placement in a foster home for adoption, and to take any and all measures, which, in the judgment of said \_\_\_\_, may be for the best interests of my said child.<sup>12</sup> (emphasis added).

The Reporter's Notes following the relinquishment rule state that the requirement that relinquishments to a private individual be made in "[t]he

or nolo contendere without first, by addressing the defendant personally in open court, determining that the plea is voluntary and not the result of force or threats or of promises apart from a plea agreement. The court shall also inquire as to whether the defendant's willingness to plead guilty or nolo contendere results from prior discussions between the attorney for the government and the defendant or the defendant's attorney.

8. FED. R. CRIM. P. 11(c) (West Supp. 1989).

9. FED. R. CRIM. P. 11(d) (West Supp. 1989).

10. *Id.*

11. VT. STAT. ANN. tit. 15, § 432(a) (Supp. 1988); VT. R. PROB. PROC. 80.4(a) (Supp. 1988) ("before the court"). The rule, although not the statute, provides that the court may authorize another court or person to oversee the execution of the relinquishment. I focus my attention here on birth mothers because it is frequently an unwed birth mother who relinquishes a child for adoption in the private adoption context. The same relinquishment provisions would apply to those birth fathers entitled by state law to protection of their interests before the child is finally relinquished for adoption.

12. VT. R. PROB. PROC. Form 125. Form 125 is entitled "Relinquishment [-] Surrender of Child for Adoption." Two other forms, Form 125A, "Relinquishment and Power of Attorney to Consent to Adoption," and Form 125B, "Relinquishment to Agency and Surrender of Child for Adoption," contain language identical to that of Form 125 concerning "voluntarily and unconditionally surrender[ing] the said child."

judge's presence is designed to guard against relinquishments executed *as a result of ignorance or undue influence*."<sup>13</sup> (emphasis added) Presumably the court will approve the relinquishment and allow the termination proceedings to continue only after being satisfied that the birth mother's decision is not the result of ignorance or undue influence.<sup>14</sup>

In both the criminal and family law contexts, however, if the court does approve the defendants' or mothers' decisions, those individuals are bound by those decisions, and must accept responsibility for them.<sup>15</sup>

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13. VT. R. PROB. PROC. 80.4, Reporter's Notes (Supp. 1988).

14. Within 15 days of the execution of the relinquishment, the recipient of the child pursuant to the relinquishment must file with the court the relinquishment along with a petition requesting termination of the parental rights of the person signing the relinquishment. Upon receipt of the petition, the court will set the matter down for hearing giving notice to, among others, the parent who signed the relinquishment. VT. R. PROB. PROC. 80.4(a), (b) (Supp. 1988). That parent also is designated a party to the relinquishment proceeding and is entitled to be heard at the hearing. VT. R. PROB. PROC. 80.4(c) (Supp. 1988). The hearing must be convened within 10 days of the filing of the petition or the written relinquishment will no longer be valid. VT. CODE ANN. tit. 15, § 432(b) (Supp. 1988). Following the hearing, the court is empowered to terminate the birth mother's parental rights. VT. R. PROB. PROC. 80.4(d) (Supp. 1988).

While perhaps benefiting the birth mother by giving her time following the child's birth to think through her decision to relinquish her child for adoption, the delay caused by the hearing does not benefit the infant who will form bonds quickly with the temporary caretakers, only to have them broken ten days later when adoptive placement is finally possible. See J. GOLDSTEIN, A. FREUD, & A. SOLNIT, *BEYOND THE BEST INTERESTS OF THE CHILD* 22 (1979). In addition, while benefiting some birth mothers, such a waiting period may cause additional distress to other birth mothers who have made a truly informed decision prior to the child's birth and yet must live with the knowledge that they could rescind their decisions, but that they must do so quickly or be forever foreclosed. In Vermont, Forms 125, 125A, and 125B all provide that the relinquishing party "understand[s] that she] can change [her] mind at any time up to issuance of the court's order approving [the] relinquishment." VT. R. PROB. PROC. Forms 125, 125A, 125B (Supp. 1988).

15. VT. STAT. ANN. tit. 15, § 432(b) (Supp. 1988) provides that "[i]n the event of the termination of parental rights no withdrawal of the relinquishment or surrender will thereafter be allowed." The Notes of the Advisory Committee on Rules to the 1974 Amendment to Federal Rule of Criminal Procedure 11 state that "[s]pecifying [in Rule 11(c)(4)] that there will be no future trial of any kind makes this fact clear to those defendants who, though knowing they have waived trial by jury, are under the mistaken impression that some kind of trial will follow." 18 U.S.C.A. Rule 11 (Notes of Advisory Committee on Rules at 349) (West 1986).

Decisions by birth mothers relinquishing their children for adoption, or criminal defendants pleading guilty could subsequently be nullified by a court, but only for procedural irregularities or errors of substantive law that occur during the proceedings. A mistake in judgment or a change of mind on the part of the birth mother or criminal defendant does not constitute a ground for overturning the decision.

In the criminal law context, Rule 11(a)(2) provides for "conditional pleas"—pleas that "[w]ith the approval of the court and the consent of the government, a defendant may enter . . . reserving in writing the right, on appeal from the judgment, to review of the adverse determination of any specified pretrial motion." FED. R. CRIM. P. 11(a)(2) (West Supp. 1989). Defendants prevailing on such appeals are allowed to withdraw their pleas. *Id.* In the absence of a conditional plea or certain kinds of constitutional objections, however, "traditional, unqualified pleas do constitute a waiver of nonjurisdictional defects." FED. R. CRIM. P.

In the consumer context, then, the law insists that information be provided to consumers, but takes no extra steps to determine whether the information has been understood or the decision knowingly and freely made. In the criminal and family law contexts, however, the law may require not only that information be given, but also that an arm of the state, the courts, determine whether the individual understands the information and whether the person's decision is knowing and voluntary. And in those criminal and family law scenarios, if judges believe that decisions are not knowing or voluntary, they must reject them.

Perhaps the different treatment of decisionmaking in these various contexts lies in the fact that criminal law or family law matters are perceived as public concerns whereas the sale of goods or services is a private matter between seller and buyer. Perhaps the difference lies in the fact that in the criminal and family law contexts, courts are already involved in the proceedings in which criminal defendants or birth mothers find themselves, so it is simply a next step in those proceedings to attempt to protect the decisionmaking rights of the parties, as opposed to the consumer area where courts become involved, if at all, only after the fact of the sale. Perhaps the difference reflects the importance the public places on issues relating to personal freedom or the family as opposed to consumer sales. Or perhaps the difference is explained by our belief that individuals are better able—socially, psychologically, and financially—to make decisions relating to consumer goods than they are decisions relating to rights to trial or relinquishment of children, and that the effects of a “bad” or “wrong” decision by the consumer will not be nearly as devastating or irreversible as one by a criminal defendant or birth mother.

The doctrine of informed consent as it relates to patients seeking or needing medical diagnosis and treatment lies somewhere between the doctrine

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ADVISORY NOTES at 359. See *Menna v. New York*, 423 U.S. 61 (1975) (defendant's guilty plea for refusal to answer questions before grand jury after having been granted immunity did not bar claim that Double Jeopardy Clause precluded state from prosecuting him on that charge after he had been sentenced to jail term (that he had served) on charge of contempt of court for failure to testify before grand jury); *Blackledge v. Perry*, 417 U.S. 21 (1974) (defendant's plea of guilty to enhanced charge after he chose to exercise right to trial de novo on original charge did not preclude due process challenge to prosecution on enhanced charge). Rule 11(h) further provides that those errors made by the court in attempting to comply with Rule 11 “shall be disregarded” if they do not affect “substantial rights.” FED. R. CRIM. P. 11(h) (West 1986). Examples of harmless error include the judge's failure to explain to the defendant all the essential elements of the crime at issue as long as the defendant's responses indicate an awareness of all the elements, the judge's understating the maximum penalty for the crime charged as long as the maximum penalty imposed does not exceed that explained, and the judge's failure to comply with Rule 11(c)(5) relating to defendants' statements under oath which could later be used against defendants in a prosecution for perjury or false statement because that failure has no bearing on the validity of the plea. FED. R. CRIM. P. ADVISORY NOTES at 363.

In the family law context, see, e.g., *Tarver v. Jordan*, 225 Ga. 749, 750-51, 171 S.E.2d 514, 515 (1969); *Application of Hendrickson*, 159 Mont. 217, 222-23, 224, 496 P.2d 1115, 1117-18, 1119 (1972); *Ex parte Schultz*, 64 Nev. 264, 273, 181 P.2d 585, 589 (1947).

of disclosure of information in the consumer context and the practices in the criminal and family law contexts of not only disclosing information but also testing the recipients' comprehension of that information and then subjecting their decisions to review.

In theory, the purpose of the doctrine of informed consent is to protect patient autonomy and provide patients with more control over decisions concerning the care and treatment of their bodies.<sup>16</sup> Those concepts of autonomy and self determination are drawn from the traditional, liberal sense of protecting the individual against the state. The focus of this article, however, is not the traditional individual-against-the-state concept of autonomy (as it might be were the article's concern the right to refuse treatment<sup>17</sup> as opposed to the right to have information about and to consent to treatment). Rather, this article focuses on individual autonomy in the private, patient-doctor relationship. Although patients require protection by the state in order to acquire the information they need for medical decisionmaking,<sup>18</sup> and as I argue later,<sup>19</sup> need further protection to engage in actual decisionmaking, the question of individual autonomy in the context of informed consent arises in the private rather than the public sphere. So although the doctrine of informed consent is founded on and frequently described in terms of classical liberal theory, I use autonomy and self determination here in much more private and personal terms.

Decisionmaking and the law's treatment of decisionmaking in the health care context lies somewhere along the continuum between the consumer setting on one end and the criminal and family law contexts on the other. Like the sale of goods, patients' relationships with physicians and physicians' provision of services to patients are private, outside the public realm, with no court or other state interference authorized or required before the service is provided. Like the criminal and family law contexts, however, health care decisions made by patients implicate deeply personal matters relating to bodily integrity and personal freedom. And like a decision to plead guilty or to relinquish a child for adoption, a "bad" or "wrong" decision in the health care context could be irreversible and even fatal.

In practice, the doctrine of informed consent operates much like the disclosure laws in the consumer area. The law in many jurisdictions requires that physicians disclose to patients certain information concerning the patients' condition, proposed diagnostic or treatment alternatives, and the risks

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16. The courts' articulated purpose behind the doctrine of informed consent and the focus of this article is patient autonomy and self determination. If the articulated purpose of the doctrine is met, however, other possible results such as greater patient compliance with recommended therapy, speedier recovery, and less medical malpractice litigation might be achieved as well. See *infra* notes 117 and 125 and accompanying text for discussions of the effect of informed consent on patient compliance and malpractice suits.

17. See *supra* note 3.

18. See *infra* notes 28-71 and accompanying text for a discussion of disclosure requirements that various jurisdictions require.

19. See *infra* text pages 412-13, 415-19, 426.      ◊



and benefits associated with those alternatives.<sup>20</sup> The law does not mandate, however, that following such disclosure physicians or any other person or institution test the patients' understanding of the information disclosed.<sup>21</sup> In most instances, so long as physicians make certain disclosures to patients<sup>22</sup> and sufficiently document those disclosures, both law and medicine consider any subsequent decision that the patients make to be "informed,"<sup>23</sup> thereby shielding physicians from liability for having treated patients without consent.<sup>24</sup>

20. See *infra* notes 28-71 and accompanying text for a discussion of disclosure rules in the health care context.

21. Although the notion of "informed consent" implies both *disclosure of information by physicians and comprehension of that information by patients* in order that patients can make truly "informed" decisions about their health care, the courts' emphasis in informed consent cases has been on disclosure to almost the total exclusion of concern for patients' understanding of the information disclosed. See, e.g., *Canterbury v. Spence*, 464 F.2d 772, 780 n.15 (1972) (stating that "focus of attention" in what is described as "duty to disclose" cases is "more properly" upon physicians' disclosure to patients rather than upon patients' understanding and actual consent to treatment).

22. See *infra* notes 28-71 and accompanying text for a discussion of the physician's duty to disclose.

23. Some state legislatures have enacted statutes providing that a written consent to medical or surgical treatment that complies with mandated requirements concerning disclosure and that is signed by the patient to whom it applies creates a presumption that informed consent has been given. See FLA. STAT. ANN. § 766.103(4)(a) (West Supp. 1990); GA. CODE ANN. § 31-9-6(d) (1989) ("in the absence of fraudulent misrepresentations of material facts in obtaining the same"); IDAHO CODE § 39-4305 (1988) ("in the absence of convincing proof that it was secured maliciously or by fraud[;]" establishes presumption of "informed awareness of the giver of such consent[;]" lack of writing does not invalidate consent); IOWA CODE ANN. § 147.137 (West 1989); LA. REV. STAT. ANN. § 40:1299.40 A (West 1990) ("in the absence of proof that execution of the consent was induced by misrepresentation of material facts"); ME. REV. STAT. ANN. tit. 24, § 2905(2) (West Supp. 1988) ("may be subject to rebuttal only upon proof that such consent was obtained through fraud, deception or misrepresentation of material fact"); NEV. REV. STAT. § 41A.110 (1986); N.C. GEN. STAT. § 90-21.13(b) (1985) ("subject to rebuttal only upon proof that such consent was obtained by fraud, deception or misrepresentation of a material fact"); OHIO REV. CODE ANN. § 2317.54 (Baldwin 1989) ("in the absence of proof by a preponderance of the evidence that the person who sought such consent was not acting in good faith, or that the execution of the consent was induced by fraudulent misrepresentation of material facts, or that the person executing the consent was not able to communicate effectively in spoken and written English or any other language in which the consent is written[;]" except as to those grounds, "no evidence shall be admissible to impeach, modify, or limit the authorization for performance of the procedure or procedures set forth in such written consent"); TEX. REV. CIV. STAT. ANN. art. 4590i, §§ 6.05-6.07 (Vernon Supp. 1989); UTAH CODE ANN. § 78-14-5(2)(e) (1989) ("unless the patient proves that the person giving the consent lacked capacity to consent or shows by clear and convincing proof that the execution of the written consent was induced by the defendant's affirmative acts of fraudulent misrepresentation or fraudulent omission to state material facts"); WASH. REV. CODE ANN. § 7.70.060 (Supp. 1989) (failure to use consent form not evidence of failure to obtain informed consent). The documentation called for in these statutes relates to disclosures physicians are required to make to patients, not to patients' comprehension of the information disclosed. But see IOWA CODE ANN. § 147.137(2) (West 1989) (requiring consent form to state that all questions asked by patient have been answered in "satisfactory" manner); LA. REV. STAT. ANN. § 40:1299.40 A(b) (West 1990) (same); UTAH CODE ANN. § 78-14-5(2)(e) (1989) (same).

24. Professor Katz, in his very thoughtful book on informed consent and the relationship

In terms of actual decisionmaking or accountability for those decisions, however, the law and its expectations as it relates to decisionmaking in health care operate much differently from the law and its expectations in the consumer, criminal, or family law contexts. Although the law has established the principle that patients are autonomous individuals entitled to make their own decisions concerning their medical care,<sup>25</sup> neither the law nor medicine encourages or fosters, let alone *requires*, such decisionmaking by patients. Instead, both law and medicine encourage patients to let their doctors make decisions for them. The result of failing to require or even encourage patients to make their own health related decisions is that, unlike consumers, criminal defendants, and birth mothers, patients (and, I think, law and medicine) do not expect that they must accept responsibility for those decisions.<sup>26</sup>

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between physician and patient, states that although judges intended in developing the doctrine of informed consent "to improve the climate of conversation between physicians and patients," judges' distrust of "patients' capacities to make their own decisions" undercuts the intention behind the doctrine. J. KATZ, *THE SILENT WORLD OF DOCTOR AND PATIENT* xvi (1984). Professor Katz draws a clear distinction between "the *legal* doctrine [of informed consent], as promulgated by judges, and the *idea* of informed consent, based on a commitment to individual self-determination." *Id.*

25. Patient autonomy in decisionmaking may be limited by compelling state interests. See *supra* note 3.

26. There may be some similarity between the law's attitude concerning patient decision-making and patient responsibility and the law's general attitude toward the defense of assumption of the risk. As the authors of the standard treatise on tort law write:

The defense of assumption of risk is in fact quite narrowly confined and restricted by two or three elements or requirements: first, the plaintiff must know that the risk is present, and he must further understand its nature; and second, his choice to incur it must be free and voluntary. Since in the ordinary case there is no conclusive evidence against the plaintiff on these issues, they are normally for the jury to decide.

W. KEETON, D. DOBBS, R. KEETON, & D. OWEN, *PROSSER AND KEETON ON THE LAW OF TORTS* 486-87 (5th ed. 1984). That attitude, however, relates to implied as opposed to express assumption of the risk. *Id.* at 493. Informed consent in the health care context falls into a classification more clearly analogous to express assumption of the risk. In fact, in many jurisdictions, execution of an informed consent form by patients prior to treatment gives rise to a presumption that all informed consent requirements have been met and the patient will be held to a standard of having been adequately informed. See *supra* note 23. Although one who purports to have assumed a risk expressly may for a variety of reasons later be found not to have done so (for example, inequality of bargaining power between the parties; activities giving rise to risk that relate to public interest such as public utilities or common carriers; agreements that purport to excuse conduct more extreme than negligence such as willful, wanton, or reckless conduct, or intentional torts; or agreements that otherwise violate public policy), should none of those reasons exist, individuals assuming the risk will be held to the agreement if the unfortunate consequences to which they consented actually occur. See *Winterstein v. Wilcom*, 16 Md. App. 130, 293 A.2d 821 (Ct. Spec. App. 1972).

