

# INFORMED CONSENT DOES NOT MEAN RATIONAL CONSENT

## COGNITIVE LIMITATIONS ON DECISION-MAKING

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If all decisions by the patient could be made on an intelligent basis; if all patients had sufficient scientific background and sufficient knowledge of the human body; if the decisions of all patients could be sufficiently free of the fear of the unknown, of superstition and other extraneous influences upon the decision-making processes; if all patients were able to understand the physician and communicate with him; if the physician were not faced with these and various other impediments, doctor-patient accord would be a problem of manageable proportions.<sup>1</sup>

### INTRODUCTION

Is "informed consent" to medical treatment an oxymoron? While the concept of consent is old in our law,<sup>2</sup> the notion that such a consent must be

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<sup>1</sup> LaCaze v. Collier, 434 So. 2d 1039, 1049 (La. 1983).

<sup>2</sup> Indeed, the origins of the informed consent doctrine are said to date back over 200 years to the King's Bench case *Slater v. Baker and Stapleton*, 95 Eng. Rep. 860 (K.B. 1767). More recently, Judge Cardozo set forth the principle of consent, which has since become the *de rigeur* quote for informed consent cases and articles: "Every human being of adult years and sound mind has a right to determine what shall be done with his own body." *Schloendorff v. Society of N.Y. Hosp.*, 211 N.Y. 125, 129, 105 N.E. 92, 93 (1914), *overruled on other grounds*; *Bing v. Thunig*, 2 N.Y.2d 656, 143 N.Y.S.2d 1, 143 N.E.2d 3 (1957).

"informed" is relatively recent,<sup>3</sup> being first espoused only 35 years ago.<sup>4</sup> As in other areas of the law, the doctrine has undergone rapid development and change since then. The policy forwarded by this law is protecting the autonomy of the patient, inasmuch as the right to make decisions regarding personal matters, such as choices between treatment alternatives or none at all, is a sine qua non of self-determination.<sup>5</sup> Informed consent, as envisioned by the law, has been succinctly described as "when information is disclosed by a physician to a *competent* person, that person will *understand* the information and *voluntarily* make a *decision* to accept or refuse the recommended medical procedure."<sup>6</sup>

Thus, the law has placed upon physicians a duty to disclose information regarding diagnosis and treatment in order to enable their patients to make decisions enlightened by that information. Yet, individuals' ability to make decisions in their own best interest<sup>7</sup> may be questioned, based on knowledge gained in the last 25 years regarding the cognitive and intellectual limits to people's decision-making skills. The general thrust of this research is that people receive little training in decision-making. As a result, they rely upon simplified rules of thumb. These heuristics may serve them reasonably well in many situations, but can lead to serious errors, including overestimating some risks and underestimating others, as well as allowing one's choices to be manipulated by subtle and apparently irrelevant aspects of how options are presented.<sup>8</sup> If information is intended to allow patients to make informed, knowledgeable, rational decisions in their own best interest, then under the current legal definition of consent,

<sup>3</sup> For an excellent overview of the development of the doctrine from the viewpoint that informed consent is yet "another front in the assault on the fault requirement" for civil liability, see Meisel, *The Expansion of Liability for Medical Accidents: From Negligence to Strict Liability, by Way of Informed Consent*, 56 NEB. L. REV. 51, 63 (1977).

<sup>4</sup> *Salgo v. Leland Stanford Bd. of Trustees*, 154 Cal. App. 2d 560, 317 P.2d 170 (1957) (reversing the jury verdict for plaintiff and remanding for a new trial, where the trial judge's instruction that the doctrine of *res ipsa loquitur* applied as a matter of law was prejudicial error; the court held that it was not within lay knowledge whether, but for an act of negligence, paralysis would result from a translumbar aortography procedure).

<sup>5</sup> "[T]he justification for informed consent is couched in rights language—the patient's right to self-determination—and the primary concern of the law is to prescribe the duties that devolve upon physicians in order that this right be protected." R. FADEN & T. BEAUCHAMP, *A HISTORY AND THEORY OF INFORMED CONSENT* 25 (1986).

<sup>6</sup> Meisel & Roth, *What We Do and Do Not Know About Informed Consent*, 246 J. A.M.A. 2473, 2473 (1981) (emphasis in original) (citing Meisel, Roth, & Lidz, *Toward a Model of the Legal Doctrine of Informed Consent*, 134 AM. J. PSYCHIATRY 285-9 (1977)).

<sup>7</sup> "A decision is considered optimal if an individual chooses the course of option that is in his or her own best interests, exploiting fully the available evidence . . . at the time the decision is made . . ." Fischhoff, *Cognitive and Institutional Barriers to "Informed Consent"*, in TO BREATHE FREELY 170 (M. Gibson ed. 1985).

<sup>8</sup> See *infra* notes 138-52 and accompanying text.

the notion of consent as informed is a legal fiction. The present law simply cannot ensure attainment of that goal.

The law of informed consent holds that it is the right of the patient to choose a course of treatment and requires physicians to disclose sufficient information to enable that decision. In effect, the law recognizes the individual's right to refuse treatment or to choose between alternative treatments and suffer (or enjoy) the consequences of that choice. At times, this may mean the "rational" choice of socially-discouraged goals, in which case a philosophical argument arises over whether society should allow individuals to undertake exceedingly risky activities. More troubling, and the topic of the present analysis, is what should be done when individuals make poor choices because they lack either critical information or the intellectual skills needed to use that information effectively when identifying courses of action. If people cannot make decisions well, then the current notion of autonomy is just an illusion.

This article begins by examining the current law of informed consent, focusing on the duty to disclose information. The cognitive and intellectual limitations on judgment under uncertainty and the potential effects of such limitations on the law are then discussed. Finally, general proposals for more detailed research on patient decision-making and possible improvements in physician-patient communications are provided.