While physicians *qua* defendants may view informed consent as a vehicle by which patients assume the risk of certain consequences attendant on medical procedures, there is a critical difference between a pure assumption of the risk defense and an informed consent defense. The risks explained to and accepted by the patient during the informed consent process are risks which could occur *even though the physician performs the procedure using all due care*

This article examines the doctrine of informed consent as it exists today both in theory and in practice in health care. It focuses especially on the law's ambivalence toward patients' rights in terms of acquisition and comprehension of information and decisionmaking. Part II discusses briefly the nature of the informed consent doctrine as developed by the courts. Part III illustrates by examples drawn from actual practice settings the failure of the doctrine of informed consent if our concern is not only physicians' duty to disclose, but also patients' comprehension and decisionmaking powers. Part IV argues that patients must be encouraged and expected to make decisions concerning their health care, and to take responsibility for those decisions. That section reviews physicians' objections to further expansion of the informed consent rules and offers suggestions to improve the quality of patient decisionmaking, including a shift in the power balance between doctor and patient. Part V concludes the article with a discussion rejecting both the status quo of the doctrine of informed consent and any return to prior days where the law did not impose on physicians a duty to disclose information *or* grant to patients a right to comprehend.<sup>27</sup> Instead, the conclusion advocates changes in the current system which would give patients greater ability, encouragement, and responsibility in terms of comprehending the information they need in order to make truly informed decisions about their health care and actually making those decisions.

## II. THE LAW OF INFORMED CONSENT<sup>28</sup>

The legal doctrine of informed consent was first announced in 1957, when the California Court of Appeal in *Salgo v. Leland Stanford Jr. Univ. Bd. of Trustees*<sup>29</sup> stated in *dicta*<sup>30</sup> that

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*and with no negligence.* The risks assumed pursuant to the standard assumption of the risk defense are risks arising out of *negligent* conduct. So, while following adequate disclosure and comprehension patients may agree to assume risks arising from nonnegligent conduct on the part of physicians, they are not agreeing to assume the risks of negligent conduct by the physicians.

27. The legal doctrine of informed consent was first set forth in *dicta* in 1957 by the California District Court of Appeal in *Salgo v. Leland Stanford Jr. Univ. Bd. of Trustees*, 154 Cal. App. 2d 560, 317 P.2d 170 (1957). *Salgo* was a medical malpractice case in which a jury verdict for the plaintiff was reversed due to error in the trial court's jury instruction on the issue of *res ipsa loquitur*. The California Court of Appeal also addressed the question of physicians' duty to make certain disclosures to patients because of the likelihood that the same issue might be raised on retrial. *Id.* at 564 n.4, 578, 317 P.2d at 172 n.4, 181.

28. This discussion is intended to be a brief overview of the law of informed consent. For more in-depth discussions of the history and content of the doctrine, see J. KATZ, *supra* note 24, at 48-84; I *President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research, Making Health Care Decisions: A Report on the Ethical and Legal Implications of Informed Consent in the Patient-Practitioner Relationship* 18-23 (1982); Andrews, *Informed Consent Statutes and the Decisionmaking Process*, 5 J. LEGAL MED. 163, 175-80 (1984); Pernick, *The Patient's Role in Medical Decisionmaking: A Social History of Informed Consent in Medical Therapy* in III *President's Commission Report, supra*, at App. E.

29. 154 Cal. App. 2d 560, 317 P.2d 170 (Dist. Ct. App. 1957).

30. See *supra* note 27.

A physician violates his duty to his patient and subjects himself to liability if he withholds any facts which are necessary to form the basis of an intelligent consent by the patient to the proposed treatment. Likewise the physician may not minimize the known dangers of a procedure or operation in order to induce his patient's consent.<sup>31</sup>

The court went on, however, to explain that physicians' overriding concern must be their patients' welfare, and that they must use discretion in disclosing information to avoid alarming patients who would decline treatment in the face of a "minimal risk," or increasing the risk to patients because of apprehension that the disclosure would cause.<sup>32</sup> The court concluded its discussion of the physician's duty to disclose by stating that "[t]he instruction given should be modified to inform the jury that the physician has such discretion consistent, of course, with the full disclosure of facts necessary to an informed consent."<sup>33</sup>

The *Salgo* court's discussion of "informed consent"—i.e., the physician's duty to disclose—was brief and undetailed. The court did not discuss what it meant by "full disclosure," and other than providing physicians with a defense that would come to be called the "therapeutic privilege," it did not elaborate on the bounds of physician "discretion" in making less than a "full disclosure" to patients. The court did not discuss the basis for the doctrine of informed consent, a reference point for establishing a standard, causation, or defenses other than the therapeutic privilege.

Three years later the Kansas Supreme Court in *Natanson v. Kline*<sup>34</sup> decided a medical malpractice case in which one of the alleged grounds of the physicians'/defendants' negligence was failure to warn the patient/plaintiff of the injuries possible from treatment with radioactive cobalt. Although the *Natanson* court phrased the issue in the case as whether the physician obtained the informed consent of the patient to treatment,<sup>35</sup> the court treated the case as one of duty to disclose (as opposed to one of a patient's right to understand). As other courts would subsequently find,<sup>36</sup> the *Natanson* court explicitly found that a physician's failure to disclose to a patient certain information resulting in a lack of the patient's "informed consent" to a procedure or therapy was not a traditional action in battery

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31. *Salgo v. Leland Stanford Jr. Univ. Bd. of Trustees*, 154 Cal. App. 2d 560, 578, 317 P.2d 170, 181 (1957). Ironically for the medical profession that objects to the burden imposed on it by the doctrine of informed consent, the language that the *Salgo* court used was taken verbatim from the *amicus curiae* brief submitted to the court by the American College of Surgeons. J. KATZ, *supra* note 24, at 60.

32. *Salgo*, 154 Cal. App. 2d at 578, 317 P.2d at 181.

33. *Id.*

34. 186 Kan. 393, 350 P.2d 1093 (1960).

35. *Natanson v. Kline*, 186 Kan. 393, 404, 350 P.2d 1093, 1102 (1960).

36. See *Canterbury v. Spence*, 464 F.2d 772, 793 (D.C. Cir. 1972), *cert. denied*, 409 U.S. 1064 (1972); *Cobbs v. Grant*, 8 Cal. 3d 229, 240-41, 502 P.2d 1, 8, 104 Cal. Rptr. 505, 512 (1972); *Scott v. Bradford*, 606 P.2d 554, 556-57 (Okla. 1979).

(an unconsented to touching), but instead was an action in negligence.<sup>37</sup>

Unlike the court in *Salgo*, the *Natanson* court did discuss the nature of the patient's right pursuant to the doctrine of informed consent, the standard for determining whether the physician breached the duty to disclose, and defenses available to the physician. The patient's right to receive information prior to making a decision concerning medical care, the court wrote, is based upon "the premise of thorough-going self determination" and the belief that "each man is considered to be master of his own body, and he may, if he be of sound mind, expressly prohibit the performance of life-saving surgery, or other medical treatment" even though the physician might disagree with the patient's decision.<sup>38</sup>

Despite the fact that the *Natanson* court declared the physician's duty to disclose to be based on the patient's right "of thorough-going self determination," the court used medical practice, not patient autonomy, as the standard to define that duty.<sup>39</sup> In addition to stating that a physician's

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37. *Natanson*, 186 Kan. at 401-06, 350 P.2d at 1100-03. The difference between an action in battery and an action in negligence is significant to the parties. For example, in a battery action plaintiffs need to prove only that they did not consent to a touching by the physician and that the physician performed such a touching. *Cobbs*, 8 Cal. 3d at 240, 502 P.2d at 8, 104 Cal. Rptr. at 512. In a negligence action based upon an alleged failure by the physician to disclose certain information, plaintiffs must prove not only that the physician failed to make such disclosure but also that the undisclosed risk materialized, harming the plaintiff, and that a reasonable patient in the plaintiff's condition would have refused the procedure if the physician had made the disclosure. *Canterbury*, 464 F.2d at 790-91. Furthermore, in negligence actions based on breach of a duty to disclose, physicians have more defenses available to them than would be available in a battery action. The defense to an allegation of battery is consent (or presumed consent in an emergency situation). See *Kohoutek v. Hafner*, 383 N.W.2d 295, 298 (Minn. 1986). Defenses to an allegation of failure to disclose include emergency, therapeutic privilege, patient's prior knowledge of the information not disclosed, or immateriality of information not disclosed. See *Canterbury*, 464 F.2d at 788-89. In battery cases, plaintiffs do not need to present expert testimony on the issue of consent. The question in such cases is whether the physician told the patient the nature and character of the procedure and whether the patient consented. *Kohoutek*, 383 N.W.2d at 299. In negligence actions based on a breach of the duty to disclose, however, some jurisdictions require plaintiffs to present expert testimony to show that the reasonable medical practitioner would have made the disclosures the plaintiff alleges were not made. See, e.g., DEL. CODE ANN. tit. 18, § 6853 (1989) (unless "malpractice review panel has found negligence to have occurred and to have caused the alleged personal injury or death"); N.H. REV. STAT. ANN. § 507-C:2 I, II (1983); TENN. CODE ANN. §§ 29-26-115(b), 29-26-118 (1980); VT. STAT. ANN. tit. 12, § 1909(e) (Supp. 1988). Physicians held liable for battery might be required to pay punitive damages and medical malpractice insurance coverage may not extend to intentional torts such as battery. *Cobbs*, 8 Cal. 3d at 240, 502 P.2d at 8, 104 Cal. Rptr. at 512. Finally, in some jurisdictions the statute of limitations for negligence actions may extend longer than that for intentional torts. See *Canterbury*, 464 F.2d at 793-94.

38. *Natanson*, 186 Kan. at 406-07, 350 P.2d at 1104.

39. *Id.* at 409, 350 P.2d at 1106. "The duty of the physician to disclose, however, is limited to those disclosures which a reasonable medical practitioner would make under the same or similar circumstances." *Id.* (emphasis added).

So long as the disclosure is sufficient to assure an informed consent, the physician's choice of plausible courses should not be called into question if it appears, all

liability for alleged failure to disclose would be judged by a standard based upon the actions of a reasonable medical practitioner, the *Natanson* court attempted to define in greater detail the particulars of the required disclosures. At one point in its opinion the court stated that the physician was obligated to make "a reasonable disclosure . . . of the nature and probable consequences of the suggested or recommended . . . treatment, and . . . a reasonable disclosure of the dangers within his knowledge which were incident to, or possible in, the treatment he proposed to administer."<sup>40</sup> Later in the opinion the court stated that the physician had an obligation "to disclose and explain to the patient *in language as simple as necessary* the nature of the ailment, the nature of the proposed treatment, the probability of success or of alternatives, and *perhaps* the risks of unfortunate results and unforeseen conditions within the body. . . ."<sup>41</sup> Although the "in language as simple as necessary" statement might be read as implying that the patient's right of "informed consent" includes the right to understand the information disclosed by the physician, nothing else in *Natanson v. Kline* gives any indication that the doctrine is concerned with anything other than the physician's duty to disclose. Furthermore, the physician was privileged not to disclose for therapeutic reasons.<sup>42</sup> In addition, the court stated that the physician was not subject to liability for a failure to disclose information if the patient "fully appreciate[d]" the danger involved in the proposed treatment, because there would be no causal link between the physician's failure and the patient's consent.<sup>43</sup> The court did not explain how a patient's "full appreciation" of the dangers would be determined, except to note that, as in any malpractice case, the burden of proof throughout the case would rest on the patient/plaintiff.<sup>44</sup>

In 1972 the United States Circuit Court of Appeals for the District of Columbia decided *Canterbury v. Spence*,<sup>45</sup> an informed consent case—again a physician's duty to disclose rather than a patient's right to understand case<sup>46</sup>—in which the court imposed and evaluated the physician's duty not

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circumstances considered, that the physician was motivated only by the patient's best therapeutic interests and he proceeded *as competent medical men would have done in a similar situation*.

*Id.* at 409-10, 350 P.2d at 1106 (emphasis added).

40. *Id.* at 410, 350 P.2d at 1106.

41. *Id.* (emphasis added).

42. *Id.* at 406, 350 P.2d at 1103.

43. *Id.* at 410, 350 P.2d at 1106.

44. *Id.*

45. 464 F.2d 772 (D.C. Cir. 1972).

46. *Canterbury v. Spence*, 464 F.2d 772, 780 n.15 (D.C. Cir. 1972). The *Canterbury* court clearly drew a distinction between the physician's duty to disclose and the patient's right to comprehend the information disclosed, and noted that "[i]n duty-to-disclose cases, the focus of attention is more properly upon the nature and content of the physician's divulgence than the patient's understanding or consent" and that "the physician discharges the duty when he makes a reasonable effort to convey sufficient information although the patient, without fault of the physician, may not fully grasp it." *Id.*

by the standard of care in the profession, but instead, given "[r]espect for the patient's right of self-determination[,] by law."<sup>47</sup> The scope of the physician's duty to disclose was to be shaped by the patient's need to know, by that "information *material* to the decision."<sup>48</sup>

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47. *Id.* at 784.

48. *Id.* at 786 (emphasis added). Prior to the *Canterbury* decision at least three state intermediate appellate courts had decided failure to disclose cases in which the court discussed a patient-based standard of disclosure. *Berkey v. Anderson*, 1 Cal. App. 3d 790, 82 Cal. Rptr. 67 (Dist. Ct. App. 1969); *Cooper v. Roberts*, 220 Pa. Super. 260, 286 A.2d 647 (1971); *Hunter v. Brown*, 4 Wash. App. 899, 484 P.2d 1162 (1971), *aff'd*, 81 Wash. 2d 465, 502 P.2d 1194 (1972). In *Berkey v. Anderson* the California District Court of Appeal discussed the lack of informed consent as a "technical battery." *Berkey*, 1 Cal. App. 3d at 793 n.1, 803, 82 Cal. Rptr. at 69 n.1, 76-77. The court, in discussing the requirements of informed consent, quoted extensively from *Salgo v. Leland Stanford Jr. Univ. Bd. of Trustees*. *Id.* at 803-04, 82 Cal. Rptr. at 77. The *Berkey* court described the doctor-patient relationship as being fiduciary in nature, and stated that the law applicable to that relationship would be that relating to fiduciary relationships rather than that of the standard practice of physicians in the community. *Id.* at 805, 82 Cal. Rptr. at 78. The court also noted, however, that there was evidence in the case that even the professional standard of care had been violated. *Id.* at 805-06, 82 Cal. Rptr. at 78.

The *Cooper* court referred to surgery performed without the patient's informed consent as a "technical assault." *Cooper v. Roberts*, 220 Pa. Super. 260, 265, 286 A.2d 647, 649 (1971). The court described the doctor-patient relationship as contractual. *Id.* at 268, 286 A.2d at 651. The court rejected the professional standard of care as it relates to informed consent, and instead, quoting from *Berkey v. Anderson*, 82 Cal. Rptr. at 78, adopted a duty to disclose based on "all those facts, risks and alternatives that a reasonable man in the situation which the physician knew or should have known to be the plaintiff's would deem significant in making a decision to undergo the recommended treatment." *Id.* at 267, 286 A.2d at 650. The court went on to state that because the duty to disclose was based on a reasonableness standard, expert testimony need not be provided on the issue of disclosure. *Id.* at 268-69, 286 A.2d at 651. Finally, the court described its "determination to be the most equitable balance between the patient's right to control what happens to his body, and the interest of fostering the practice of responsive, progressive medicine." *Id.* at 269, 286 A.2d at 651.

In *Hunter* the Washington Court of Appeals, like the California District Court of Appeal in *Berkey*, described the doctor-patient relationship as a fiduciary one. *Hunter v. Brown*, 4 Wash. App. 899, 905, 484 P.2d 1162, 1166 (1971). The duty to disclose, the court said, "extends beyond the realm of *risks* . . . [and includes] all material *facts* [including alternatives] which reasonably should be known if [the] patient is to make an informed and intelligent decision." *Id.* at 906, 484 P.2d at 1166. The court stated that it was immaterial whether the failure to disclose was willful or attributable to negligence. *Id.* The court noted that physicians could offer in defense proof of compliance with the professional standard of care, and that such evidence "should be weighed as any other evidence and be judged by 'reasonable man' standards of conduct." *Id.* at 907, 484 P.2d at 1167. The *Hunter* court also quoted from *Salgo*, 154 Cal. App. 2d at 578, 317 P.2d at 181, on the issue of therapeutic privilege, and from *Berkey*, 1 Cal. App. 3d at 805, 82 Cal. Rptr. at 78, on the issue of fiduciary relationship. *Id.* at 906-07, 484 P.2d at 1166-67. The Washington Supreme Court affirmed *Hunter v. Brown* on appeal, devoting little discussion to the informed consent issue, but noting that "no medical standard as to telling the patient need be proved . . . [where u]nder the circumstances and considering this was elective surgery for the attempted improvement of appearance only, the necessity of disclosure is too clear to require medical testimony." *Hunter v. Brown*, 81 Wash. 2d 465, 468, 502 P.2d 1194, 1196 (1972). So, prior to the *Canterbury* court's decision, several state intermediate appellate courts had begun to move away from a professionally based

Having stated that physicians have a duty to disclose information to patients which is "material" to their decisions, the court was faced with having to define further the standard of materiality. The court noted that "all risks potentially affecting the decision must be unmasked[,]""<sup>49</sup> and that "[o]ptimally for the patient, exposure of a risk would be mandatory whenever the patient would deem it significant to his decision. . . ."<sup>50</sup> Such a standard, however, would place the physician in the role of second-guessing the ideas of patients on the issue of what is "material."<sup>51</sup> Instead, the court adopted a definition of materiality defining a risk as material "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 forego the proposed therapy."<sup>52</sup> The court included among the topics to be communicated from physician to patient "the inherent and potential hazards of the proposed treatment, the alternatives to that treatment, if any, and the results likely if the patient remains untreated."<sup>53</sup> The court dismissed arguments that physicians would not be able to communicate this information to patients so that the lay person/patient could understand the information, "at least in a rough way."<sup>54</sup>

The court did, however, excuse physicians from a duty to disclose where the information would not be material to the patient's decision, where the patient had already discovered the potential hazards of treatment, where the patient was unconscious or in an emergency situation where the harm from a failure to treat would be imminent and would outweigh possible harm due to the treatment, and where disclosure would defeat the therapeutic course of the treatment.<sup>55</sup> The court also excused physicians from a duty to disclose information concerning dangers related to proposed treatment of which patients of average sophistication would already be aware,<sup>56</sup>

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standard to a patient based standard of disclosure. Those cases, however, were still tied to older theories of intentional tort, contract, or fiduciary relationship. None of the cases developed the bases for the patient based standard or its elements with the thoroughness and detail of the *Canterbury* court. It is because of that thoroughness and detail that I use *Canterbury* as the paradigm for the patient based standard of disclosure.