## I. DISCLOSURE FOR INFORMED CONSENT

In upholding the sovereignty of the individual, the law has focused on several facets of informed consent: (1) the legal competence of the patient to make a decision; (2) the lack of coercion of the patient, allowing freedom of choice; and, (3) the provision of sufficient information to allow the patient to make a knowledgeable choice. A substantial body of literature has evolved addressing the competency of children,<sup>9</sup> the elderly,<sup>10</sup> and per-

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<sup>9</sup> Weithorn & Campbell, *The Competency of Children and Adolescents to Make Informed Treatment Decisions*, 53 CHILD DEVELOPMENT 1589 (1982) (testing 9, 14, 18, and 21-year-olds' capacity to make normatively competent choices in medical scenarios). See also Lewis, *Minor's Competence to Consent to Abortion*, 42 AM PSYCHOL 84, 87 (1987) (reviewing studies of decision-making in adolescents, and concluding that present research "gives no basis for restrictions on minors' privacy in decision-making on the grounds of competence alone").

<sup>10</sup> See, e.g., Tymchuk, Ouslander, & Rader, *Informing the Elderly: A Comparison of Four Methods*, 34 J AM GERIATRICS SOC Y 818 (1986) (noting improved recall with communications using simplified writing); Taub, Baker, & Sturt, *Informed Consent for Research: Effects of Readability, Patient Age, and Education*, 34 J AM GERIATRICS SOC Y 601 (1986) (and references cited therein) (finding that comprehension varies indirectly with age and directly with years of education); Baker, *Competent for What?*, 79 J. NAT'L MED. A 715 (1987) (discussing the effects of senile dementia and Alzheimer's disease on competency issues in general).

sons suffering from various psychotic<sup>11</sup> and emotional<sup>12</sup> disorders to make informed medical decisions. When a patient is deemed to be incompetent, a competent adult will be empowered to act on the patient's behalf.<sup>13</sup> Generally, a patient is considered legally competent when he or she can understand the information provided and is aware of the right to make a choice.<sup>14</sup>

A large body of literature also has developed on the issue of patient understanding, where recall ability is typically used as a proxy for comprehension.<sup>15</sup> The legal concept of competency does not, however, consider the patient's ability to use that information so as to increase the likelihood of an optimal decision. Thus, while clearly unreasonable decisions may call the patient's competence into question, there have been no judicial or legislative requirements for ensuring that medical patients<sup>16</sup> can make decisions in ways consistent with the normative rules of decision theory, what will be termed "rational" decisions in this article.<sup>17</sup> As is discussed in Section II of this article, understanding, as measured by the recall of separable bits of information, cannot guarantee that patients have and can apply the decision-making skills needed to use that information.

Many authors have addressed the potentially coercive effects<sup>18</sup> of

<sup>11</sup> See, e.g., Stanley & Stanley, *Psychiatric Patients' Comprehension of Consent Information*, 23 *PSYCHOPHARM BULL.* 375 (1987) (finding that acute psychiatric patients did not differ significantly from a control group of medical patients in their ability to recall consent information)

<sup>12</sup> See generally Applebaum, Roth, Lidz, Benson, & Winslade, *False Hopes and Best Data: Consent to Research and the Therapeutic Misconception*, 17 *HASTINGS CENTER REP.* 20 (1987) (discussing the importance of clearer disclosure to patients especially to avoid the "therapeutic misconception" whereby patients consent to clinical research, such as double-blind drug experiments, without realizing the true goals of the research and the fact that they might be assigned to a placebo group)

<sup>13</sup> See generally Note, *Appointing an Agent to Make Medical Treatment Choices*, 84 *COLUM. L. REV.* 985 (1984) (discussing the inadequacy of present laws in protecting the interests of incompetent patients)

<sup>14</sup> Meisel & Roth, *Toward an Informed Discussion of Informed Consent: A Review and Critique of the Empirical Studies*, 25 *ARIZ. L. REV.* 263, 272 (1983) (reviewing most of the pre-1983 empirical studies of communications and patient comprehension and attitude, finding significant methodological defects in an overwhelming majority of the work)

<sup>15</sup> Of course, the ability to recall information does not mean that the individual comprehends the information. Comprehension requires, among other things, the assimilation of the information into one's existing knowledge. See *infra* notes 153-57 and accompanying text

<sup>16</sup> More stringent requirements for competency have been spelled out for mental patients making decisions regarding treatment or participation in experiments. See, e.g., *FLA. STAT.* § 394.459(3) (1988) ("A patient is incompetent to consent to treatment if his judgment is so affected by his mental illness that he lacks the capacity to make a well-reasoned, willful, and knowing decision concerning treatment") This article questions everyone's capacity to make well-reasoned decisions

<sup>17</sup> Throughout this article, the use of the terms "rational" or "nonrational" will refer to decision-theoretic rationality, that is, decisions that follow the von Neumann-Morgenstern axioms. J. VON NEUMANN & O. MORGENSTERN, *THEORY OF GAMES AND ECONOMIC BEHAVIOR* (3d ed. 1953). The term "irrational" will be avoided, inasmuch as colloquial use often has much excess meaning, including aspersions of having wrong values as well as of pursuing those values ineffectively

<sup>18</sup> Generally consent can be vitiated by "any element of force, fraud, deceit, duress, coercion, or undue influence." *CAL. HEALTH & SAFETY CODE* § 24173(e) (West 1984)

stress,<sup>19</sup> familial pressures,<sup>20</sup> and medical setting pressures.<sup>21</sup> The decision-making problems discussed here are a separate set of problems, which could, in principle, be aggravated by pressures that reduce people's ability to think at all.

Exactly what and how information needs to be communicated to the patient under the laws of informed consent is the primary focus of this article. The informed consent doctrine represents a legal standard imposed upon, interpreted by, and implemented by the medical community. The law, as embodied in statutes and judicial decisions, imposes a positive duty of disclosure upon physicians.<sup>22</sup> In addition to differences and difficulties in defining what is required to be disclosed, this body of law has remained unaware of the cognitive limitations of medical practitioners, patients, jurists, and jurors. The duty to disclose that devolves upon pharmaceutical manufacturers and physicians is examined in the following sections.

### A. Pharmaceuticals

Disclosure requirements for pharmaceuticals have been mandated by Congress by amendment to the Federal Food, Drug and Cosmetics Act.<sup>23</sup> Specifically, the Act requires that the labeling<sup>24</sup> of drugs bear "(1) adequate directions for use; and (2) such adequate warnings against use in those pathological conditions or by children where its use may be dangerous to health, or against unsafe dosage or methods or duration or administration or application, in such manner and form, as are necessary for the protection of users."<sup>25</sup> Clause (1) does not apply to situations in which the Food and Drug Administration (FDA) has found that the disclosure requirements

<sup>19</sup> Carnerie. *Crisis and Informed Consent: Analysis of a Law-Medicine Malocclusion*. 12 AM J L & MED 55 (1986) (discussing these issues in detail, with special emphasis on the effect of stress on the thinking of patients being told about serious disease, such as cancer, and suggesting a waiting period to help patients to master these stresses). Accord Morrow, Gootnick, & Schmale, *A Simple Technique for Increasing Cancer Patients' Knowledge of Informed Consent to Treatment*. 42 CANCER 793 (1978); Klein & Klein, *Delivering Bad News: The Most Challenging Task in Patient Education*. 58 J AM OPTOMETRIC A 660 (1987) (discussing means of overcoming stress-induced learning blocks).

<sup>20</sup> Carnerie. *supra* note 19, at 85.

<sup>21</sup> That a physician or hospital will refuse further treatment if the patient refuses to sign a consent form certainly creates pressure on patients to sign. It is not willful coercion inasmuch as the threat of liability leaves medical practitioners no choice but to withhold treatment under such circumstances.

<sup>22</sup> Simply responding to patient questions does not fulfill a physician's obligation, inasmuch as patients may not have the knowledge or the assertiveness to ask questions. For example, the court in *Canterbury v. Spence*, 464 F.2d 772, 783 n.36 (D.C. Cir.), *cert. denied*, 409 U.S. 1064 (1972), stated: "We discard the thought that the patient should ask for information before the physician is required to disclose. . . . The patient may be ignorant, confused, overawed by the physician or frightened by the hospital, or even ashamed to inquire."

<sup>23</sup> 21 U.S.C. §§ 301-392 (1982 & Supp. 1989).

<sup>24</sup> "The term 'labeling' means all labels and other written, printed, or graphic matter (1) upon any article or any of its containers or wrappers, or (2) accompanying such article." *Id.* § 321(m).

<sup>25</sup> *Id.* § 352(f).

are not necessary for protection of the health and safety of the public.<sup>26</sup> Prescription drugs,<sup>27</sup> inasmuch as they are used exclusively under the supervision of a physician, are exempt,<sup>28</sup> and the rules promulgated by the FDA require that the information furnished be such as to assist the practitioner in safely prescribing the drug.<sup>29</sup>

The physician is a "learned intermediary"<sup>30</sup> interposed between the pharmaceutical companies and the patient. The information provided by the companies must allow the physician to decide about the use of the drug and to safely prescribe and monitor such use. The federal statute and regulations do not, however, specify any more precisely what information is necessary for an informed choice, nor set forth definitive guidelines for determining what "manner and form"<sup>31</sup> are necessary for the protection of the consumer. Thus, securing informed consent to drug treatment is the obligation of the prescribing physician, and the duty to disclose is determined by the state laws of informed consent.<sup>32</sup>

<sup>26</sup> *Id.*

<sup>27</sup> *Id.* § 353(b)(1): "A drug intended for use by man which . . . because of its toxicity or other potentiality for harmful effect, or the method of its use, or the collateral measures necessary to its use, is not safe for use except under the supervision of a practitioner licensed by law to administer such drugs . . . FDA rules require identification of the general identity of over-the-counter drugs. 21 C.F.R. § 201.61 (1989); quantity, *id.* § 201.62; and, pregnancy-nursing warnings, *id.* § 201.63. The rules require that directions be provided "under which the layman can use a drug safely and for the purposes for which it was intended." *id.* § 201.5, but exempt drugs "insofar as adequate directions for common uses thereof are known to the ordinary individual." *Id.* § 201.116. The "intended use" of a drug is the "objective intent of the persons legally responsible for the labeling of the drug," which is determined by, *inter alia*, "labeling claims, advertising matter, or oral or written statements." *Id.* § 201.128. Further, various states have statutes setting forth disclosure requirements for over-the-counter drugs. *E.g.*, FLA. STAT. ANN. ch. 499 (West 1988).

<sup>28</sup> 21 U.S.C. § 353(b)(2) (1982 & Supp. 1989). Liability may result for failure to warn in cases where prescription drugs have been provided to other than licensed medical practitioners after which a patient was injured without being warned of the risks. *See Reyes v. Wyeth Laboratories*, 498 F.2d 1264 (5th Cir.), *cert. denied*, 419 U.S. 1096 (1974) (defendant liable for plaintiff's paralytic poliomyelitis resulting from Sabin trivalent oral polio vaccine, which was provided directly to a municipal health agency). *See generally*, Comment, *Informed Consent to Immunization: The Risks and Benefits of Individual Autonomy*, 65 CAL. L. REV. 1286 (1977) (discussing state informed consent laws as applied to mass immunization programs).

<sup>29</sup> 21 C.F.R. §§ 201.100(c)(1) & (d)(1) (1989). These sections require that labeling have "adequate information for its use, including indications, effects, dosages, routes, methods, and frequency and duration of administration, and any relevant hazards, contraindications, side effects, and precautions under which practitioners licensed by law to administer the drug can use the drug safely and for the purposes for which it was intended . . ." (emphasis added). Specific information requirements for prescription drugs include the following: description; clinical pharmacology; indications and usage; contraindications; warnings; precautions; adverse reactions; drug abuse and dependence; overdosage; dosage and administration; and, how supplied. *Id.* §§ 201.56 & 201.57.