49. *Canterbury*, 464 F.2d at 787 (footnote omitted).

50. *Id.*

51. *Id.*

52. *Id.*, quoting Waltz & Scheuneman, *Informed Consent to Therapy*, 64 Nw. U.L. REV. 628, 640 (1970).

53. *Id.* at 787-88.

54. *Id.* at 782 n.27. Despite the court's language concerning patients' comprehension of information disclosed by physicians—"Some doubt has been expressed as to ability of physicians to suitably communicate their evaluations of risks and the advantages of optional treatment, and as to the lay patient's ability to understand what the physician tells him" (emphasis added) and "So informing the patient hardly taxes the physician, and it must be the exceptional patient who cannot comprehend such an explanation at least in a rough way" (emphasis added)—the court's focus remained disclosure by physicians and *not* comprehension by patients. *Id.*

55. *Id.* at 788-89.

56. *Id.* at 788.



apparently without a requirement that any given patient actually be "of average sophistication." Such an approach is consistent with the court's discussion of the causation element of an action brought against a physician for failure to disclose.

In order for a patient to recover for a physician's failure to warn the patient of a material risk, the undisclosed risk must materialize and must be harmful to the patient.<sup>57</sup> The *Canterbury* court did not create a cause of action based solely on failure to disclose without a consequent injury connected to the information not disclosed.<sup>58</sup> The causal connection between the undisclosed information and the patient's harm exists only where the patient would have opted against the treatment which caused the injury if the disclosure had been made.<sup>59</sup> And causation is to be judged by an objective standard; regardless of what the individual patient might have done had the physician disclosed the material risk, where the *reasonable patient* would have opted for treatment even if the material risk had been disclosed, causation is not proved and the patient cannot recover against the physician.<sup>60</sup> While protecting the physician from patients' hindsight evaluations of what they would have done had the physician disclosed the risks, the use of the objective standard to determine causation directly undermines the notion of individual self determination and autonomy in decisionmaking upon which the doctrine of informed consent is reportedly based.

Shortly after the District of Columbia Circuit rendered its decision in *Canterbury v. Spence*, the California Supreme Court and the Rhode Island Supreme Court followed suit. In *Cobbs v. Grant*,<sup>61</sup> the California Supreme Court held that a physician has "a duty of reasonable disclosure of the available choices with respect to proposed therapy and of the dangers inherently and potentially involved in each."<sup>62</sup> The scope of "a duty of reasonable disclosure," the court said, "does not extend to a lengthy polysyllabic discourse on all possible complications."<sup>63</sup> The physician need not discuss "relatively minor risks inherent in common procedures, where it is common knowledge that such risks inherent in the procedure are of very low incidence."<sup>64</sup> Rather, "when a given procedure inherently involves a known risk of death or serious bodily harm," such risks must be explained to the patient along with "such additional information as a skilled practitioner of good standing would provide under similar circumstances."<sup>65</sup> The court's "skilled practitioner of good standing" language raises a question

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57. *Id.* at 790.

58. *Id.*

59. *Id.*

60. *Id.* at 791.

61. 8 Cal. 3d 229, 502 P.2d 1, 104 Cal. Rptr. 505 (1972).

62. *Cobbs v. Grant*, 8 Cal. 3d 229, 243, 502 P.2d 1, 10, 104 Cal. Rptr. 505, 514 (1972).

63. *Id.* at 244, 502 P.2d at 11, 104 Cal. Rptr. at 515.

64. *Id.* (footnote omitted).

65. *Id.* at 244-45, 502 P.2d at 11, 104 Cal. Rptr. at 515.

as to whether, beyond a duty imposed by law to disclose risks of death and serious bodily harm, the physician's duty to disclose is to be judged by a standard of care set by the medical profession. The *Cobbs* court, however, did go on to state that the physician's duty to disclose is based on the patient's right of self determination and is shaped by the patient's need, which is "whatever information is material to the decision."<sup>66</sup>

The Rhode Island Supreme Court in *Wilkinson v. Vesey*<sup>67</sup> left no ambiguity concerning the scope of the physician's duty to disclose: "[A] physician is bound to disclose all the known material risks peculiar to the proposed procedure." The court explained further that "materiality" would be based on information significant to a reasonable person in what the physician "knows or should know" to be the patient's position in deciding whether or not to submit to surgery or treatment.<sup>68</sup>

Like the court in *Canterbury v. Spence*, the courts in *Cobbs* and *Wilkinson* did not recognize a cause of action for failure to disclose alone in the absence of damages resulting from an undisclosed risk, and did impose a standard of causation based upon the objective, reasonable patient, as opposed to a subjective, individual patient.<sup>69</sup>

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66. *Id.* at 245, 502 P.2d at 11, 104 Cal. Rptr. at 515. Professor Capron has argued that by using "the patient's need" as the measure of materiality, the *Cobbs* court implicitly adopted a subjective standard for determining whether information withheld from a patient should have been disclosed. Capron, *Informed Consent in Catastrophic Disease Research and Treatment*, 123 U. PA. L. REV. 340, 407 (1974). While the court's language supports Professor Capron's argument, immediately following its statement concerning "the patient's need," the court stated: "Thus the test for determining whether a potential peril must be divulged is its materiality to the patient's decision[.]" citing in support of that statement *Canterbury v. Spence*, a case that explicitly adopted an objective standard for determining what information must be disclosed. *Canterbury v. Spence*, 464 F.2d 772, 787 (D.C. Cir. 1972); *Cobbs*, 18 Cal. 3d at 245, 502 P.2d at 11, 104 Cal. Rptr. at 515. Eight years after *Cobbs v. Grant*, the California Supreme Court described the scope of a physician's duty to disclose as being measured

by the amount of knowledge a patient needs in order to make an informed choice.

All information material to the patient's decision should be given . . . .

Material information is that which the physician knows or should know would be regarded as significant by a reasonable person in the patient's position when deciding to accept or reject the recommended medical procedure.

*Truman v. Thomas*, 27 Cal. 3d 285, 291, 611 P.2d 902, 905, 165 Cal. Rptr. 308, 311 (1980) (emphasis added; citations omitted) (holding physician has duty to disclose to patient material risks of not consenting to recommended treatment). If uncertainty existed concerning the scope of the physician's duty to disclose following *Cobbs*, the *Truman* court made clear that the scope was to be determined by an objective, reasonable person standard.

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

68. *Wilkinson*, 110 R.I. at 627, 295 A.2d at 689 (1972).

69. *Cobbs*, 8 Cal. 3d at 245, 502 P.2d at 11-12, 104 Cal. Rptr. at 515-16; *Wilkinson*, 110 R.I. at 627, 628-29, 295 A.2d at 689, 690. The *Cobbs* court also recognized the by-now familiar defenses of emergency, incompetence, therapeutic privilege, patient request not to know, or dangers remote and commonly appreciated to be remote. *Cobbs*, 8 Cal. 3d at 243-44, 245-46, 502 P.2d at 10, 12, 104 Cal. Rptr. at 514, 516. The *Wilkinson* court recognized the emergency and therapeutic privilege defenses. *Wilkinson*, 110 R.I. at 622, 628, 295 A.2d at 686, 689.

In the majority of jurisdictions, a physician's duty to disclose information to a patient is still judged by a standard based upon practice within the profession;<sup>70</sup> a growing number of jurisdictions, however, determine a physician's liability based upon a standard of information needed by reasonable patients in making decisions concerning their treatment.<sup>71</sup>

70. See *Riedisser v. Nelson*, 111 Ariz. 542, 544, 534 P.2d 1052, 1054 (1975); *Fuller v. Starnes*, 268 Ark. 476, 479, 597 S.W.2d 88, 89-90 (1980); *Hansbrough v. Kosyak*, 141 Ill. App. 3d 538, 551, 490 N.E.2d 181, 189 (App. Ct. 1986); *Woolley v. Henderson*, 418 A.2d 1123, 1129-30 (Me. 1980); *Aiken v. Clary*, 396 S.W.2d 668, 673 (Mo. 1965); *Hook v. Rothstein*, 281 S.C. 541, 553, 316 S.E.2d 690, 696-97 (Ct. App. 1984), *aff'd*, 283 S.C. 64, 320 S.E.2d 35. Almost all states establishing a *statutory* standard of care in informed consent cases have adopted the professional standard as opposed to the patient based standard. See, e.g., ARK. STAT. ANN. § 16-114-206(b)(1) (1987); FLA. STAT. ANN. § 766.103(3)(a)(1) (West Supp. 1990); IDAHO CODE § 39-4304 (1985); KY. REV. STAT. ANN. § 304.40-320(1) (Michie/Bobbs-Merrill 1988); ME. REV. STAT. ANN. tit. 24, § 2905(1)(A) (West Supp. 1989); NEB. REV. STAT. § 44-2816 (1988); N.H. REV. STAT. ANN. § 507-C:2(II)(a) (1983); N.Y. PUB. HEALTH LAW § 2805-d(1) (McKinney Supp. 1990); N.C. GEN. STAT. § 90-21.13(a)(1) (1985); TENN. CODE ANN. § 29-26-115(a)(1), (2) (1980); VT. STAT. ANN. tit. 12, § 1909(A)(1) (Supp. 1988). But see PA. STAT. ANN. tit. 40, § 1301.103 (Purdon Supp. 1989) (patient based standard); WASH. REV. CODE ANN. § 7.70.050(1) & (2) (West Supp. 1989) (same).

71. See *Cowman v. Hornaday*, 329 N.W.2d 422, 427 (Iowa 1983); *Sard v. Hardy*, 281 Md. 432, 444, 379 A.2d 1014, 1022 (1977); *Harnish v. Children's Hosp. Medical Center*, 387 Mass. 152, 155-57, 439 N.E.2d 240, 243-44 (1982); *Cornfeldt v. Tongen*, 295 N.W.2d 638, 640 (Minn. 1980); *Largey v. Rothman*, 110 N.J. 204, 213-15, 540 A.2d 504, 509-10 (1988) (overruling *Kaplan v. Haines*, 51 N.J. 404, 241 A.2d 235 (1968), which had affirmed the same case, 96 N.J. Super. 242, 257, 232 A.2d 840, 848 (1967). The superior court's decision had held that the physician's duty to disclose was to be judged against the practice of the reasonable medical practitioner). See also *Nickell v. Gonzalez*, 17 Ohio St. 3d 136, 139, 477 N.E.2d 1145, 1148 (1985); *Wheeldon v. Madison*, 374 N.W.2d 367, 375 (S.D. 1985).

*Scott v. Bradford*, decided by the Oklahoma Supreme Court, represents an exception to the majority of cases in recognizing more autonomy in individual patients. 606 P.2d 554 (Okla. 1979). In holding that physicians must make "full disclosure of all *material risks* incident to treatment[,] and in defining a risk as being material "if it would be likely to affect [a] patient's decision," the *Scott* court followed the *Canterbury* approach adopting a standard of informed consent based upon a patient's right to self determination. *Id.* at 558. The *Scott* court, however, differed from the *Canterbury* approach on the issue of causation. Rather than adopting a reasonable patient standard of causation, the *Scott* court decided that the patient's right of self determination compels a subjective standard of causation; i.e., if patients testify that they would have declined treatment had a material risk been disclosed, then the issues of plaintiffs' credibility and of causation must be left to the finder of fact, even if the reasonable person would not have refused the treatment had the disclosure been properly made. *Id.* at 559. Despite the *Scott* court's recognition of the right of patients to make decisions different from those made by "reasonable" patients under the same or similar circumstances, the court did not go further and find a cause of action based upon failure to disclose alone, absent actual injury caused by the undisclosed risk. Furthermore, like all the other informed consent cases, *Scott v. Bradford* was a physician's failure to disclose rather than a patient's failure to comprehend case.

For another variation in the causation standard, see *Fain v. Smith*, 479 So. 2d 1150, 1154-55 (Ala. 1985) where the court held that the causation standard is "objective," but stated that "the objective standard requires consideration by the factfinder of what a *reasonable person with all of the characteristics of the plaintiff*, including his idiosyncrasies and religious beliefs, would have done under the same circumstances." (emphasis added). *Fain v. Smith*,

### *The Doctrine of Informed Consent in Practice*

I spent the 1988 Spring Term on a six month sabbatical leave as an observer in a 900 bed medical center. Two of the things to which I paid most attention during my time there were the relationship between physician and patient in terms of the information provided from physician to patient, and, just as important, the method by which the information was provided.<sup>72</sup>

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479 So. 2d 1150, 1154-1155 (Ala. 1985). Two dissenting justices individually interpreted the majority's statement of causation as being subjective, rather than objective. *Id.* at 1163-64 (Jones, J., dissenting), 1164 (Adams, J., dissenting). In a forceful dissent, Justice Jones argued in favor of the court's adopting a "patient's perspective" standard. Justice Jones favored the term "patient's perspective" as opposed to "subjective," because he believed the term "subjective" to be "an editorial comment disfavoring its application" whereas "reference to the 'reasonable person' standard as 'objective' carries its own inference of acceptance." *Id.* at 1157 n.2 (Jones, J., dissenting). Justice Jones explained that his

resolve that the "patient's perspective" standard is the proper causation standard . . . is strengthened by the result of the hypothetical "flip-side" [argument]. . . Suppose that, as in the present case, [the patient] underwent a pulmonary arteriogram and his heart was punctured. At trial, however, [the patient] concedes that he gave informed consent to the doctors for the performance of the procedure. But he then argues that the consent was invalid because the "reasonable person" would not have consented . . . .

Logically, if the law allows patients to be unreasonable when they *give* consent, the law should allow them to be unreasonable when they *withhold* consent. *Id.* at 1159.

See also *Leyson v. Steuermann*, 5 Haw. App. 504, 517 n.10, 705 P.2d 37, 47 n.10 (1985) (adopting "a modified objective standard that determines the question [of causation] from the viewpoint of the *actual patient acting rationally and reasonably*" (emphasis added)).

According to a survey that Louis Harris and Associates conducted for the President's Commission, 42% of physicians and 46% of patients believe that the physician should disclose the information that the *particular patient* being treated would consider relevant to a decision of whether or not to accept proposed treatment, *i.e.*, a subjective standard. Harris, *Views of Informed Consent and Decisionmaking: Parallel Surveys of Physicians and the Public*, in II *President's Commission Report*, *supra* note 28, at App. B, Tables 5-11, 5-12. Twenty-one per cent of physicians and 28% of patients believe disclosure should be based on what the *average reasonable patient* would consider relevant in making a decision, *i.e.*, an objective standard. *Id.* Twenty-six per cent of physicians and 18% of patients believe disclosure should be based on what the *average reasonable practitioner* would disclose under the same or similar circumstances, *i.e.*, the professional practice standard. *Id.*

72. An issue that arose early in my time at the hospital—and that was never resolved to my satisfaction—was the manner in which I was introduced to patients. I believed upon beginning my sabbatical (and now) that "informed consent" means providing information to patients so they can make informed choices, and providing those patients with an appropriate atmosphere in which to make those choices. Throughout my six months at the medical center, only two physicians consistently (a few more sporadically) introduced me to patients by my name with a description of my status at the hospital (*i.e.*, a professor of health law interested in issues of decisionmaking in the health care context) and gave those patients an opportunity to refuse my presence during their examinations or conversations with the physicians. Only one of those two physicians explained my status to the patients outside of my presence so that patients would not feel pressured by my presence into agreeing to my observation. Of those patients to whom the physician announced my purpose, only one (an adolescent male who resisted even his nurse/mother's presence in the examining room) refused to have me

Not only did I watch physicians—attendings and house officers—perform the rituals of informed consent with patients, but also I engaged many physicians in discussions relating to what they tell patients, how they deliver such information, and what they think of the informed consent process. The physicians with whom I came into contact are competent, serious, hard working, and well meaning. Nevertheless, the informed consent procedures that most of them used, while sometimes meeting the letter of the informed consent doctrine, rarely met what should be its spirit, *i.e.*, providing adequate information and attempting to ensure that patients understand the information so they can make knowing and voluntary decisions about medical care. Most physicians, however, would never be faulted by a court for what they do because they give the appearance of having met the doctrine's requirements and *they document everything*.<sup>73</sup>

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present. Many of those to whom I was accurately introduced were interested in my "real job" as a law professor and in my project at the hospital, and carried on conversations with me relating to both.

Perhaps the fact that only one patient refused to have me present indicates that most of the other patients to whom I was not accurately identified would have consented, and therefore, no harm resulted. I do not feel that way; both for reasons of privacy and informed decisionmaking, patients should have been informed of my identity. When I pursued the matter with the physicians with whom I was associated, they offered various explanations for their decision not to introduce me in my true capacity: patients might be frightened by the thought of malpractice if they realized a lawyer was working with their health care team; because this health care institution was a major teaching hospital, patients were accustomed to having extra observers with the team; I would be treated as a student (in fact, I was frequently introduced as "Doctor Jones," justified, I suppose, because of the juris doctor degree behind my name, but nevertheless misleading); patients would not understand the true explanation if given; patients would consent even with the accurate information; explanation would be too time consuming. *See infra* text pages 32-47 for strikingly similar physician views concerning patients' ability to understand information and take part in decisionmaking concerning their own health care.