<sup>30</sup> *Reyes*, 498 F.2d at 1276.

<sup>31</sup> *See supra* note 25.

<sup>32</sup> *See, e.g.*, *Buckner v. Allergan Pharmaceuticals, Inc.*, 400 So. 2d 820 (Fla. App. 1981) (affirming the dismissal of the complaint sounding in products liability against defendant steroid manufacturer).

## B. Physician's Disclosure Obligations

Subject to several exceptions, which are beyond the scope of this discussion,<sup>33</sup> physicians have a duty to disclose to their patients that information needed for making informed, "intelligent,"<sup>34</sup> "rational"<sup>35</sup> decisions regarding all diagnostic and therapeutic treatments. A physician may be liable to a patient if an undisclosed risk of treatment<sup>36</sup> subsequently transpires and such risk was significant enough that the reasonably prudent patient would not have consented to the proposed treatment had he or she been informed of that risk.<sup>37</sup> Thus, the failure to disclose a particular risk, alternative, or effect must be causally related to the injury suffered, that is,

<sup>33</sup> The exceptions include the following: incompetence of the patient to consent to treatment; the therapeutic privilege, which allows the physician to withhold information if, in his or her reasoned judgment, disclosure would be too upsetting or otherwise would seriously interfere with treatment or adversely affect the condition of the patient; and, the emergency exception, which arises in situations where attempting to secure consent would detrimentally affect proper treatment. *Carrie*, *supra* note 19. Physicians also are excused from disclosure obligations if the patient waives the right to informed consent by expressing a desire not to be told. *See also* Meisel, *The "Exceptions" to the Informed Consent Doctrine: Striking a Balance Between Competing Values in Medical Decision Making*, 1979 WIS. L. REV. 413, 487 (discussing the development of these exceptions to promote values other than individual autonomy: "the health of the individual for the individual's own sake, the maintenance and promotion of the health of loved ones, and the assurance that the medical and related professions are free to practice responsibly in accordance with sound professional dictates")

<sup>34</sup> *Canterbury*, 464 F.2d at 780

<sup>35</sup> *Id.* at 789

<sup>36</sup> Risks of treatment are outcomes resulting without the negligence of the treating physician. An outcome that is nonnegligently caused is one that arises in a certain percentage of cases regardless of the care of the physician due to physiological susceptibilities of a patient, or one that arises from an act or failure to act of the physician that is within the standard of care. *Meisel, supra* note 3, at 52-53. The physician also must disclose the risks of refusing treatment or diagnosis. *Truman v. Thomas*, 165 Cal. Rptr. 308, 611 P.2d 902 (1980) (patient refused pap smears over a long time period and subsequently died from cervical cancer); *Crisler v. Spak*, 122 Misc. 2d 355, 471 N.Y.S.2d 741 (1983) (plaintiff refused surgical exploration of a pinched nerve in her leg, which turned out to be caused by a malignant tumor, necessitating amputation)

<sup>37</sup> The objective "reasonably prudent patient" causation standard is followed by an overriding majority of courts. *See, e.g., Canterbury*, 464 F.2d at 790-91. *See also* Waltz & Scheuneman, *Informed Consent to Therapy*, 64 NW U.L. REV. 628, 646-48 (1970); UTAH CODE ANN. § 78-14-5(f) (1987) ("reasonable prudent person in the patient's position"). For an excellent judicial debate on the causation issue, see *Fain v. Smith*, 479 So. 2d 1150 (Ala. 1985). A few courts allow the use of a subjective standard focused on the plaintiff's probable actions had he or she been told of the since-manifested risk. *See, e.g., Scott v. Bradford*, 606 P.2d 554 (Okla. 1979). For a criticism of this case, see Note, *Malpractice: Doctrine of Informed Consent Adopted*, 33 OKLA. L. REV. 197, 198-99 (1980): "[T]he opinion offers no substantive guidelines to the practicing physician as to what is required under law to ensure adequate informed consent." *But see* Trichter & Lewis, *Informed Consent: The Three Tests and a Modest Proposal for the Reality of the Patient as an Individual*, 21 S. TEX. L.J. 155 (1981) (supporting the subjective approach as a means to achieve full disclosure); Seidelson, *Medical Malpractice: Informed Consent Cases in "Full Disclosure" Jurisdictions*, 14 DUQ. L. REV. 309 (1976) (discussing the inadequacy of the objective standard in preserving the patient's right of self-determination)

Alaska appears to have legislatively adopted this standard. ALASKA STAT. ANN. § 09.55.556(a) (1983) (emphasis added):

“but for” the lack of disclosure, the decision would have been different and, likewise, the untoward outcome.

The standards controlling disclosure vary from state to state, with the federal courts applying the substantive law of the states in which they sit.<sup>38</sup> For the purposes of this analysis, a distinction between the characterization of the failure to secure informed consent<sup>39</sup> as a technical battery<sup>40</sup> or negli-

A health care provider is liable for failure to obtain the informed consent of a patient if the claimant establishes by a preponderance of the evidence that the provider has failed to inform the patient of the common risks and reasonable alternatives to the proposed treatment or procedure, and that but for that failure *the claimant* would not have consented to the proposed treatment or procedure

The Alaskan appellate courts have not yet interpreted or applied this statute. The most recent informed consent decision, however, included overtones of a subjective standard *Poulin v. Zartman*, 542 P.2d 251 (Alaska), *on rehearing*, 548 P.2d 1299 (Alaska 1976) (where a premature baby was blinded from oxygen administered to treat a cyanotic condition)

The Supreme Court of North Carolina went so far as to hold that subjective causation was applicable, even though the legislature had mandated an objective standard for claims arising on or after July 1, 1976. N.C. GEN. STAT. § 90-21 13(a)(3) (1985), and even though the learned court had to overrule its own precedent, established in *Watson v. Clutts*, 266 N.C. 153, 136 S.E.2d 617 (1964) *McPherson v. Ellis*, 305 N.C. 266, 287 S.E.2d 892 (1982) (reversing a jury verdict for defendant on this issue) Such judicial law by exception violates constitutional rights to equal protection and due process as well as the fundamental jurisprudential concept of *stare decisis*. The decision also represents a blatant rejection of the public policy of the state as adopted by the legislature

<sup>38</sup> *Eric Railroad Co. v. Thompkins*, 304 U.S. 64 (1938). See, e.g., *Keyser v. St. Mary's Hosp.*, 662 F. Supp. 191 (D. Idaho 1987) (applying Idaho law) Conflicts of law raise an interesting issue. What happens when a plaintiff from a prudent patient jurisdiction is treated at a major medical facility in a professional jurisdiction, or vice versa? If in personam jurisdiction can be gained over the physician or the medical facility due to, perhaps, interstate advertising or physician referral, and sufficient contacts with the forum state are established, then the plaintiff may be able to have the law of the forum state applied to the out-of-state practitioner. See *Hitchcock v. United States*, 665 F.2d 354 (D.C. Cir. 1981) (applying D.C. law where D.C. resident received medical care in Virginia) *But see Blakesley v. Wolford*, 789 F.2d 236 (3d Cir. 1986) (finding a true conflict between the informed consent laws of Pennsylvania and Texas, and deciding that, on the facts presented, Texas law should apply) The compensatory goals run headlong into the regulatory goals of the informed consent laws in these cases, for it is unreasonable to expect physicians to alter their disclosure practices when treating out-of-state patients. Compare *Scott v. Bradford*, 606 P.2d 554 (Okla. 1979) (prospective application of materiality standard and subjective causation) with *Halley v. Birbiglia*, 390 Mass. 540, 458 N.E.2d 710 (1983) (retroactive application of materiality standard)

<sup>39</sup> It is well established that the failure to secure consent is a battery, an unallowed touching of the plaintiff's body. For example, battery arises when the patient has consented to one particular treatment and another is performed. See, e.g., *Bang v. Charles T. Miller Hosp.*, 251 Minn. 427, 88 N.W.2d 186 (1958) (plaintiff consented to a prostate resection uninformed that his sperm ducts would most likely be tied off); *Corn v. French*, 71 Nev. 280, 289 P.2d 173 (1955) (consent to exploratory surgery, not mastectomy).

<sup>40</sup> E.g., *Gray v. Grunnagle*, 423 Pa. 144, 223 A.2d 663 (1966) (where there was an inherent risk of paralysis in a spinal operation: battery); *Belcher v. Carter*, 13 Ohio App.2d 113, 234 N.E.2d 311 (1967) (undisclosed danger of radiation burns from X-ray treatments: battery) Pennsylvania continues to characterize the lack of informed consent as a battery, with some strange results. See Comment, *Informed Consent in Pennsylvania—The Need for a Negligence Standard*, 28 VILL. L.

gence or malpractice<sup>41</sup> will be unnecessary, inasmuch as the standards of disclosure are independent of the identification of the tort. The scope of disclosure as developed in the courts and legislatures is discussed in this section.

### 1. *The Professional Standard*

The traditional view is that the physician must inform a patient of that information regarding diagnosis, risks, and alternative treatment or procedures as would customarily be given to a patient in the same or a similar situation by other practitioners of the same school,<sup>42</sup> training, and experience, at the time of treatment, in the same community.<sup>43</sup> This standard is consistent with the standard of care generally applicable to physicians and other professionals in malpractice cases.

This standard has been codified by 13 states in an attempt to "provide certainty and clarity"<sup>44</sup> to the law, and to provide some relief from the medical malpractice insurance crisis that arose in the mid-1970s.<sup>45</sup> The statutes take various forms, including: (1) those that define the standard for determining a sufficient disclosure;<sup>46</sup> (2) those that provide affirmative de-

REV 149 (1982); Merz. *The Informed Consent Doctrine in Pennsylvania: Lack of Supreme Court or Legislative Direction Leaves Law Limping*. 137 PITT. LEGAL J 223 (1989)

<sup>41</sup> The most important case making the distinction that failure to secure an informed consent should be treated as negligence is *Natanson v Kline*. 186 Kan 393. 350 P.2d 1093 (1960). *modified*, 187 Kan 186. 354 P.2d 670 (1961). See generally Halligan. *The Standard of Disclosure by Physicians to Patients: Competing Models of Informed Consent*. 41 LA L. REV 9 (1980) (discussing the impact of the common law of deceit on courts' characterizations of informed consent cases as battery or negligence)

<sup>42</sup> *Kaplan v Haines*. 96 N.J. Super 242. 232 A.2d 840 (1967). *aff'd per curiam*. 51 N.J. 404. 241 A.2d 235 (1968). *overruled*. *Largey v Rothman*. 110 N.J. 204. 540 A.2d 504 (1988) (adopting the *Canterbury* rule)

<sup>43</sup> The community standard has been abrogated in some states by statute. see, e.g., W. VA. STAT § 55-7B-3 (Supp. 1988). while being expressly reaffirmed in others. e.g., DEL. CODE ANN tit 18, § 6852 (Supp. 1988); FLA. STAT § 766.103 (Supp. 1989); IDAHO CODE § 39-4304 (1985); NEB. REV. STAT § 44-2816 (1988)

<sup>44</sup> IDAHO CODE § 39-4301(2) (1985)

<sup>45</sup> See, e.g., W. VA. STAT § 55-7B-1 (Supp. 1988)