Throughout my leave, I was torn over whether to continue if patients were not informed of my true identity and purpose in being there. I stayed, without ever giving those with whom I was associated an ultimatum of "introduce me accurately or I will leave." I clearly needed them and their good will—of which there was a great deal—if I was to complete my leave and successfully observe decisionmaking in the health care context. I "settled" for discussing the issue of my introduction with everyone with whom I worked. I continue to carry with me a nagging feeling that I chose the wrong approach.

73. By statute in some states a written consent form signed by the patient or by someone authorized to represent the patient creates a presumption that the state's informed consent requirements have been met. *See, e.g.*, FLA. STAT. ANN. § 766.103(4)(a) (West Supp. 1989); GA. CODE ANN. § 31-9-6(d) (1989) ("in the absence of fraudulent misrepresentations of material facts in obtaining the same"); IDAHO CODE § 39-4305 (1988) ("in the absence of convincing proof that it was secured maliciously or by fraud[;]" establishes a presumption of the "informed awareness of the giver of such consent[;]" lack of writing does not invalidate consent); IOWA CODE ANN. § 147.137 (West 1989); LA. REV. STAT. ANN. § 40:1299.40 A (West 1990) ("in the absence of proof that execution of the consent was induced by misrepresentation of material facts"); ME. REV. STAT. ANN. tit. 24, § 2905(2) (West Supp. 1988) ("may be subject to rebuttal only upon proof that such consent was obtained through fraud, deception or misrepresentation of material fact"); NEV. REV. STAT. § 41A.110 (1986); N.C. GEN. STAT. § 90-21.13(b) (1985) ("subject to rebuttal only upon proof that such consent was obtained by fraud,

From my observations, many physicians disclose to patients the benefits and to a lesser extent the risk elements of proposed medical treatments. There is little or no discussion, however, of alternatives,<sup>74</sup> or if there is a

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deception or misrepresentation of a material fact"); OHIO REV. CODE ANN. § 2317.54 (Baldwin 1989) ("in the absence of proof by a preponderance of the evidence that the person who sought such consent was not acting in good faith, or that the execution of the consent was induced by fraudulent misrepresentation of material facts, or that the person executing the consent was not able to communicate effectively in spoken and written English or any other language in which the consent is written;" except as to those grounds, "no evidence shall be admissible to impeach, modify, or limit the authorization for performance of the procedure or procedures set forth in such written consent"); TEX. REV. CIV. STAT. ANN. art. 4590i, §§ 6.05-6.07 (Vernon Supp. 1989); UTAH CODE ANN. § 78-14-5(2)(e) (1989) ("unless the patient proves that the person giving the consent lacked capacity to consent or shows by clear and convincing proof that the execution of the written consent was induced by the defendant's affirmative acts of fraudulent misrepresentation or fraudulent omission to state material facts"); WASH. REV. CODE ANN. § 7.70.060 (Supp. 1989) (failure to use consent form not evidence of failure to obtain informed consent).

74. This observation is not consistent with the results of physicians polled by the Harris Survey. Harris, *supra* note 71, at 17-316. The Harris Survey indicated that 96% of the physicians interviewed said they initiated discussions with their patients concerning the nature and purpose of the treatment option they recommended, 99% initiated discussions concerning the patients' diagnosis and prognosis, 95% initiated discussions concerning the likely side effects of the proposed treatment, 81% initiated discussions concerning a 1% risk of death or serious disability, and 84% initiated discussions concerning the pros and cons of the recommended treatment when compared to treatment alternatives. *Id.* at Table 3-2. My observations were more consistent with those reported by Lidz & Meisel, *Informed Consent and the Structure of Medical Care*, in II *President's Commission Report*, *supra* note 28, App. C, and Appelbaum & Roth, *Treatment Refusal in Medical Hospitals*, in II *President's Commission Report*, *supra* note 28, App. D, both of which were on-site observational studies.

Lidz and Meisel report that

informed consent is largely absent from the clinic; it is almost exclusively a creature of law.

... In fact, information is sometimes provided to patients, and patients sometimes make decisions. But when this happens, and it does not very frequently, the explanation for it most likely does not lie in law, but in medical custom. And we are convinced that this medical custom is deeply engrained and to date has not experienced much change under the influence of law.

Lidz & Meisel, *supra*, at 320.

Appelbaum and Roth write that

There has been a great deal of discussion about the ability of patients to understand and thoughtfully employ intrinsically complicated medical data. For the refusers on the wards examined in this study, such a dispute was academic at best. *Often patients were not told what treatment or procedure had been ordered for them, much less asked to decide whether or not to accept it. The purpose of the procedure was frequently obscure and the risks commonly went unmentioned. Presentation of alternatives was extraordinarily rare.*

Appelbaum & Roth, *supra*, at 472 (emphasis added).

All three studies were subject to limitations. See Appelbaum & Roth, *supra*, at 414; Harris, *supra* note 71, at 36-52; Lidz & Meisel, *supra*, at 390-91. My own observations were random and probably of no statistical significance. Nevertheless, my own observations coupled with the Lidz and Meisel and Appelbaum and Roth studies and their collective contrast to much of the Harris Survey, indicate that the answers that physicians and patients give to questions concerning health care decisionmaking in the abstract may be very different from

discussion of alternatives, it is not unusual for the information giver to phrase—some might use the word “slant”—the information in such a way that the patient will almost certainly choose the alternative favored by the physician. Rarely does a physician attempt to test a patient’s understanding of the information that has been provided, beyond a perfunctory “Do you have any questions?”<sup>75</sup> to which the patient almost invariably responds in the negative.

A few examples. I watched an anesthesiologist go through his informed consent protocol with surgery patients when they came to the hospital for preadmission testing. Before he saw them, the patients had received the hospital’s anesthesia consent form by which they were to acknowledge that the anesthesiologist had explained the process and alternative methods of anesthesia to them, and that they were aware of the “more common or unusually serious possible risks which may accompany the anesthesia,” including adverse drug reactions, brain damage, cardiac arrest, nerve injury, disturbance of cardiac rhythm, respiratory problems, injury to teeth or dental work, damage to arteries and veins, sore throat, hoarseness, headache, minor pain or discomfort, and awareness under anesthesia.<sup>76</sup> By signing the form, patients also acknowledged that they “understand that there are other risks and complications which are not listed above but which may accompany this anesthesia.”<sup>76</sup> Finally, of course, patients agree that they have read the form carefully, that they understand its contents and significance, that they had the opportunity to ask questions, and that they had received answers to those questions. The recitation of these “facts” sounds not unlike an affirmation of religious faith. The analogy is apt.

Upon seeing the patients, the anesthesiologist asked if they had read the consent form. All acknowledged rather nervously that they had. The anesthesiologist would recognize that the patients were nervous, and he would tell them that their nervousness was a sign of their normalcy. He would then explain that the consent form they had read listed every bad result that has ever occurred through the use of anesthesia since 1822, and that the form was necessary because the law said doctors had to tell patients these things. Without discussing any particular risk, he would assure the patients that since they were basically healthy people (apart, I suppose, from the condition for which they were to be treated) he did not expect any of those risks to occur in their cases. He explained the various methods of anesthesia to each patient, but his presentation was clearly different depending on whether *he* believed the patient should have a spinal or a general anesthetic. (Local anesthetic was rarely an issue due to the procedures

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what occurs when physicians and patients face actual situations. This view is supported by the President’s Commission’s finding that surveys often “overstate the frequency with which information is disclosed and may present a rosier, more homogeneous picture of medical practice” than would be found in on-site investigation. I *President’s Commission Report*, *supra* note 28, at 9.

75. Consent form on file in the office of the author.

76. Consent form on file in the office of the author.

to be performed.) He always asked the patients if they had any questions. As I had been forewarned, the patients almost never did, except possibly to ask how long the surgical procedure would last, a question which the anesthesiologist said he was not qualified to answer. The entire conversation between physician and patient lasted no more than five minutes. After that, the patient was sent off to sign the consent form in front of a nurse-witness. I do not know if patients had separate discussions with a nurse either before or after their meeting with the anesthesiologist.<sup>77</sup> Judging from the looks on their faces, the tone of their voices, and their questions or lack thereof, I am fairly confident that although the letter of the informed consent doctrine may have been met in terms of disclosure of benefits, risks, and alternatives,<sup>78</sup> the patients did not understand the disclosure. Certainly no one ever tested their understanding.

An acquaintance of mine, who happens to be a physician, tells an even more graphic story about anesthesia consent at another hospital. She arrived at the hospital at 6 a.m. to have minor, "day stay" surgery. While she was in the surgical holding area, she received that hospital's anesthesia consent form, which listed in detail not only all the risks that could occur, but also presented her with the "odds" of any risk occurring; for example the chances of mild disturbances of cardiac rhythm were 1:100, serious disturbances of cardiac rhythm were 1:200, myocardial infarct, 1:2,000, and cardiac arrest, 1:5,000.<sup>79</sup> My acquaintance had the ability to read and understand the terms and the statistics presented her in written form, something which many lay people could not do (myocardial infarct? aspiration resulting in pneumonia?). The anxiety that the presentation of the form immediately prior to her surgery caused, however, prevented her from doing so. She signed the form because she knew that the surgery had to be performed.

These two examples raise issues in terms of the adequacy of the information disclosed to the patient and the manner in which it is disclosed. Although the information set forth on the consent forms may in fact have disclosed the alternatives available to the patients and the material risks

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77. One nurse told me that if nurses were convinced that patients did not understand the procedures they were "agreeing" to undergo, the nurses would send them back to their physicians for further instruction. She also told me that "surgeons don't like that," but that nurses regard themselves as patient advocates whose purpose in part is to educate and support patients. Others told me, however, that a nurse's only role in witnessing a patient's signing of a consent form is to attest to the fact that the signature is that of the patient, not that informed consent was actually achieved.

78. I say "may have been met" because, although the anesthesiologist disclosed to the patients the benefits, risks, and alternatives to the proposed anesthesia, he did not give the impression, at least to me, that any of this information was to be taken very seriously. He was giving them this information because the law said he had to do so. The Harris Survey revealed that 48% of the general public and 20% of physicians regard the primary purpose of consent forms to be to protect physicians from lawsuits. Harris, *supra* note 71, at Table 5-15.

79. Consent form on file in the office of the author.



inherent in those alternatives, the nature of the presentations—in one case a written form presented immediately prior to the procedure and in the other a written form accompanied by a nonspecific, rather off the cuff discussion with a physician—were not designed to enhance or test the patients' understanding of the material presented.

Another of the major issues relating to informed consent is the physician's ability and inclination to present information in a manner such that the patient will choose the alternative the physician thinks best regardless of what the patient might choose to do if the information were presented differently.

Cancer treatment presents the classic case of informed consent, especially when discussing alternatives. Joan Parks<sup>80</sup> is a sixty-two year old patient whom physicians diagnosed four years ago as having uterine cancer. The cancer was treated over the years with radiation therapy. During a recent routine visit, her oncologist, Dr. Adams, discovered that not only had her cancer recurred, but also that it had recurred in multiple organs. (Dr. Adams believed that the cancer was occurring at multiple sites rather than metastasizing from site to site.) He immediately consulted with Dr. Barnes, the radiologist who had performed the prior radiation therapy, and with Dr. Collins, another oncologist. The three then spoke with Ms. Parks together.

While Ms. Parks was still in the examining room, Dr. Adams told her of the recurrence of her cancer and of its serious nature. He explained to her that he thought she had two options—exteneration (surgical removal of her uterus, ovaries, birth canal, bladder, and colon) or chemotherapy. Dr. Adams quite carefully laid out most of the risks and benefits of the two treatment options.<sup>81</sup> Ms. Parks stated that she understood what Dr. Adams was saying and that she would choose treatment with chemotherapy. Among other things, Ms. Parks indicated that her daughter-in-law had had cancer and had been treated with chemotherapy. Ms. Parks said she knew that the side effects from chemotherapy were very serious, but that she did not want to undergo surgery and she did not want to wear urinary and colostomy bags.

Until that point, Dr. Barnes had been silent. After Ms. Parks expressed her wish to undergo treatment with chemotherapy rather than surgery, however, Dr. Barnes repeated at great length and in great detail the risks and side effects of chemotherapy. He said nothing concerning the risks of surgery.

Before the three physicians met again with Ms. Parks and her husband, they conferred alone. Dr. Barnes told Dr. Adams that he disagreed with

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80. The names of all parties have been changed to protect their identities.

81. For the sake of brevity, I am omitting most of the information Dr. Adams disclosed to Ms. Parks. Significantly, however, one of the risks Dr. Adams did not explain to Ms. Parks was what could happen to a patient iatrogenically or otherwise, during a hospital stay projected to last at least 30 days, which hers was.

Dr. Adams' assertion that chemotherapy was an option for Ms. Parks, and he stated that he would prefer that she have no treatment at all rather than to be treated with chemotherapy. Dr. Collins agreed with Dr. Barnes, and told Dr. Adams that she wanted him to "talk Ms. Parks out of chemotherapy."

A few minutes later, Ms. Parks, along with her husband, met with Dr. Adams, Dr. Barnes, and Dr. Collins in a conference room. Dr. Adams explained to them the nature of Ms. Parks' disease, and he outlined for them the options he viewed as feasible, adding this time to surgery and chemotherapy the option of no treatment.<sup>82</sup> Again, he explained the risks and benefits of each alternative.<sup>83</sup> Before anyone else could speak, Dr. Barnes once again reiterated the dangers and risks inherent in chemotherapy, and he told Ms. Parks that he would prefer her to have no treatment at all rather than chemotherapy. At that point, Ms. Parks said she would prefer surgery and a surgical date was set.

Dr. Adams fulfilled much of his duty to Ms. Parks in disclosing to her the risks and benefits of the alternative treatments feasible for her type of cancer.<sup>84</sup> Although no one ever attempted to test her comprehension of the information disclosed, Ms. Parks' comments and questions, based in part on her prior four year history with cancer, seemed to indicate that she understood the options presented to her.<sup>85</sup> Ms. Parks' first decision to choose treatment by chemotherapy was probably an informed one. Her change of mind, however, was more problematic. It followed two presentations by Dr. Barnes in which he clearly slanted information towards the choice he believed appropriate. In fact, he indicated that Ms. Parks' initial

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82. While the short-term survival rate for an individual in Ms. Parks' condition choosing surgery was better than that for a person choosing chemotherapy or no treatment, the five year survival rate for any of the options was the same—virtually zero.

83. Again, omitting the hazards associated with a prolonged hospital stay.

84. Theoretically, Dr. Adams could be subject to liability for breaching the duty to disclose if Ms. Parks were to suffer an injury during her prolonged hospital stay due to a risk associated with hospitalization which had not been explained to her; she would, of course, have to prove not only that the undisclosed risk materialized causing her injury, but also that a reasonable patient would have chosen to forego the surgery had the risk been disclosed. *But see* Scott v. Bradford, 606 P.2d 554, 559 (Okla. 1979) (in Oklahoma, causation is judged by subjective standard—would *this patient* have refused recommended treatment had undisclosed information been disclosed—as opposed to objective standard—would the *reasonable patient* have refused this treatment had undisclosed information been disclosed).

85. Patients suffering from a chronic illness seem to have a better understanding of their conditions and the alternatives available to them, probably due to their communication with health care providers over long periods of time where much that they are told is reinforced in later visits with their physicians. *See* Lidz & Meisel, *supra* note 74, at 385; II *President's Commission Report*, *supra* note 28, at 11. My own observations were consistent with that conclusion. It also seemed to me that those obstetrical patients who by late in their pregnancies had received regular prenatal care were quite well informed concerning their conditions and the alternatives available to them, again probably because of repeated contact with health care personnel that allowed repetition and reinforcement of important information.

choice was so inappropriate he would prefer her to choose no treatment rather than her treatment of choice.<sup>86</sup>

The scenarios I discussed above are primarily "outside-the-house"—anesthesia information provided at preadmission testing, usually (although not always as my acquaintance's situation illustrated) several days before admission, or treatment information discussed in the physician's office before the decision to treat is even made. I had been cautioned repeatedly that informed consent procedures are followed more closely—more information is provided, patients' comprehension is tested more—when patients meet with their private physicians who have known and treated them for years in the physicians' offices. While Ms. Parks' case may illustrate that point, the fact that she received more information did not guarantee better decisionmaking on her part. And clearly the preadmission anesthesia procedure did not foster informed decisionmaking.

Even assuming that informed consent procedures are followed more closely and the conversation between physician and patient is better in the private office, many patients do not have private physicians, and instead are treated in neighborhood clinics or emergency rooms. Even those patients who return to the clinic on a regular basis for continuing care often do not see the same physician at each visit. The notion that even private patients have long-standing, warm relationships with their kindly family doctors is becoming much less likely in our society where patients are highly mobile and more doctors practice in groups rather than as solo practitioners.

Furthermore, even if informed consent procedures are carried out better in the physician's private office, many important decisions must be made once a patient is hospitalized. The actual process of informed consent falls even shorter of its theoretical goals, however, once the patient is admitted.<sup>87</sup>

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86. The Harris Study reported that 75% of all physicians said they believed that they had a responsibility to try to persuade a patient to accept the "medically indicated" course of treatment. Harris, *supra* note 71, at Table 6-8. See *infra* text pages 421-25, 428-29 for a discussion of physicians' reluctance to let their patients make the "wrong" decision.

Physicians whom I observed were not always successful in getting patients to change their decisions, even if the physicians disagreed strongly with the patient's choice. In one scenario I observed, a patient with genital warts chose treatment by laser, necessitating the use of general anesthesia, because she wanted to feel nothing during the procedure. Her physician felt strongly that she should be treated with an acidic compound. Treatment with acid while painful, could be performed in the physician's office without anesthesia. The healing time following such treatment would be less—and also perhaps less painful—than that following laser surgery. In explaining the risks of the two treatments to the patient, the physician said *three* times, "I want you to understand that the risks involved with the treatment I recommend are bleeding and infection; the risks involved with the treatment you are choosing are bleeding, infection, and *death*." Each time he emphasized the word "death" (a risk because of the general anesthesia). Each time, the patient indicated that she understood the risks and that she opted for laser surgery under general anesthesia.

87. While patients may frequently acquire more information about their conditions and treatments once they are in-patients, Lidz and Meisel caution that the information patients acquire after admission, frequently from nurses, should not be confused with information

At least two reasons contribute to this shortcoming: first, the "status" of the in-patient, and second, the health care providers' inclination not to comply with informed consent formalities for "routine" procedures.

It is only natural that patients confined to a hospital bed, undergoing diagnostic tests or palliative or curative treatment, perhaps not wearing their own clothes, or in any event wearing "night clothes" as opposed to "street clothes," isolated from family, friends, and familiar environments, perhaps sharing that room with someone very ill, being ministered to by strangers, would feel more vulnerable than they would as out-patients. Not only are hospital in-patients reported to feel less autonomous than out-patients,<sup>88</sup> but also they are reported more likely to agree to recommended tests and procedures because they feel "not worthwhile" about themselves and deeply grateful to their physicians; consequently, they want to be "good."<sup>89</sup> In-patients may also fear abandonment by their physicians should they disagree with or reject the physicians' recommendations.<sup>90</sup>

The second reason for the further decline in the application of the informed consent procedures once patients are hospitalized is that so much of what occurs in the hospital is "routine" (at least to the providers), and therefore, the providers do not deem formal disclosure and consent requirements to be necessary.<sup>91</sup> The notion of routineness and lack of necessity to

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necessary to the patient for informed decisionmaking.

Nor, by and large, did patients understand it that way. More important, it did not necessarily include the full information that the informed consent doctrine requires for patient decisionmaking. It emphasized heavily the nature of the procedure, but the purposes, risks (aside from some information about discomforts), benefits, and alternatives were completely ignored.

Lidz & Meisel, *supra* note 74, at 373.

In many instances, by the time a patient is admitted to a hospital, the decision to proceed with surgery has been made. *Id.* at 329. See also Lidz *et al.*, *Barriers to Informed Consent*, 99 Ann. Internal Med. 539, 540 (1983).

88. See Lidz & Meisel, *supra* note 74 at Table 1.

89. Thompson, *Psychological Issues in Informed Consent* in III President's Commission Report, *supra* note 28 at Appendix H.

90. Katz, *Physician-Patient Encounters "On a Darkling Plain"*, 9 W. NEW ENG. L. REV. 207, 210 (1987).

91. Lidz & Meisel, *supra* note 74, at 393. Lidz and Meisel, in their study, distinguished between surgery, a "rare" event in the medical course of patients and "frequent" events such as the administration of medication. They found that there was greater patient participation in decisionmaking involving the "rare" as opposed to the "frequent" decisions. *Id.* at 335. But see Handler, *supra* note 1, at 1007-08 (distinguishing between surgeon's view of informed consent process ("informed consent is a legally-imposed obstacle that must be negotiated" because of one time nature of procedure to be performed) and renal specialist's view when working with chronically ill renal dialysis patients (informed consent is process of explaining, persuading, sharing of information, providing patients with power, and sharing decisionmaking because dialysis is ongoing process that can be successful only when patients understand and participate in their care). Handler's view of the informed consent process as it relates to chronically ill patients is similar to my own observations of chronic care patients. See *supra* note 85.

Lidz and Meisel also found differences in types of decisionmaking once patients were

make disclosure or seek consent for many procedures performed on patients once they enter hospitals is reinforced by the admitting process. Upon entering the hospital, while in the Admissions Office under the supervision of an admitting clerk, the patient signs a form "authoriz[ing] Medical Center personnel to administer care and treatment to me and to perform diagnostic procedures, tests, x-rays, surgical procedures or other treatment considered necessary and advisable by the physicians who attend me."<sup>92</sup> The patient also acknowledges, of course, that "the practice of medicine and surgery is not an exact science, and . . . that no guarantees have been made to me concerning the results of my treatment."<sup>93</sup> What procedures are "routine," however, may exist in the eye of the provider. For example, on the medical side of a patient's care, the physician treating a patient may seek additional consent before a lumbar puncture is performed. On the surgical side, however, the physician may not seek the extra consent because *the physician* is more accustomed to treating patients invasively.<sup>94</sup> More procedures are also deemed to be routine in the intensive care unit and in the trauma room, again evidencing perhaps more the day-to-day aggressiveness of the intensive care and trauma physicians than the actual routineness of the procedure.<sup>95</sup>

#### IV. PHYSICIANS' OBJECTIONS AND PATIENTS' RESPONSIBILITIES

When I discuss with physicians the idea of informed consent, both its substance and the manner in which it is carried out, their responses to me

hospitalized based on the nature of the treatment (for example, surgery lends itself to a greater focus on particular treatment as opposed to a medical problem that poses more complexity and less certainty), and on who is in charge of a patient's care (for example, one chief resident versus various members of a team, and a highly versus loosely structured daily routine for that team). Lidz & Meisel, *supra* note 74, at 336-39, 339-42. See also Lidz *et al.*, *supra* note 87, at 542-43.

92. Consent form on file in the office of the author. An admitting officer indicated to me that this form was considered to be a "general consent form" as opposed to an "informed consent form." She said that "informed consent forms" are signed in the physician's office or during preadmission testing when the procedures to be performed, along with the risks and benefits of and the alternatives to the procedures are explained to the patients. See *supra* notes 75-78 and accompanying text for a discussion of the informed consent process at the time of preadmission testing. The "general consent" does not have to be "informed," she said, because the procedures consented to—tests, x-rays, even some surgical procedures—are deemed to be routine.

93. Consent form on file in the office of the author.

94. I was told that lumbar punctures are also considered "routine" for pediatric patients even if they are not so considered for adults, because pediatricians need the lumbar puncture's refined diagnostic capabilities to aid in diagnosing meningitis.

95. While it makes sense that the disclosure and consent process often is foregone in the trauma room under a defense of medical emergency, it is also foregone even when the emergency has passed. I observed one instance in which a physician gave a pregnant woman little choice in deciding whether to have her pelvis x-rayed. The trauma surgeon told me that while he would explain the necessity of the x-ray to the patient, if she were to refuse then he would order it against her wishes. He said that the woman, not the fetus, was his patient, and that the risk to the fetus from one x-ray is minor compared to the risk to the patient if her pelvis were broken.

are consistent:<sup>96</sup> patients neither understand nor remember what they are told, in large part because the information to be conveyed is too technical for patients to grasp and is knowable and understandable only by physicians after years of schooling and training; testing patients' understanding of what they have been told is too time consuming and too expensive in terms of the physician's additional duties to this patient and others; patients want physicians to make decisions for them; physicians can convince almost any patient to do what the physician thinks is best for the patient.

Each of these responses is based on a belief that, despite the law's expressed position that patients are autonomous beings who deserve the right to make decisions concerning what will and will not be done to them, patients are unable to make those decisions in a knowing, competent manner.<sup>97</sup> Therefore, the law must protect them. It attempts to protect patients' decisionmaking powers through the doctrine of informed consent by requiring physicians to disclose to patients the benefits, the inherent

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96. They are not necessarily consistent, however, with responses physicians gave in the Harris Survey. See *supra* note 74 and accompanying text, and *infra* note 129 and accompanying text for examples of differences and similarities between physicians' responses as individuals in private conversations to issues relating to informed consent and physicians' responses to similar issues when asked during the Harris Survey.

97. For example, even physicians in the Harris Survey said that only 79% of their patients were able to understand most aspects of their treatments and conditions even if the physicians devoted reasonable time and effort to the explanations. Harris, *supra* note 71, at Table 2-18. Seventy-five per cent said it is their responsibility to persuade patients to accept a medically indicated course of treatment when patients disagree with their physicians' recommendations. *Id.* at Table 6-8. See *infra* text pages 421-25, 428-29 for discussions concerning physicians' unwillingness to allow their patients to make the "wrong" decisions.

Even though the law expresses the belief that patients have the right to be autonomous decisionmakers, what the law has done, rather than what the law has said, supports physicians' beliefs that patients are unable to make appropriate decisions concerning their health care. As Professor Katz wrote,

Courts have not acknowledged their failure to place effective authority in patients' hands. Though judges have felt morally bound to announce that patients ought to be enabled to guide their medical fate, they considered this position unsatisfactory in application and subjected it to extensive modifications. That such modifications significantly tampered with the basic posit of patients' self-determination and that altogether judicial commitment to individual decision-making was not very firm, were never clearly admitted. Judicial concern about patients' capacity to make medical decisions and about the detrimental impact of disclosure on patients proved to be more influential than self-determination in shaping the informed consent doctrine, even though the validity of these concerns rests more on conjecture than fact.

Katz, *Informed Consent—A Fairy Tale? Law's Vision*, 39 U. PITT. L. REV. 137, 141 (1977). The President's Commission also noted that

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.

1 *President's Commission Report*, *supra* note 28, at 31 n.49.

risks, and the alternatives to any proposed treatment. Since, however, physicians believe that patients are unable to understand such information or to make autonomous, rational, "right" decisions, once physicians have made such disclosures our inquiry stops. Patients' rights have been protected; they have been "informed." Now, if physicians act in a parentalistic manner—phrasing information for patients in such a way that their decisions are virtually foreordained, or actually making decisions when patients say "I'll do anything you suggest, doctor"—it is because that is what is best for the patient.

The "protection" afforded patients by the law's unwillingness to require that physicians give patients the opportunity to comprehend the information on which their decisions are ultimately based, and by physicians' beliefs that patients cannot understand the information provided or want physicians to make most decisions for them actually results in a self-fulfilling prophecy that patients not only cannot but will not take responsibility for their decisions and their actions. Correlative to the *right* of individuals to be autonomous and self determinative is the *responsibility* to be so.<sup>98</sup> And along with that responsibility goes the expectation that patients will be held responsible for their decisions, even if their decisions lead to less than favorable results. If physicians make adequate disclosure to patients about their medical conditions and treatment alternatives, and if patients comprehend that information and make a decision based on it, patients should not be able to recover in medical malpractice actions against physicians, absent, of course, injury caused by physician negligence in performing the procedure.

One can, of course, imagine scenarios in which patients will allege they were misinformed, that their comprehension of the material disclosed was not adequately tested, that the manner in which the material was disclosed caused them to forego necessary treatment or caused them mental or emotional distress, or that physicians "allowed" them to make "wrong" decisions contrary to the physician's best medical judgment. The issues of misinforming, failing to test comprehension, or disclosing in a negligent manner are all questions for the finder of fact, just as failure to disclose is now.<sup>99</sup> The question of physician liability for failing to dissuade patients from the decisions they have made is, however, a different issue. While

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98. Requiring patients to exercise their right of self determination and to take responsibility for the decisions they make does not mean that patients must act by themselves without encouragement, assistance, or support from others. In fact, such support is crucial to patients making decisions. See *infra* notes 144-145 and accompanying text for further discussion on this point.

99. Understandably, physicians worry that a finder of fact—especially a jury—will be swayed in its decision by a sympathetic plaintiff who alleges a medical injury. That fear may be justified. Nevertheless, the fear should not be greater than it is in any case where an injured plaintiff sues an allegedly negligent defendant. The fact that *some* juries may act out of sympathy does not mean that *all* injured patients should be precluded from suing their physicians.

physicians may have a duty to ensure that patients understand the information provided, and if requested, to offer their own recommendations, to say that physicians have the right to override patients' decisions should they believe those decisions to be incorrect, and that if physicians fail to do so they can be held liable for injury resulting from the patients' decisions would be absolutely inconsistent with the view of patients as autonomous, self determining individuals.<sup>100</sup>

Either patients are autonomous and capable of making decisions concerning their own medical care or they are not. If they are not, or if that right is not of the great importance we articulate, we need to stop imposing on the medical profession and on patients criteria which are costly, time consuming, and sometimes frightening. If patients are autonomous and capable of making decisions concerning their health care, and if that right is important to us as individuals and as a society, we must act in a way that encourages and enables patients to exercise that responsibility. The current informed consent facade does not protect that right or encourage that responsibility. We need to create a new self-fulfilling prophecy.<sup>101</sup>

*Patients neither understand nor remember what they are told.*

When advised of the duty of disclosure pursuant to the informed consent criteria, physicians often say "How can I possibly teach my patients all

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100. See *Truman v. Thomas*, 27 Cal. 3d 285, 295-96, 611 P.2d 902, 908, 165 Cal. Rptr. 308, 314 (1980). Even though a physician has a duty to disclose to patients material risks of failing to consent to recommended tests or treatment, a "suggestion that a physician *must* perform a test on a patient who is capable of deciding whether to undergo the proposed procedure, is directly contrary to the principle that it is the *patient* who must ultimately decide which medical procedures to undergo." *Id.*

101. One reason that informed consent rules do not better protect the patient is, of course, the courts' and physicians' beliefs that patients are incapable of understanding the material they need to consider in making choices concerning their health care, and incapable of making such decisions in any event. See *supra* note 97 and accompanying text. Another reason, however, is that lawyers and judges with no direct experience in health care (except perhaps as patients themselves) framed the informed consent rules to be applied by physicians with no direct experience in law (except perhaps as parties to suits). The only role patients played in the development of the informed consent doctrine was as initiators of the suits which raised the issue. Ideally, for the principles of informed consent to be best effectuated, the standards should be developed in a forum where all those concerned with and experienced in the law, medicine, and patients' interests are represented. While the legislature might be one such forum, I really have in mind a smaller, more representative group—perhaps a specially appointed task force made up of lawyers, doctors, and laypersons/patients—whose sole purpose would be to develop informed consent guidelines. I would further recommend that the lawyer and lay members of the task force spend a significant amount of time in a health care setting watching the day-in, day-out delivery of health care with a special focus on the interrelationship between health care providers and patients in a decisionmaking context. In order to develop realistic rules, the rulemakers must observe—and understand—the realities of the settings in which the rules will be applied. See Applebome, *Judge Rules Quadriplegic Can Be Allowed to End Life*, N.Y. Times, Sept. 7, 1989, at A-16, col. 1, 4 (reporting that judges attending first National Conference of the Judiciary on Bioethical Issues being held in September, 1989, would hear medical and legal experts discuss "some of the vexing legal issues posed by advances in medicine and science").



that I know after twenty or more years of formal education and subsequent years of training and practice? They need to be doctors themselves to understand everything about their disease or injury and the possible treatments available."<sup>102</sup> The objective of the duty to disclose rule, however, is not to turn every patient into a physician, but rather to give patients the basic knowledge they need to have when they make decisions.<sup>103</sup> The *Natanson* court urged physicians to use "*language as simple as necessary*" when making disclosures to patients,<sup>104</sup> and the *Cobbs* court specifically stated that the duty to disclose "does not extend to a lengthy polysyllabic discourse on all possible complications."<sup>105</sup>

Physicians argue that even if patients could understand what physicians tell them, the human capacity to attend to conversation and to remember what has been said is limited at best.<sup>106</sup> A discussion between physician and

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102. Physicians responding to the Harris Survey indicated their belief that only 79% of their patients were able to understand most aspects of their treatments and conditions even if physicians devoted reasonable time and effort to the explanation. Harris, *supra* note 71, at Table 2-18. McKinlay, however, in a study of obstetrical patients, discovered that physicians vastly underestimated their patients' ability to understand medical terminology related to their conditions. McKinlay, *Who is Really Ignorant—Physician or Patient?*, 16 J. HEALTH & SOC. BEHAV. 3, 8-9 (1975).

103. In a study of geriatric patients' capacity to consent to participation in research projects, Stanley *et al.* found that geriatric patients, although comprehending less than other patients about research protocols explained to them, make decisions equally reasonable to those of younger patients. Stanley *et al.*, *The Elderly Patient and Informed Consent*, 252 J.A.M.A. 1302, 1305 (1984). The researchers concluded from their findings that "[i]t may be that only a basic awareness of relevant information is necessary to make reasonable decisions. . . ." *Id.*

104. *Natanson v. Kline*, 186 Kan. 393, 410, 350 P.2d 1093, 1106 (1960).

105. *Cobbs v. Grant*, 8 Cal. 3d 29, 244, 502 P.2d 1, 11, 104 Cal. Rptr. 505, 515 (1972). As the President's Commission noted,

Professionals should recognize, and lawyers and courts should perhaps be reminded, that patients' interests are not well served by detailed technical expositions of facts that are germane neither to patients' understanding of their situations nor to any decisions that must be made. Such recitations are not legally required, nor should they be. Overwhelming patients with a mass of unintelligible technical data that they are ill-prepared to comprehend or use, particularly at what may be a stressful time, can be as destructive of the communication process and its goal of enhanced understanding as giving too little information is. Similarly, reciting "all the facts" in a blunt, insensitive fashion can also destroy the communication process, as well as the patient-professional relationship itself. The professional's goal should be a tactful discussion, sensitive to the needs, intellectual capabilities, and emotional state of the particular patient at that time, in terms that the patient can understand, assimilate, and work with as part of the ongoing decisionmaking process.

I *President's Commission Report*, *supra* note 28, at 71.