<sup>46</sup> For example, N.Y. PUBLIC HEALTH LAWS § 2805-d (McKinney 1985 & Supp. 1989). specifies that "[l]ack of informed consent means the failure to disclose to the patient such alternatives and the reasonably foreseeable risks and benefits involved as a reasonable medical practitioner under similar circumstances." See also IDAHO CODE § 39-4304 (1985); NEB. REV. STAT § 44-2816 (1988); VT. STAT ANN tit 12, § 1909 (Supp. 1988) The Idaho statute and its judicial interpretation present an interesting twist to the attempt by some legislatures to reign in malpractice litigation. The Supreme Court of Idaho held in *Rook v Trout*. 113 Idaho 652. 747 P.2d 61 (1987). that the 1976 statute did not abrogate the patient-based common-law standard adopted in *LePelley v Grefenson*. 101 Idaho 422. 614 P.2d 962 (1980). To reach this holding. the court exercised linguistic gymnastics to avoid the plain language of the statute. The court also failed to explain how a 1976 statute could be expected to be drafted with a clear intent to abrogate the common law adopted in a case arising four years after the legislation was passed. While the *LePelley* court

fenses for physicians meeting the standard of disclosure;<sup>47</sup> (3) those that define the evidential burden on the plaintiff to establish the cause of action;<sup>48</sup> (4) one state creates a cause of action for failure to disclose, in general terms, "[t]he material risks generally recognized and accepted by reasonably prudent physicians . . . ;"<sup>49</sup> and, (5) one state requires that breach of the professional standard be found by a physician reviewing the case before the filing of the complaint.<sup>50</sup> Including the above, a slight majority of states follow the professional standard.<sup>51</sup>

Some states, perhaps exhibiting legislative difficulty with absolute deference to physicians in establishing a standard of care,<sup>52</sup> have specified what type of information is to be provided. These lists may include general information about treatment, risks, alternatives, and out-

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arguably was not bound in its decision by the 1976 statute inasmuch as the case arose in 1972, the court nonetheless was obligated to look at the legislation as it reflects public policy choice and because it would control cases arising in the future. This the court failed to do. It will be interesting to see if the Idaho legislature responds to this piece of judicial legerdemain.

<sup>47</sup> Florida Medical Consent Law, FLA STAT ANN § 766.103 (1988) is representative, prohibiting recovery where "the action of the [physician] in obtaining the consent of the patient . . . was in accordance with an accepted standard of medical practice among members of the medical profession with similar training and experience in the same or similar medical community." *Id.* § 766.103(3)(a)(1). See ME REV STAT ANN tit 24, § 2905 (Supp 1988).

<sup>48</sup> Arkansas' statute specifies that "the plaintiff shall have the burden of proving . . . that the medical care provider did not supply that type of information regarding the treatment, procedure, or surgery as would customarily have been given to a patient . . . by other medical care providers with similar training and experience." ARK STAT ANN § 16-114-206(b)(1) (1987). See also DEL. CODE ANN tit 18, § 6852 (Supp 1988); KY REV STAT ANN § 304.40-320 (Michie/Bobbs-Merrill 1987); N H REV STAT ANN § 507-C:2 (1983); TENN CODE ANN § 29-26-118 (1980).

<sup>49</sup> GA CODE ANN § 31-9-6.1(a)(3) (1985 & Supp 1988). The consequences deemed to be important include "infection, allergic reaction, severe loss of blood, loss or loss of function of any limb or organ, paralysis or partial paralysis, paraplegia or quadriplegia, disfiguring scar, brain damage, cardiac arrest, or death." *Id.* § 31-9-6.1(e)(2).

<sup>50</sup> Illinois, while not establishing a statutory standard for physicians' disclosures, does require plaintiff's attorney's certification that a medical expert "has, after reviewing the medical record and other relevant materials involved in the particular action, concluded that a reasonable health professional would have informed the patient of the consequences of the procedure." ILL ANN STAT ch 110, ¶ 2-622 (Smith-Hurd Supp 1989).

<sup>51</sup> The professional standard of disclosure is judicially recognized in the following cases: *Fain*, 479 So 2d at 1150 (interpreting the professional standard embodied in the state's general medical malpractice statute as controlling); *Rodriguez v. Jackson*, 118 Ariz 13, 574 P.2d 481 (1977); *Conrad v. Imatiani*, 724 P.2d 89 (Colo. App 1986); *Wozniak v. Lipoff*, 242 Kan 383, 750 P.2d 971 (1988); *Rice v. Jaskolski*, 412 Mich 206, 313 N.W.2d 893 (1981); *Cress v. Mayer*, 626 S.W.2d 430 (Mo. App 1981); *Hill v. Squibb & Sons*, E.R., 181 Mont 199, 592 P.2d 1383 (1979); *Beattie v. Thomas*, 99 Nev 579, 668 P.2d 268 (1983); *Hook v. Rothstein*, 281 S.C. 541, 316 S.E.2d 690 (S.C. App 1984); *Dessi v. United States*, 489 F.Supp. 722 (E.D. Va. 1980) (applying Virginia law); *Stundon v. Stadnik*, 469 P.2d 16 (Wyo. 1970).

<sup>52</sup> It may be argued that absolute discretion creates a dilemma for physicians: if more information is disclosed in a particular case, the community standard for disclosure is raised by some amount, in turn requiring that more information be disclosed in the future. As a result, physicians would be motivated to disclose no more than is absolutely necessary.

comes<sup>53</sup> as well as detailed lists of potential outcomes.<sup>54</sup> Some statutes further require that information be provided in a manner that allows the reasonable patient to understand the information<sup>55</sup> or "to make a knowledgeable evaluation."<sup>56</sup> The limited extent to which courts have attended to the form and content of disclosure is discussed in Section II.<sup>57</sup>

## 2. The Prudent Patient Approach

Beginning with the Pennsylvania Superior Court ruling in *Cooper v. Roberts*,<sup>58</sup> and followed shortly thereafter by the District of Columbia Court of Appeals' decision in *Canterbury v. Spence*,<sup>59</sup> a significant number of states have adopted what has come to be known as the "prudent patient" or "materiality" standard of disclosure.<sup>60</sup> Most of these states have judicially recognized the standard,<sup>61</sup> while a few states