106. See Epstein & Lasagna, *Obtaining Informed Consent*, 123 ARCH. INTERNAL MED. 682, 684-85 (1969) (study showing comprehension, maximum retention of information by patients, and ability to utilize information intelligently most likely to occur when presentation of data is brief, as opposed to long and detailed); Muss *et al.*, *Written Informed Consent in Patients with Breast Cancer*, 43 CANCER 1549 (1979). Of 100 breast cancer patients, 0 to 24 months after the beginning of chemotherapy, only 57% of adjuvant therapy patients could correctly name the drugs they were taking and only 22% of advanced therapy patients could

patient concerning disease or injury, the need for treatment, and the risks, benefits and alternatives attendant to the patient's condition and proposed treatment can be extremely stressful. Given this added stress, the patient's ability to attend and remember may be even more limited.<sup>107</sup>

In fact, some physicians will find it difficult to convey technical—or even nontechnical—information to some patients.<sup>108</sup> Moreover, the attention

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do so; advanced therapy patients, however, had more complicated drug regimens than adjuvant therapy patients. Furthermore, patients in both groups who took the drugs orally had better recall of drug names; only 29% of the adjuvant therapy patients *correctly* responded that their therapy was intended to cure their disease, and 35% of the advanced therapy patients *incorrectly* responded that their treatment was intended to cure their disease. *Id.* at 1552-53. *See also* Robinson & Merav, *Informed Consent: Recall by Patients Tested Postoperatively*, 22 ANN. THORACIC SURG. 209, 210-12 (1976) (4 to 6 months following cardiac surgery, patients, all of whom had chronic heart disease, were previously hospitalized for diagnostic and therapeutic procedures, and, according to their doctors, had been well informed concerning their planned surgery and had understood the information given, had primary recall ranging from 10% to 43% and secondary (assisted) recall ranging from 23% to 51% on 6 categories of information relating to their surgery (diagnosis and nature of illness—33% primary, 46% secondary; proposed operation—26%/51%; risks of operative procedure—35%/42%; potential complications—10%/23%; benefits of proposed operation—29%/47%; alternative methods of management—43%/43%)). The patients' recall may have been dulled, because by the time their recall was tested (4 to 6 months postoperatively), their surgical recovery was complete and successful. It is also possible that the researchers' premise that the information given to the patients and their understanding of it were good was a misjudgment.

107. "Poor recall ability, however, may have little bearing on [a patient's] ability to give informed consent." Stanley *et al.*, *supra* note 103, at 1302. In their study, Stanley *et al.* found that neither intelligence nor attention span accounted for poorer comprehension scores among elderly patients as opposed to younger patients. *Id.* at 1305.

108. Communication difficulties between physician and patient often relate to far more than the complexity of the information to be conveyed. For example, as Thompson points out, patients, when given a list of possible risks that could accompany a given procedure, may have problems understanding the likelihood of one of the risks occurring versus the likelihood of two or more occurring, *i.e.*, patients may "understand" the information disclosed but misconstrue its importance. Thompson, *supra* note 89, at 96, 98. Thompson also states that linguistic expressions of probability cause problems; in communicating among themselves, physicians often mean different things when using terms such as "likely," "probable," "expected," or "moderate" benefits or risks. *Id.* at 97, *citing* Bryant & Norman, *Expressions of Probability: Words and Numbers*, 302 N. ENG. J. MED. 411 (letter) (1980). Without having numbers attached to expressions of probability, patients may not understand the probabilities of occurrence of various risks and benefits. *Id.* at 96-97.

Other causes of communication difficulties may be more personal. Men and women may communicate differently, *see, e.g.*, C. GILLIGAN, IN A DIFFERENT VOICE (1982), or react to each other differently, *see* McKinlay, *supra* note 102, at 6. In the McKinlay study, two medical doctors, one male and one female, evaluated actual and perceived comprehension of frequently used medical terms by lower working class users and underusers of obstetrical services. While in general the two evaluators agreed on the subjects' understanding of the study's terms, when they disagreed the male evaluator consistently rated the subjects' understanding lower (*i.e.*, less evidence of understanding) than did the female evaluator. Members of different cultures, races, and ethnic groups may communicate differently. *See* Hahn, *Culture and Informed Consent: An Anthropological Perspective*, in III President's Commission Report, *supra* note 28, App. F. For example, the hospital in which I observed served a large Hispanic population. It is apparently a widely held belief within that community that if a woman is sterilized by

span and memories of patients will vary. But, feared difficulty in communication and short patient attention spans are not sufficient reasons to fail to attempt to communicate with patients in the most effective way possible.

In addition to or in lieu of conversations with their patients, some physicians give patients brochures or videotapes describing the patient's condition and the proposed treatment. While generally better than nothing, this alternative has a number of drawbacks. Neither the brochure nor the videotape will be individualized to any one patient, some patients do not read well or have difficulty comprehending what they read, and some patients will not use the educational materials because of fear or denial.<sup>109</sup>

Another alternative available to physicians in informing patients is to tape record the physician's conversation with the patient.<sup>110</sup> Ideally, the physician would explain to the patient in that conversation the patient's condition and the alternative treatments available, with the risks and benefits attendant on each. Either during or at the end of the conversation, the

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way of tubal ligation, her fallopian tubes will "grow back together again" in five years. If that were so, of course, tubal ligation would be a temporary as opposed to a permanent method of preventing conception, and might be a method of choice for women who do not want to be pregnant presently but may want to conceive a child at a later date. An effort was made to ensure that all the obstetrical house officers knew of this community belief so they could reinforce with these women in very specific terms that once a tubal ligation is performed, the tubes will not grow back together again. I witnessed several of these conversations, and invariably the women patients expressed great surprise at that revelation. Upon hearing the information, several chose not to undergo tubal ligation, but instead to use alternative, temporary forms of birth control. In some cases, age, level of education, and socioeconomic status may also impact on communication between physicians and patients. See Stanley *et al.*, *supra* note 103, at 1305 for a study concluding that while elderly patients show significantly poorer comprehension of consent information than do younger patients, the "reasonableness" of their choices does not differ from that of younger patients. See also McKinlay, *supra* note 103, at 9 (suggesting that obstetricians' consistently underestimating level of word comprehension of lower working class patients could be a result of socio-economic differences between doctors and patients). For excellent discussions and thorough analyses of communication between physicians and patients, see J. KATZ, *supra* note 24 and responses to Dr. Katz's book in *Symposium: Perspectives on J. Katz, The Silent World of Doctor and Patient*, 9 W. NEW ENG. L. REV. 1-226 (1987); see also Kaufmann, *Medical Education and Physician-Patient Communication*, III *President's Commission Report*, *supra* note 28, App. I; Oratz, *Achieving Aesthetic Distance: Education for an Effective Doctor-Patient Relationship*, in III *President's Commission Report*, *supra* note 28, App. J.

109. The problem posed by patients who refuse to utilize understandable material to which they have access is a problem for the patient, not the physician. Patients must be encouraged and expected to take advantage of educational material presented to them, just as they must be expected and encouraged to make decisions. However, just as treatment cannot be administered to patients contrary to their will, patients cannot be forced to use information available to them, no matter how important or how clearly stated the information may be.

110. For a review of others' suggestions to improve the informed consent process, see I *President's Commission Report*, *supra* note 28, at 115-28; Andrews, *supra* note 28, at 163, 180-217; Carnerie, *Crisis and Informed Consent: Analysis of a Law-Medicine Malocclusion*, 12 AM. J. LAW & MED. 55, 89-96 (1986); Note, *Informed Consent: From Disclosure to Patient Participation in Medical Decisionmaking*, 76 NW. U. L. REV. 172, 192-95 (1981). See also *infra* note 118.

physician would afford the patient the opportunity to ask questions. When the conversation ended, patients would be given the tape to take home so that patients could review the tape whenever and as often as they wanted, alone or with family or friends present, in a more relaxed atmosphere. If questions arose, or if the patients did not understand parts of the conversation with the physician, they could call the physician and get further elaboration or clarification.<sup>111</sup>

The physician also could keep a copy of the tape as part of the documentation of the patient's treatment. The fear of litigation that grips physicians leads them to document patients' charts extensively. Much of that documentation, however, is not related to patient care, and is not intended to inform and guide other caretakers in their work with patients, which is the traditional purpose for documentation. Instead, the purpose of this extensive documentation is to protect the physician should the patient have a bad result and sue.

Written documentation in a chart, however, is of questionable effectiveness. Whether the physician writes a detailed description of the conversation with the patient in terms of diagnosis and treatment or merely notes "Discussed with patient her medical condition and explained to her the risks, benefits, and alternatives related to various treatment plans," it is still the physician's word against the patient's when she says that, although she signed the consent form, the physician really had not explained to her the risks, benefits, or alternatives.<sup>112</sup> One physician told me that documentation of disclosure in the chart was sufficient because "After all, the documentation was not done with going to court in mind." My own impression, however, is that "going to court" is frequently in mind when physicians make chart notes.<sup>113</sup>

The plan to tape record conversations between physician and patient and to provide a copy of the tape to a patient is not without its drawbacks. Some patients and perhaps more physicians may be reluctant to speak in front of a tape recorder. Some patients will not have access to a tape recorder to replay the tape once they leave the physician's office. Again, because of fear or denial, some patients will ignore the tape and never play it. The tape recording process has its greatest potential for effectiveness when the physician sees the patient as an out-patient, and then sends the

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111. Robinson & Merav report that since January, 1975, tape recordings have been made of informed consent conversations with their cardiac surgery patients. Robinson & Merav, *supra* note 106, at 209. They do not indicate, however, whether patients were provided with the tapes for reinforcement or for recall of the informed consent information following the initial conversations.

112. But see *supra* notes 23 and 73 for examples of state statutes providing that a consent form signed by or on behalf of a patient that meets the disclosure requirements of state law creates a rebuttable presumption that the informed consent requirements were actually met.

113. Forty-eight per cent of the general public and 20% of the physicians interviewed in the Harris Survey indicated that "[t]he primary purpose of consent forms is to protect physicians from lawsuits." Harris, *supra* note 71, at Table 5-15.

patient home to return at a later date for the proposed treatment.<sup>114</sup> Use of tape recorders would not be feasible or effective with in-patients when the proposed treatment is to occur immediately. It might be moderately effective with in-patients for whom the proposed treatment is scheduled in the future, but even then, the stressful atmosphere of the institution would diminish its effectiveness.

*Testing patients' understanding of what they have been told is too resource intensive.*

There is no question that testing patients' understanding of the knowledge conveyed to them about their condition and treatment alternatives is time consuming, and therefore costly. Testing raises the cost of physicians' services to individual patients, and it reduces the number of patients the physicians can see, thereby denying or delaying physicians' services to other patients.<sup>115</sup>

One reason that testing patients' comprehension is so resource intensive is that testing comprehension necessarily implies that if patients are found not to comprehend what they have been told, physicians are under a further obligation to continue to communicate with patients until patients do understand. What of the adult, competent patients who will not comprehend what is being told to them despite repeated explanations, either because they are intellectually incapable of grasping the information or because they are psychologically incapable for reasons such as denial? These patients by definition cannot give "informed consent" to the proposed procedure.

In the case of the noncomprehending patient, the law could say that if the patient still fails to comprehend after the information giver has provided a certain quantum of information and has tried certain methods of explanation, the procedure may be performed and the information giver not be held liable should the patient, or someone on the patient's behalf, later raise a question of uninformed consent. Such an approach, however, violates our concern that patients be able to make their own decisions. Moreover,

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114. For a discussion of medical decisionmaking occurring along a continuum of time rather than at any particular moment see Lidz *et al.*, *supra* note 87, at 540.

115. Twenty-one per cent of physicians polled in the Harris Survey believed that the time spent discussing diagnosis, prognosis, and treatment with patients could be better spent in physically taking care of patients. Harris, *supra* note 71, at Table 5-15. The Harris Survey found that physicians' attitudes concerning informed consent were influenced by their workload, the composition of their patient population, the recency of their training, and their practice setting. As the number of patients treated per hour increased, so did physicians' belief that time spent talking with patients could be better spent physically treating them; such a belief also was prevalent as the percentage of physicians' patients who were old and ill increased. *Id.* at 161. More recent medical school graduates and physicians practicing in a hospital setting were more likely to believe that the time spent providing treatment information to patients is essential, and would not be better spent by physically caring for patients. Also, as the percentage of patients perceived to be capable of understanding treatment increases in a physician's practice, the more likely physicians are to believe that time spent talking with patients is valuable, and not necessarily better spent physically treating them. *Id.* at 162.

that approach also raises a serious problem for physicians, who, at the time of treatment, must determine when a sufficient attempt has been made in terms of both quantity of information and procedure of informing, to inform patients of what they need to know in making medical treatment decisions.

An alternative approach is to treat noncomprehending patients similarly to incompetent patients; *i.e.*, along with providing the pertinent information to the patient, physicians might also talk at the same time to another person of the patient's choice. There is always a possibility, of course, that the person chosen by the patient will comprehend no better than the patient, and admittedly we must draw the line somewhere and recognize that some patients and even their surrogates will not understand what is happening to them or how it is going to happen. Before we draw that line, however, we must try to give patients the information they need to make the decision, and if they are incapable of understanding the information, we must offer protection to patients by providing the information to others as well.<sup>116</sup>

It is not a bad idea to have another person of the patient's choosing present at *any* information giving session. Two people may understand and remember better than one. Two people can discuss the information presented, clarifying some of it for themselves or seeking clarification of that which they do not understand, and the nonpatient can provide support and guidance for the patient. A patient who understands better may also be more compliant during treatment and recovery, and therefore may recover faster resulting in a better overall outcome for patient and physician.<sup>117</sup>

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116. Assuming that a patient and the patient's surrogate both are incapable of understanding the information provided, the patient clearly needs further protection in making health care decisions. While the analogy of court appointed guardians for persons incompetent to make decisions may come to mind, we should first consider less cumbersome and less costly alternatives. For example, hospitals, or state departments of health or public welfare might employ trained patient ombudspersons who *could* understand the information provided by physicians, who *could* frame questions on behalf of the patient, and who *could* help patients make decisions. The ombudsperson must be an independent agent provided for the patient, not employed by a physician. For a similar situation see *infra* note 121 and accompanying text.

117. Stone estimates that "one third to one half of all patients fail to follow fully the treatments prescribed for them." Stone, *Patient Compliance and the Role of the Expert*, 35 J. Soc. ISSUES 34, 36 (1979). Obviously, when patients fail to comply, they do not receive the full benefit of their treatment; patients may suffer recurrences of infections, drug overdoses, excessive responses to one drug because of underutilization of another, or an incorrect evaluation of the efficacy of a treatment regimen because undetected noncompliance may lead to misdiagnosis or errors in evaluating the new treatment. *Id.* at 36. Patients are more likely to adhere to directions about their care when necessary information is effectively transmitted to them, and when their interaction with physicians is satisfactory. *Id.* at 37-39. Stone suggests that in order to increase patient compliance, health care providers should explore patients' situations not only as to their medical conditions, but also as to their ability to receive recommendations and follow through on treatment. The more the patients are involved in this process, the more compliant they will be. *Id.* at 54.

Stone also suggests that in order to anticipate patients' difficulties in utilizing the

Assuming we choose to test comprehension, how might that be done? Physicians could ask patients to explain their understanding of their condition and the alternative treatments available to them. Or patients could be asked to write out their understanding of what the physician has explained, in essence drafting their own consent forms.<sup>118</sup> Problems will

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information they are given, health care providers need sufficient knowledge of human behavior and its variations, such as impediments in language, vocabulary, or conceptual understanding; differences in expectations relating to desirability or possibility of outcomes; differences in role expectations relating to rights, duties, and responsibilities; and failure of reception because of emotional states like stress, frustration, or insults to the patients' self-esteem. *Id.* Finally, Stone suggests that health care providers must understand the process of communication, and must develop the necessary skills to ensure that patients hear and comprehend what is being done. *Id.*

Egbert *et al.* report that a group of intra-abdominal surgical patients given special instructions prior to surgery concerning the type and duration of pain they could expect following surgery and nondrug related techniques for controlling the pain (for example, deep breathing, relaxation, special techniques for turning in bed), required only one-half the narcotics, and were released from the hospital 2.7 days earlier than a control group of similar patients who had received no such instruction. Egbert *et al.*, *Reduction of Postoperative Pain by Encouragement and Instruction of Patients*, 270 N. ENG. J. MED. 825, 825-27 (1964).

Handler suggests that although informed consent has generally failed in the health care context, there are certain specific areas in which it has succeeded. Handler, *supra* note 1, at 1012. One of those areas is in the care of the chronically ill patient requiring kidney dialysis. *Id.* at 1005-08. Handler believes that the doctrine has been successfully implemented in chronic care cases, because it is to the advantage of both physicians and patients to have patients understand and use information to care for themselves, a situation giving rise to better health for the patient and a better result for the physician. *Id.* at 1005-08. It would seem, therefore, that if autonomy, self-determination, and respect for the individual patient are not incentives enough to cause doctors to involve their patients in decisionmaking, other incentives, such as greater compliance with directions, faster recovery, and fewer malpractice suits would be adequate incentive.

Nedelsky argues that persons tend to be rewarded or to feel successful when they do what others wish, but that such compliance is not autonomy. Nedelsky, *supra* note 1, at 24. In general, that is true. In the health care context, however, if patients are given information about *what* they are being asked to do and *why* they are being asked to do it, and then are afforded the opportunity to ask questions concerning the directions and to make decisions based on the information given and answers received, compliance would be the result of autonomous decisionmaking, and the reward—to both patient and doctor—would be the possibility of better and faster patient recovery.

For further discussion of the effects of disclosure and nondisclosure of information on factors such as patient compliance and recovery, see I *President's Commission Report*, *supra* note 28, at 99-102; Lidz *et al.*, *supra* note 87, at 540; Muss *et al.*, *supra* note 106, at 1555-56; Rockwell & Pepitone-Rockwell, *The Emotional Impact of Surgery and the Value of Informed Consent*, 63 MED. CLINICS OF N. AM. 1341, 1342, 1345-46, 1349 (1979); Stanley *et al.*, *supra* note 103, at 1305-06; Wilson, *Behavioral Preparation for Surgery: Benefit or Harm?* 4 J. BEHAV. MED. 79, 96-97 (1981).