<sup>53</sup> DEL CODE ANN tit 18, § 6852 (Supp 1988); FLA STAT ANN § 766.103 (1988); IDAHO CODE § 39-4301 (1985); IND CODE ANN § 16-9-5-1-1 (Burns Supp 1988); KY REV STAT ANN §§ 304.40-320 (Michie/Bobbs-Merrill 1987); ME REV STAT ANN tit 24, § 2905(B) (Supp 1988) (specifying the "usual and most frequent risks and hazards"); NEV REV STAT § 41A.110 (1981); N H REV STAT ANN § 507-C:2 (1983); N Y PUB HEALTH LAWS § 2805-d (McKinney 1985 & Supp 1989); VT STAT ANN tit 12, § 1909 (Supp 1988); each identify information required in such general terms

<sup>54</sup> E.g., GA CODE ANN § 31-9-6.1 (Supp 1988); IOWA CODE ANN § 147.137(1) (West Supp 1988); LA REV STAT ANN tit 40, § 1299.40 (West 1977 & Supp 1989)

<sup>55</sup> E.g., FLA STAT ANN § 766.103 (1988); KY REV STAT ANN §§ 304.40-320 (Michie/Bobbs-Merrill 1987); ME REV STAT ANN tit 24, § 2905(B) (Supp 1988)

<sup>56</sup> VT STAT ANN tit 12, § 1909(a)(1) (Supp 1988)

<sup>57</sup> Several commentators have espoused the idea that comprehension is required for an informed consent, and that a duty to help the patient develop sufficient knowledge to make a decision, to consider and weigh the different factors involved, should be placed upon physicians. See, e.g., Note, *Malpractice: Toward a Viable Disclosure Standard for Informed Consent*, 32 OKLA. L. REV. 868 (1979) (proposing a detailed checklist for disclosure)

<sup>58</sup> 220 Pa. Super. 260, 286 A.2d 647 (1971)

<sup>59</sup> 464 F.2d 772 (D.C. Cir.), cert. denied, 409 U.S. 1064 (1972)

<sup>60</sup> In several states, the materiality standard places an *extra* disclosure obligation upon the physician, in addition to those imposed by the professional standard. *Cobbs v. Grant*, 104 Cal. Rptr. 505, 502 P.2d 1 (1972); *Cornfeldt v. Tongen*, 195 Minn. 278, 262 N.W.2d 684 (1977), modified, 295 N.W.2d 638 (Minn. 1980); *Nelson v. Patrick*, 326 S.E.2d 45 (N.C. App. 1985), interpreting N.C. GEN. STAT. § 90-21.13 (1985). A few courts apply the materiality approach, but allow that evidence of a professional standard of disclosure might be "relevant and material" to the withholding of information. *Klink v. G.D. Searle & Co.*, 26 Wash. App. 951, 614 P.2d 701 (1980); *Wasem v. Laskowski*, 274 N.W.2d (N.D. 1979). Lastly, some courts exclude evidence of a professional standard as irrelevant to the issue of materiality. *Creasey v. Hogan*, 48 Or. App. 683, 617 P.2d 1377 (1980); *Rogers v. Lu*, 335 Pa. Super. 595, 485 A.2d 54 (1984) (testimony of nurse to standard disclosure practice of defendant excluded). This latter approach could cut both ways—a jury could find a risk to be immaterial despite a physician practice of disclosure in the community.

<sup>61</sup> The patient based standard of disclosure has been adopted in the following cases: *Cobbs v. Grant*, 104 Cal. Rptr. 505, 502 P.2d 1 (1972); *Logan v. Greenwich Hosp. Ass'n*, 191 Conn. 282, 465 A.2d 294 (1983); *Crain v. Allison*, 443 A.2d 558 (D.C. App. 1982); *LePelley v. Grefenson*, 101 Idaho 422, 614 P.2d 296 (1980). *but see supra* note 46; *Cowman v. Hornaday*, 329 N.W.2d 422

have statutorily adopted it<sup>62</sup> or legislatively supported it after judicial adoption.<sup>63</sup>

The prudent patient standard embodies the concept that the rights to be informed about risks and about alternative treatments and to make the treatment decision are solely those of the patient. Therefore, the adequacy of disclosure should be determined by what information is material to the decision of the patient, that is, what the reasonable patient needs to know in order to make an intelligent, rational decision.

According to the *Cooper* court, the physician must disclose "all those

(Iowa 1983); *Percle v. St. Paul Fire and Marine Ins. Co.*, 349 So. 2d 1289 (La. App.), writ denied, 350 So. 2d 1218 (La. 1977), but see *infra* notes 73-75 and accompanying text; *Sard v. Hardy*, 281 Md. 432, 379 A.2d 1014 (1977); *Harnish v. Children's Hosp. Medical Center*, 387 Mass. 152, 439 N.E.2d 240 (1982); *Cornfeldt v. Tongen*, 195 Minn. 278, 262 N.W.2d 684 (1977) (duty to disclose "significant" risks); *Phillips v. Hull*, 516 So. 2d 488 (Miss. 1987); *Largey v. Rothman*, 110 N.J. 204, 540 A.2d 504 (1988); *Gerety v. Demers*, 92 N.M. 396, 589 P.2d 180 (1980); *Nickell v. Gonzalez*, 17 Ohio St. 3d 136, 477 N.E.2d 1145 (1985); *Scott v. Bradford*, 606 P.2d 554 (Okla. 1979); *Getchell v. Mansfield*, 260 Or. 174, 489 P.2d 953 (1971), but see *infra* note 63; *Cooper v. Roberts*, 220 Pa. Super. 260, 286 A.2d 647 (1971); *Wilkinson v. Vesey*, 110 R.I. 606, 295 A.2d 676 (1972); *Cunningham v. Yankton Clinic*, 262 N.W.2d 508 (S.D. 1978); *Miller v. Kennedy*, 11 Wash. App. 272, 522 P.2d 852 (1974), *aff'd per curiam*, 85 Wash. 2d 151, 530 P.2d 334 (1975); *Cross v. Trapp*, 294 S.E.2d 446 (W. Va. 1982); *Scaria v. St. Paul Fire and Marine Ins. Co.*, 68 Wis. 2d 1, 227 N.W.2d 647 (1975).