118. Miller and Willner suggest a two part consent form in an experimental setting, one part of which would be a written "quiz" testing the subjects' understanding of information conveyed to them. Miller & Willner, *The Two-Part Consent Form: A Suggestion for Promoting Free and Informed Consent*, 290 N. ENG. J. MED. 964 (1974). Questions that the authors suggest, paraphrased here, include the following: what benefit, if any, will you receive from the treatment?; what alternative treatments are available?; are there any dangers to this

naturally arise because some patients have poorly developed verbal and oral articulation skills, or some patients will be so anxious that they cannot respond accurately, but the fact that the proposed system will not work in all cases does not mean that we should not try it where it might work.

Obviously, testing patients' comprehension—having patients explain their understanding of the material presented to them, and having physicians re-explain to noncomprehending patients and/or their representative the information needed to effectuate an informed consent—will be costly to physicians and patients in terms of time and money. We need not assume, however, that the giving of information to patients and the testing of comprehension must be done by physicians. There are alternatives, particularly in specialty areas. For example, a physician or group of physicians specializing in oncology could utilize the services of a specially trained nurse or medical social worker who, after the physicians' initial conversation with patients about their conditions and available treatments, could then assume further responsibility for testing the patients' understanding of the information previously conveyed, for helping patients to frame appropriate questions about their health care, for clarifying misconceptions, and for acting as an intermediary between patient and physician should more information be needed or required.

Some will object to this proposal because it removes the explanation of medical matters from the one who has the particular expertise in the area.

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procedure?; if so, what are they?; how long will you be in the hospital?; what will happen if you decline this treatment? *Id.* at 965. Such a quiz could easily be adapted for use with patients in a nonexperimental setting. Miller and Willner believe that not only would such a form give patients more time to consider their actions and increase interaction between patients and providers, but also that patients' responses to the quiz could help the information provider assess the clarity of the information provided. *Id.* at 966.

Grabowski, O'Brien, and Mintz have developed what they refer to as "well structured information forms" with correlated multiple choice items to increase the likelihood that the subjects taking part in their research understand consent material, and that the consent is demonstrable. Grabowski, O'Brien, & Mintz, *Increasing the Likelihood that Consent is Informed*, 12 J. APPLIED BEHAV. ANALYSIS 283 (1979). Within their consent material, they include a description of the consent procedure, a statement of the study's purpose, a description of the experimental procedure and alternatives, and a statement indicating that the subject can withdraw from the study at any time. Additional features which the authors believe contribute to providing information effectively include clear section headings (for example, "drugs you may receive"), use of familiar language ("drink" rather than "ingest"), and clear summary statements. The provision of this information is followed by a multiple choice format in which all questions must be answered correctly if an individual is to be considered a subject. Subjects making incorrect responses are required to reread relevant portions of the consent material. *Id.* Retesting 6 weeks following the information-giving process showed good patient recall, with all patients answering correctly 75% to 100% of the questions asked. *Id.*

Although the Miller and Willner, and Grabowski, O'Brien, and Mintz "quizzes" present interesting possibilities for testing patient comprehension of information provided, even with such formal testing mechanisms patient comprehension may manifest itself as less than optimal because of "test anxiety." Whether because of such anxiety or poor comprehension itself, however, such quizzes might help to identify deficiencies in patients' understanding of information provided and to enable information providers to correct those deficiencies.



Yet physicians are quick to concede that they do not believe they have the time to carry on these extended conversations, and, at least in principle, society demands an informed patient. Furthermore, at least one study has found that patients to whom chemotherapy was explained by personnel other than or in addition to doctors believed that they had received more adequate instruction than did those patients for whom the doctor was the sole informant, and they exhibited greater comprehension of the information disclosed than did those patients informed solely by the doctor.<sup>119</sup> The study's authors hypothesized that those patients provided with information by alternative informants were better informed because patients are likely to be more at ease and more conversational with personnel other than doctors, because doctors have less time than alternative personnel to spend on detailed, repetitious explanations, because doctors may use too much medical terminology, confusing their patients, and because patients will not ask questions of doctors because they do not want to appear ignorant, they do not want to offend the doctors by appearing to question their judgment, and they do not want to take time away from the doctors' busy schedules.<sup>120</sup>

The physician should not view the alternate information provider as an infringement on medical expertise, but rather as an able assistant<sup>121</sup> who not only may help patients understand better what is happening to them, but also, because the patients understand better, may make them more compliant, leading to a faster, safer, more successful recuperation.<sup>122</sup>

Obviously, the staff assistant will not come without an expenditure of resources. The fees for their services, however, will be far less per hour than the fees of the busy oncological or cardiac surgeon.<sup>123</sup> And the fee

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119. Muss *et al.*, *supra* note 106, at 1555-56.

120. *Id.* at 1555. See McKinlay, *supra* note 102, at 8-9 (doctors show a "clear tendency . . . to employ words without expecting patients to understand their meaning").

121. The nature of the employment relationship between the physician and the alternative information provider raises a serious dilemma. If the alternate were to be a direct employee of the physician, there could develop between them a long-term, cooperative relationship. The physician could train the alternate and the alternate could become familiar with the physician's practice, relationship with patients, and communication skills. On the other hand, an alternate who is dependent on a physician for employment might not be as free in communicating with patients. For example, would the alternate fear loss of employment or other, albeit less drastic, reprisals if a patient, after talking with the alternate, chose no treatment or a treatment other than the one recommended by the physician? See Lidz & Meisel, *supra* note 74, at 373 (noting that reliance on nurses in hospital setting to take primary role in informing patients presents problems; because physicians and not nurses make treatment decisions, nurses providing information as part of the decisionmaking process may be seen as challenging physicians' authority).

122. See *supra* note 117 (for authorities discussing effects of disclosure and nondisclosure of information on factors such as patient compliance and reporting of side effects).

123. Fees paid for the services of the alternate also pose a dilemma. While the fees will certainly be less than those charged by a physician, they must be commensurate with the skill required and the importance attached to communication skills in the health care setting. Given the community of non-physician health care providers, it is likely that many of the alternate information givers will be women. It is important that this position not be underpaid because of the long history of economically undervaluing work traditionally performed by women.

should be reimbursable by third party payers.<sup>124</sup> In fact, if a patient who understands more recovers better and faster, the staff assistant may in the long run reduce the overall cost of the patient's medical care. Furthermore, patients who understand their conditions and the alternative treatment plans, and who are encouraged to and do exercise control over decisionmaking are less likely to bring lawsuits for malpractice against physicians when a previously explained unpleasant outcome occurs.<sup>125</sup> And even if patients do bring suit, they are less likely to prevail, again to the benefit of physician and third party payers, particularly private insurance companies.

*Patients want physicians to make decisions for them.*

While I do not believe that patients want physicians to make decisions for them in all cases, I believe, and my period of observation bore out, that in many cases patients do request or allow physicians to make decisions

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Because of the importance of shared decisionmaking based on mutual trust, not only for the promotion of patient well-being and self-determination but also for the therapeutic gains that can be realized, the [President's] Commission recommend[ed] that all medical and surgical interventions be thought of as including appropriate discussion with patients. *Reimbursement to the professional should therefore take account of time spent in discussion rather than regarding it as a separate item for which additional payment is made.*

I *President's Commission Report*, *supra* note 28, at 5 (emphasis added).

Fifty-four per cent of the patients polled in the Harris Survey indicated that they would *not* be willing to pay more for physicians to spend more time with them explaining *routine* care; 38% said they would be willing to pay more for such services. Harris, *supra* note 71, at Table 3-11. It is unclear from the survey whether the 54% are simply unwilling to spend more money on routine medical care, or whether they believe that such information should already be provided in exchange for the fees they pay. It is also unclear what percentage of patients would be willing to pay their physicians more for spending more time with them in a nonroutine situation.

The Harvard School of Public Health has recommended a change in Medicare payments to physicians which would compensate internists and family practitioners more equitably than now for their cognitive skills and time spent with patients. Tolchin, *Changes Urged in Payments to Doctors*, N.Y. Times, Sept. 29, 1988, at A-18, col. 4-6. Doctor William C. Hsiao, a medical economist and director of the study, stated that because of the recommended changes in payment structures, "Americans will benefit because physicians will be willing to spend more time with them, offer advice on preventive medicine, and spend more time with families." *Id.* at col. 6.

125. See Annas, *Avoiding Malpractice Suits Through the Use of Informed Consent*, LEGAL MED. ANN. 219, 226-27 (1977) (and sources cited therein). Rockwell & Pepitone-Rockwell, *supra* note 117, at 1345, 1348. See also I *President's Commission Report*, *supra* note 28, at 119:

From the viewpoint of the health care system as a whole, a physician's saving time by failing to educate a patient may be a false economy. Even for the individual practitioner, improved initial communication may save time later by avoiding misinformation or misunderstandings, including those that lead to a malpractice action by a dissatisfied patient.

for them.<sup>126</sup> There are a number of reasons for this response. First, patients, even if they have been informed and do understand the information provided to them, feel vulnerable and overwhelmed because of their condition, the treatment alternatives available to them, the bad results possible with either the condition or the treatment, and if they are in-patients, by their physical surroundings. For patients who have not understood the information offered—who have not had their comprehension tested, who have not been reformed—the vulnerability is even greater, and the temptation to say, “Doctor, you decide” is even more understandable.<sup>127</sup> Second, physicians do know much more than patients about the medical aspects of their conditions and treatment alternatives. After all, physicians have spent years training to care for and then caring for patients, so patients expect them to know what treatment will ensure the best result.<sup>128</sup> Third, physicians, too, believe that because of their years of training and experience, they are better decisionmakers than patients, and they therefore encourage and support patients in relinquishing or delegating decisionmaking powers to them.<sup>129</sup> Fourth, and perhaps most important, few of us like to make hard

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126. The Harris Survey revealed that 72% of all patients questioned preferred an approach to decisionmaking in which physicians discuss alternatives with patients, and the two decide together how to proceed; only 7% of those surveyed believed physicians alone should make treatment decisions. Harris, *supra* note 71, at Table 7-1. However, when asked to assume that they were diagnosed as having cancer “spread throughout the body[,]” and that they would die no matter what treatment alternative they chose, 79% of the patients surveyed replied that they alone should make the decision between “aggressive therapy” (defined as therapy which “will probably make you feel sick and will probably not help your condition”) and “supportive therapy” (defined as therapy which “will not help your condition, but will allow you to be comfortable”). Harris, *supra* note 71, at Table 8-9. Only 12% believed that the physician alone should choose between aggressive and supportive therapy in that setting, and 8% believed the decision should be made jointly between patient and physician. *Id.* When patients who had undergone surgery were asked whether their decisions were based on their trust in their physician’s judgment or their own understanding and judgment, 40% said on their physician’s judgment, 21% said their own judgment, and 31% said on their own and their physician’s judgment equally. *Id.* at Table 6-1.

127. See Katz, *supra* note 90, at 209.

128. Lidz *et al.* found that even though many patients want physicians to make decisions for them because of the physicians’ medical expertise and commitment to the patients’ best interests, patients *still want information* about their treatment. Lidz *et al.*, *supra* note 87, at 540-41. Patients’ reasons for wanting such information included better compliance to aid in their recovery, courtesy and respect for the patient, and to a lesser extent, the opportunity to veto the physician’s decision or to engage in actual affirmative decisionmaking. *Id.*

129. According to the Harris Survey, “physicians seem to indicate” a strong preference for joint decisionmaking between physician and patient, and physicians believe that they should elicit patient opinion in treatment decisions. Harris, *supra* note 71, at 189-90. Those inclinations are stronger among physicians receiving their medical degrees after 1967. They are less strong among physicians who treat a high percentage of patients who are seriously ill, patients whom they perceive to be unable to understand their treatment, and patients who are poor. *Id.* at 191.

Despite the Harris Survey’s findings that physicians and patients both prefer a joint decisionmaking model, Lidz and Meisel in their on-site study found that:

In general the physician was clearly the dominant actor in terms of making

decisions. It is always easier to let someone else decide for us. We do not have to think through the ramifications of the decision, some of which promise to be painful and unpleasant, and ultimately we do not have to take responsibility for the decision. If a bad result occurs, it is not because of something we chose; we followed doctor's orders, we did the best we could, it just happened, but nothing we did or said produced the bad result.

If we are serious about patient autonomy and decisionmaking, we must render a patient's shifting of responsibility to the physician unacceptable, and we must insist that patients take primary responsibility for making decisions relating to their health care. Actually recognizing and enforcing decisionmaking by patients will be difficult for both physicians and patients. During a discussion of informed consent and treatment for breast cancer, a surgeon expressed to me his frustration at patients who say "Doc, you decide. I'll do whatever you say." I asked him if he had ever thought to say to a patient, "I understand how you feel. This is a very hard decision for you to make; I will give you whatever information you need and want and I will support and help you while you are in the process of making a decision, but it is your body and your health and you are really the only one who can make this decision." He acknowledged that he found that to be a novel and interesting idea; he then added, however, "But I hate to see patients make the wrong decision." The notion that patients will make

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decisions about what treatments, if any, a patient was to have. Both doctors and patients saw the process this way.

(a) The doctor's ordinary role, in practice, was to decide what was to be done and to inform the patient of that decision. Ordinarily this information came in the form of a recommendation; though depending on the treatment involved or the personalities of the doctor [or] of the patient, it might be better characterized along a spectrum running from an "order" at one end to a neutral disclosure of alternatives at the other end.

(b) The patient's ordinary role, in practice, was to acquiesce in the doctor's recommendation. Patients played a more active role when the doctor presented alternatives without placing any preference on them. Sometimes patients objected to a recommendation; occasionally they vetoed it. But on balance the typical patient role was one of passive acquiescence.

Lidz & Meisel, *supra* note 74, at 391-92.

Professor Katz indicates that courts, too, believe physicians "know better than patients what is good for patients" therefore reinforcing the idea that, despite courts' language concerning self-determination and informed consent, courts believe physicians rather than patients are the appropriate decisionmakers in health care settings. J. KATZ, *supra* note 24, at xvi.

There is a certain irony in the physician-patient relationship concerning physician decisionmaking for patients. Medicine is a very inexact science. Many times absolutely exact diagnoses are not possible and "cures" can rarely be guaranteed. Physicians by training and experience know this. Patients, however, due to their beliefs that physicians possess more knowledge and better judgment skills than patients—beliefs that are reinforced by the medical profession in general and the physician-patient dynamic in particular—expect certainty in both diagnosis and decision. Physicians—claiming power based upon knowledge and experience and disclaiming ability to be certain—often appear to be hurt and annoyed at patients' demand for certainty and their inability or unwillingness to recognize physicians' limitations.

the "wrong" decision—that they will choose the "wrong" treatment alternative or no treatment at all—is one of the strongest factors reinforcing our belief that patients want physicians to make all decisions for them. Physicians express general unhappiness at having to make decisions for patients, and I believe those expressions are genuine—after all, physicians are probably no different from the rest of us in terms of wanting to avoid hard decisions. Nevertheless, they are often willing to trade off that discomfort in order to ensure that the patients make the "right" decision.<sup>130</sup>

In any given situation only the patient (presuming the patient to be a mentally competent adult)<sup>131</sup> can make the "right" decision, even if that decision is "wrong" to others. Generally, physicians express concern in terms of the "rightness" or "wrongness" of any decision in medical terms—chances of survival, chances of effective rehabilitation, etc., but in reality, that is not always the case. Physicians' opinions concerning the "rightness" or "wrongness" of any given decision are also based upon their own assumptions and biases.<sup>132</sup> For example, one physician I know tried to dissuade a patient's husband and daughter from being at the patient's bedside during the last half hour of her life because he thought it would be hard on them. Upon further discussion, however, he acknowledged that he based his opinion on his own belief that it would be too hard on himself to be at a loved one's bedside at the time of death and he would never choose to do so. In another example, a surgeon explained to me that he always talked to breast cancer patients about breast reconstruction. He explained it to me as an uncomplicated and safe procedure, and he expressed

130. Lidz *et al.* write that

The disinclination of many physicians to take informed consent seriously reflects the basic logic of medical decision making. Except for the goal of relieving acutely problematic symptoms, medical treatment is usually done only when the physician feels that a clear diagnosis has been arrived at. In almost every case, the physician believes that there is a preferred treatment for the condition. Because the diagnosis is based on the physician's knowledge and experience, and the best treatment has been determined by a combination of medical research and clinical experience, most physicians find it hard to see how the patient can choose differently except by sacrificing his or her health. Whereas the doctrine of informed consent implies that there are a series of alternative treatments from which the patient may choose, physicians usually see only superior and inferior treatments. Physicians see little to be gained by allowing a patient to choose the treatment. Thus discussions with patients that we observed very rarely involved a presentation of alternatives; *instead, the physician told the patient what was going to be done.*

Lidz *et al.*, *supra* note 87, at 541 (emphasis added).

131. A patient's competence must not be questioned merely because the patient disagrees with the physician's recommended treatment or declines all treatment. Patients who would be considered competent if they accepted a physician's recommendation must be considered equally competent even if they reject the recommendation.

132. The Harris Survey showed that of the physicians surveyed, 62% indicated that the greatest influence on the way they practice medicine is *their personal values and beliefs*. *Harris Survey*, *supra* note 71, at Table 9-6. Only 18% indicated that their medical training was the greatest influence on their practice; another 18% said their experience in practice was the greatest influence. *Id.*

his surprise that so few of his patients opted for reconstructive surgery. I wondered if his description of the procedure and his surprise were related more to his own thoughts about a woman's breasts than her own thoughts about her breasts.<sup>133</sup>

Even if we convince patients and physicians that patients can and should make decisions for themselves, a problem will remain if physicians structure information or deliver it in such a way as to make patients choose the decision which the physician assumes to be the best, either from a purely medical viewpoint or based upon the physician's assumptions about what is best for the patient and what the patient should want.

*Physicians can convince almost any patient to do what the physician believes is best for the patient.*

I have no doubts that most physicians can convince most patients to do what physicians believe is best for patients;<sup>134</sup> so can any lawyer, so can any teacher, so can any electrician, at least as far as the decisions to be made relate to the person's field of expertise. The reasons are not difficult to understand; physicians are experts in the field of medicine, they spend their lives practicing medicine, and patients know little or nothing about the technical aspects of medicine. Physicians have an air of professionalism and certainty about them. Patients are vulnerable; they are not well, and many are in an institutional setting.

Acknowledging that physicians can convince patients to do what the physician wants the patient to do is the first step in resolving the problem.

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133. See Klass, *Are Women Better Doctors?*, N.Y. Times, Apr. 10, 1988, § 6 (Magazine), at 32, 48:

Dr. Love's anecdotes are often sharp. She describes a male surgeon who explained to a patient that a particular implant used in breast reconstruction felt just like a normal breast. He meant, of course, that to someone *touching* the breast, the texture would be close to natural, not that the woman would have normal feeling in the implant.

It is also disputed whether breast reconstruction is a benign procedure. Dr. Nir Kossovsky, a leading researcher in the biological, chemical, and physical effects of implants, estimates that 40% of breast implants ultimately fail. Blakeslee, *Data Suggest that Implants May Pose Risk of Later Harm*, N.Y. Times, July 25, 1989, at C-1, col. 1.

134. See *supra* notes 80-86 and accompanying text (for illustration of patient changing her mind about treatment option seemingly because of way her physician framed one of her options).

The Harris Survey indicated that 75% of physicians responding believed it to be their responsibility to persuade a patient to accept a medically indicated course of action even when the patient disagreed with the recommendation. Harris, *supra* note 71, at Table 6-8. Lidz and Meisel found that

In addition to making a recommendation, the doctor's self-perceived role is to get the patient to go along with this recommendation if there is any hesitancy on the patient's part. This is done by some explanation about the need for the recommended treatment and the consequences of not heeding the recommendation. But in the doctor's view there is no decision for the patient to make, except whether or not to get proper medical care.

Lidz & Meisel, *supra* note 74, at 400. See Lidz *et al.*, *supra* note 87, at 541.

More important, however, is the willingness and good faith effort on the part of physicians to provide information objectively, and to allow patients to evaluate the information and make their own decisions—not an easy task.<sup>135</sup>

This problem is directly related to the issues of patients wanting physicians to make decisions for them, and physicians, even when recognizing the right and ability of patients to make decisions for themselves, despairing that patients will make the “wrong” decisions. “Rightness” or “wrongness” of decisions can be evaluated in two contexts—from a purely medical perspective (e.g., the five year survival rate following a particular regimen of treatment is fifty times greater than the five year survival rate following no treatment or a different type of treatment), and from a personal perspective (e.g., the physician who tries to dissuade the family from being at the dying patient’s bedside because the physician would not want to be at the bedside of a dying loved one). The two contexts, however, are not unrelated. The patient may choose to forego the treatment which statistics say promise her greater longevity, because she is unwilling to suffer the severe, even if short term, side effects of the treatment. Physicians may believe that if they were faced with that choice, they would certainly choose the side effects and longevity over a shorter life span, and physicians may assume that any reasonable person would make that choice. Patients, however, in the absence of compelling state interests to the contrary, have the right to act in a manner which others deem to be irrational, foolish, or stupid.<sup>136</sup> After all, the physicians are outside actors who are making judgments of irrationality, foolishness, or stupidity based upon what they would do in the same situation. Indeed, if the patient were told that the physician would choose side effects and longevity over an earlier, but less painful death, the patient may believe the physician to be irrational, foolish, or stupid.

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135. As Thompson notes, decisions are often affected by how one “frames” the information. Thompson, *supra* note 89, at 93-96. “By manipulating the form and manner of disclosures doctors can influence people’s perceptions of the risks and benefits of proposed interventions and thereby influence their choices.” *Id.* at 98. “In a choice between two options, one of which has no risk but only moderate benefits and the other of which has high risk but high potential benefits, people’s choices may vary dramatically depending on whether the options are presented as prospective losses or prospective gains.” *Id.* at 95.

Appelbaum and Roth found that in 29 of 105 patient refusals, physician response was to “reinforce” the patient, but that the information often was given in a “stereotyped fashion” with no effort to tailor the explanation to meet any individual patient’s concerns. Appelbaum and Roth, *supra* note 74, at 445. Nineteen of the twenty-nine agreed to treatment following such “reinformation.” Appelbaum and Roth observed, however, that in so agreeing, the “[p]atients often appeared to be responding to the interpersonal intervention *per se*, rather than to the specific information they received.” *Id.* at 445-46.

136. See, e.g., Application of President and Directors of Georgetown College, Inc., 331 F.2d 1010, 1017 (D.C. Cir.), *cert. denied*, 377 U.S. 978 (1964) (Burger, J., dissenting); In Re Estate of Brooks, 32 Ill. 2d 361, 373, 205 N.E.2d 435, 442 (1965); Brophy v. New England Sinai Hosp., Inc., 398 Mass. 417, 430, 497 N.E.2d 626, 633 (1986) (quoting Lane v. Candura, 6 Mass. App. 377, 383, 376 N.E.2d 1232, 1236 (1978)).

Only if physicians believe patients to be incompetent—a decision which in itself demands some expertise—should they decide that patients cannot make decisions for themselves.<sup>137</sup> Even at that point, however, physicians are not entitled to make decisions for patients, but rather they are compelled to follow the informed consent process with a substitute or surrogate decisionmaker—a family member or legal guardian. Those surrogates are entitled to the same information as the competent patient concerning the patient's condition and the risks, benefits, and alternatives to the proposed treatment option. Moreover, they are entitled to receive that information in an objective manner, and by definition, they must understand the information before they can make a decision based on that information.

*Shifting the power balance.*

Implicit in physicians' objections to enhancing and enforcing the spirit of informed consent as well as its letter, and implicit in patients' reluctance to accept responsibility for doing so is resistance to restructuring the patient-physician relationship to make the power balance between the two parties more equal. It is not enough for the law to say to doctors, "Disclose,"<sup>138</sup> or for those accepting my argument to say to patients, "Decide." Rather, physicians must relinquish some of their power and patients must relinquish some of their vulnerability.

Vulnerable patients in a powerless position are not autonomous. They gain autonomy and then they exercise the control associated with autonomy—the ability to make decisions, the ability to be self determinative—only after becoming more powerful in relation to their physicians.<sup>139</sup> Patients and physicians must develop different attitudes toward each other. Ironically, patients' trust of physicians' expertise and knowledge is one of the reasons most often cited for patients' relinquishing all decisionmaking power to physicians, yet bad results for the patients themselves or for others they know, even if those bad results are not due to a physician's failure to exercise reasonable care in performing a procedure, cause patients to distrust physicians (and lead to malpractice actions by the patients against the physicians). Patients clearly need to trust more in themselves—to trust their abilities to understand information, to ask the appropriate questions, and to make the "right" decisions.

Patient self-trust does not come from trusting doctors less, but instead from doctors' and others' (including the law's) trusting patients more. If doctors were to abandon their beliefs that patients do not want certain information, that patients cannot understand that information even if they

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137. See *supra* note 131.

138. As Handler notes, attempts to alter the (doctor-patient) relationship by procedure is not sufficient. Handler, *supra* note 1, at 1012.

139. See Nedelsky, *supra* note 1, at 10 (for a discussion of an individual's "becoming" autonomous as opposed to being autonomous).



claim to want it, and that patients cannot or do not want to make decisions based on that information, and instead were to adopt beliefs that patients do want information, can understand it, and are capable of using it in making decisions, the power balance between patients and doctors would change, as would patient behavior. If doctors were to trust their patients, and if based on that trust doctors would engage their patients in dialogue concerning their patients' health care (or authorize someone else of appropriate skill and expertise to engage the patient in that dialogue), patients' perceptions of themselves should change. If others believed in them and in their abilities, patients should more readily believe in themselves. With those beliefs comes power—power to demand more information and to exercise more control over decisionmaking.<sup>140</sup>

Of course, merely wishing that the relationship between doctor and patient would become more equal in terms of power will not make it so. And it is unlikely that any simple legal declaration that the relationship must become more balanced will achieve that result. Rather, both patients and doctors need incentives to alter their relationships. Some of those incentives are economic—greater payment to physicians for more time spent talking with patients,<sup>141</sup> and greater difficulty on the part of patients pursuing malpractice actions for nonnegligent practices by physicians.<sup>142</sup> Other incentives are less tangible but even more important—faster and more successful patient recovery,<sup>143</sup> and feelings of mutual respect between physician and patient.

Moreover, patients need support in exercising their power. Along with greater power may come a sense of loss<sup>144</sup>—loss of vulnerability and loss of not having to take responsibility for decisions—and such loss may be frightening. Within the formal informed consent structure, patients may need support from trained patient advocates. Informally, patients need support from family and friends, because although the notion of autonomy sometimes implies that each individual exists unto herself or himself, none of us lives in a vacuum. All of us are affected by—and affect—those around us. Autonomous decisionmaking, even in my private sphere context, still means that individuals make decisions *for* themselves, but it

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140. See J. KATZ, *supra* note 28 (for detailed and thoughtful analysis concerning relationship between doctor and patient and potential for improving that relationship through communication and trust between parties); Handler, *supra* note 1, at 1085-94 (for a discussion, in part, of patients gaining more power and more ability to control their lives through greater participation in their relationship with their physicians. That participation, Handler believes, is based in large part on trust between the parties and on their willingness to enter into conversation with each other.).

141. See *supra* note 124 and accompanying text.

142. See *supra* note 125 and accompanying text.

143. See *supra* note 117 and accompanying text. See especially Handler, *supra* note 1, at 1005-08 (for example of mutual incentives making more equal relationship between doctor and patient).

144. See Nedelsky, *supra* note 1, at 26.

does not necessarily mean that they make decisions *by* themselves.<sup>145</sup>

#### V. INFORMED CONSENT: RISKS AND BENEFITS OF THE ALTERNATIVES

The principle behind the doctrine of informed consent is sound. Competent adult patients are autonomous human beings who have the right and the responsibility to make decisions concerning their health and their medical care. In order to make an informed and, for them, "correct" decision, patients need to know and understand all relevant information concerning their medical condition and the proposed treatment, including the risks, benefits, and alternatives to the proposed treatment.

Providing such information is much easier said than done, and there is no guarantee that the patient will understand it no matter how thoroughly and competently the information is presented. The procedures for informed consent are fraught with difficulties—objective difficulties based on the complexity of the information which should be provided and the patients' intellectual and psychological abilities to comprehend the information, and subjective difficulties based upon physicians' own biases and values. And it may be generally true that patients under the current informed consent system do not understand or remember what they are told, that testing patients' understanding of the information provided is resource intensive, that patients want physicians to make decisions for them, and that physicians can persuade patients to do whatever physicians believe best in any event.

The remaining question, then, is what to do about the application of the doctrine of informed consent? Do we continue as we have for three decades requiring physicians to provide patients with information that may meet on its face the legal criteria for disclosure but which generally does not educate patients so they can make truly informed decisions as to their medical care? Do we admit that informed consent as currently applied is a myth which burdens physicians and does not substantially protect patients, and return to prior times when physicians told patients what they thought patients needed to know, when patients were free to ask or not ask questions that physicians were free to answer or not answer, and when physicians were free from liability so long as they told patients what procedures were going to be performed and patients agreed to the performance of those procedures? Or despite difficulty and cost, do we try to comply in a better, more effective way with not only the technical requirements of the informed consent doctrine, but with the doctrine's spirit as well?

Continuation of the status quo is a poor option. Patients are not protected; physicians are burdened with requirements that mean little; the law and society's principles concerning individual autonomy and decision-making are effectuated in name only.

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145. See *id.* at 10, 12, 21 (for a discussion of being autonomous in context of relationships with others).

A return to prior practice has some attractive qualities. It would reinforce the medical expertise and professional judgment of physicians. If physicians could be held liable only where they failed to gain a patient's consent to the performance of a procedure—in essence a battery action—rather than where they unreasonably failed to inform a patient of the risks of any given procedure and one of the risks occurred—a negligence action—physicians' risk of liability would decrease.<sup>146</sup> Presumably patients would be no worse off medically than they were three decades ago before the doctrine of informed consent was first announced, or than they are today when physicians go through the motions of informed consent with the tacit approval of the law, but without really accomplishing the objective of decisionmaking by patients who comprehend the information provided. And perhaps our recent experience with informed consent criteria would cause physicians not to return to the stereotyped parentalistic days of the doctors who know best telling patients only what doctors believe patients need to know, or should know, or "can handle," but instead to discuss with patients, much as they do now, patient's conditions and proposed treatment plans.

The "return to the old days" alternative is unacceptable for a number of reasons. First, there is no guarantee that, in fact, doctors will not return exactly to the old days and stop giving patients vital information about their health care and treatment. Perhaps worse, the removal of the informed consent criteria gives legitimacy to the beliefs that patients cannot remember or understand what physicians tell them, that medical information is so specialized it can be understood only by practitioners and will always be out of the reach of the patients, those most affected by it, that testing patients' comprehension of the information takes too much physician time that could be better spent treating other patients, that patients want doctors to make decisions for them, and that physicians can persuade patients to do whatever physicians believe is best for patients. Not only does such a return give validity to these beliefs, it *invites* physicians to make decisions for patients without providing them with relevant information about their condition or proposed treatment, perpetuating the self-fulfilling prophecy that patients are not able to comprehend such information and make such decisions for themselves. Surely no physician would be ill motivated in so acting, but the temptation to prevent patients from making "wrong" decisions is too great not to motivate physicians to make those decisions for patients. The situation might be different if the decisions physicians make for patients were purely "medical" decisions, but even what we might frame as "purely medical"—such as five year survival rates—is influenced by physicians' own biases and assumptions of what patients would want to do if they had the same knowledge, expertise, and wisdom as physicians.

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146. See *supra* note 37 (for a discussion of distinction between action in battery and action in negligence).

If we abolished the current informed consent criteria, I do not believe that the so-called consumer movement would make patients any more demanding of information or of a role in the decisionmaking concerning their own medical care. While it is a popular belief that consumers ask more questions, read more studies, think more thoughts before making major decisions, I am not convinced that they use the same process in their relationships with their physicians as they use with appliance dealers. No matter how consumer oriented one might be, there is a difference between understanding, comprehending, coping with, and making decisions about one's medical care and doing the same when purchasing consumer goods. Medical treatment, like waiving one's rights in a criminal law or family law context, frequently involves long-term, sometimes irreversible, sometimes life or death matters. Patients are vulnerable—because of their health condition, perhaps because of an institutional setting, because the physicians with whom they are dealing possess an aura of expertise and professionalism which, the patient may perceive, if rejected could lead to long term negative effects or even death. If we decide not to buy a new refrigerator today the worst that can happen is that we cannot store foods that need to be chilled in warm weather. We can come back tomorrow or next month or next year and buy the refrigerator without long term adverse side effects (as long as we do not try to eat the food which needed to be chilled and was not). If we decline medical treatment, tomorrow may be too late. Even against the backdrop of formal informed consent criteria, the consumer movement has not made patients substantially more eager or more willing to raise questions or discuss their conditions with their physicians.<sup>147</sup> Without that formality, not only might patients not be more eager and willing to raise those questions and have those discussions, but they may be even less willing to do so than they are now.

I do not advocate treating informed consent and decisionmaking in the health law context as it is treated in parts of criminal or family law. It would be impossible—and unnecessary—for a state authorized agent to provide information to patients, to test their comprehension of that information, and then to evaluate the quality of their decisions. It would not be impossible, however, for physicians or their designates, once informing patients as the law currently requires about their diagnostic and treatment options, to test the patients' comprehension of that information and then at least encourage and preferably require that patients make those diagnostic or treatment decisions.<sup>148</sup> The corollary to such a proce-

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147. See Muss *et al.*, *supra* note 106, at 1555.

148. Such a plan does not preclude patients from seeking or physicians from giving recommendations concerning proposed procedures or therapies. Physicians must be careful, however, to provide recommendations in an objective manner to avoid persuading patients that the recommendations are to be followed because the physicians believe they are the only legitimate course available. For an illustration of a physician's phrasing information in such a manner that the patient was dissuaded from her original (informed?) decision as to treatment, and opted instead for the treatment preferred by the physician, see *supra* notes 80-86 and accompanying text.

cedure, of course, would be that, barring negligence in the informed consent procedure or in the performance of the actual medical procedure, patients, like criminal defendants and birth mothers, would be held responsible for the decisions they make.

There is no question that alternative ways to inform patients about their conditions and possible treatment plans, to improve patients' understanding and memory of what they are told, and to support patients in making decisions will cost more in terms of objective health care provider resources—for example, time—whether a physician or an alternate provides the information and support. And there is a more subjective cost. For the principles of informed consent to work, physicians, patients, and society must change their views about the doctor-patient relationship. We must not only have faith in patients' willingness to be active participants in their medical care, but we must encourage them to do so as well. The cost of such participation for the medical profession is to realize that the profession's knowledge and experience is not omnipotent. The cost of such participation for patients is to relinquish their vulnerability and to accept responsibility for making their own decisions.

Both costs are high. If we mean what we say, however, about patient autonomy and informed decisionmaking, we should try to make it work. If we try and fail, we can then reevaluate both the goals and the procedures attendant on the informed consent doctrine. It seems unfair, however, to have pretended for three decades that the informed consent doctrine is effective in patient care when it has not met its goals in terms of patients and has burdened physicians with its requirements. The courts were not wrong when they set forth the doctrine of informed consent based on a notion of protecting patient autonomy. It is still a goal worth pursuing. In doing so, we might find that not only is it possible to meet the requirements of informed consent, but also that once the requirements are met, the doctrine's goals will be achieved as well.