Indiana generally is recognized as following the materiality standard, but the courts allow the materiality issue to go to the jury only in those instances where "the situation is clearly within the realm of laymen's comprehension, as where disclosure is so obvious that laymen could recognize the necessity of such disclosure." *Ellis v. Smith*, 528 N.E.2d 826, 828 (Ind. App. 1988). *Accord* *Revord v. Russell*, 401 N.E.2d 763 (Ind. App. 1980); *Frantz v. Community Hosp., Inc.*, 412 N.E.2d 122 (Ind. App. 1980); *Kranda v. Houser-Norborg Medical Corp.*, 419 N.E.2d 1024 (Ind. App. 1981); *Searcy v. Manganhas*, 415 N.E.2d 142 (Ind. App. 1981).

<sup>62</sup> The Texas and Utah legislatures have adopted the materiality standard. TEX. CODE ANN. art. 4590i, § 6.02 (Vernon Supp. 1989); UTAH CODE ANN. § 78-14-5 (1987). But see *Wallach & Berry, Informed Consent in Texas: A Proposal for Reasonableness and Predictability*, 18 ST. MARY'S L.J. 835 (1987) (criticizing the Texas Supreme Court's interpretation of the statute as an emasculatation of the common-law professional standard, leaving Texas law in a quagmire).

<sup>63</sup> Statutory support for the materiality standard after judicial adoption includes PA. STAT. ANN. tit. 40, § 1301.103 (Purdon's Supp. 1988); WASH. REV. CODE ANN. § 7.70.050 (Supp. 1989). See also IND. CODE ANN. § 16-9.5.1-1 (Burns Supp. 1988) (raising a rebuttable presumption that consent is informed if the material risks and reasonable alternatives have been explained to the patient). For a discussion of how the Indiana courts interpret the requirement of disclosing material risks, see *supra* note 61. IOWA CODE ANN. § 147.137 (West Supp. 1988) has been interpreted as a codification of the materiality standard. *Pauscher v. Iowa Methodist Medical Center*, 408 N.W.2d 355, 361 (Iowa 1987). The requirements under OHIO REV. CODE ANN. § 2317.54 (Baldwin Supp. 1988) are similar to that of Indiana, requiring disclosure of "reasonably known risks." See also OR. REV. STAT. § 677.097 (1989) (requiring disclosure "in substantial detail" only after a description in general terms and an affirmative response by the patient to the physician's question whether a more thorough explanation is desired); *Tiedemann v. Radiation Therapy Consultants*, 299 Or. 238, 701 P.2d 440, 446 (1985) (finding that the statute "codified the essence of the *Getchell* decision . . . with some modification"); *Arena v. Gingrich*, 305 Or. 1, 748 P.2d 547 (1988) (adopting a subjective causation approach). Two other courts adopted the materiality standard and were subsequently rebuffed by statute. *Zeleznik v. Jewish Chronic Disease Hosp.*, 47 A.D.2d 199, 366 N.Y.S.2d 163 (1975); *Small v. Gifford Mem. Hosp.*, 133 Vt. 522, 349 A.2d 703 (1975).

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. . . . The physician is bound to disclose only those risks which a reasonable man would consider material to his decision . . . ."<sup>64</sup> The *Canterbury* court's interpretation of such materiality was simple: "all risks potentially affecting the decision must be unmasked."<sup>65</sup> The *Canterbury* court and the overwhelming majority<sup>66</sup> of other courts applying this standard have recognized that it is unreasonable to require full disclosure of a nearly infinite array of remotely possible effects. For example, the California Supreme Court,<sup>67</sup> in adopting the *Canterbury* rationale, explicitly qualified the full disclosure requirement by practicalities:

First, the patient's interest in information does not extend to a lengthy polysyllabic discourse on all possible complications. A minicourse in medical science is not required; the patient is concerned with the risk of death or bodily harm, and problems of recuperation. Second, there is no physician's duty to discuss the relatively minor risks inherent in common procedures, when it is common knowledge that such risks inherent in the procedures are of very low incidence.<sup>68</sup>

The court continued to illustrate its concept of what might be considered common knowledge: "For example, the risks inherent in the simple process of taking a common blood sample are said to include hematoma, dermatitis, cellulitis, abscess, osteomyelitis, septicemia, endocarditis, thrombophlebitis, pulmonary embolism and death, to mention a few."<sup>69</sup> The Oregon Supreme Court formulated the practicality issue in the following way: "A correct test would be to require the disclosure of all the 'material' risks, results that might well occur, not dangers that are extremely remote; risks that are of serious consequences, not unexpected results that are of little consequence."<sup>70</sup> The *Canterbury* court noted in

<sup>64</sup> *Cooper*, 286 A 2d at 650. *Accord Wilkinson*, 295 A 2d at 689

<sup>65</sup> *Canterbury*, 464 F 2d at 786-87

<sup>66</sup> The trial court in *Congrove v Holmes*, 37 Ohio Misc 95, 104, 308 N E 2d 765, 771 (1973), in relying upon and misconstruing *Canterbury*, required full disclosure. The court granted summary judgment for the plaintiff, where the physician failed to disclose the possibility of vocal cord paralysis inherent in a bilateral thyroidectomy, holding that "[a]ny adverse result from an operation which is within the realm of the dangers and risks involved and which is not revealed to the patient is automatically compensable: as a matter of law." The Supreme Court of Ohio has repudiated *Congrove*, specifying that full disclosure is not required in that state. *O'Brien v Angley*, 63 Ohio St 2d 159, 166, 407 N E 2d 490, 495 (1980)

<sup>67</sup> *Cobbs*, 502 P 2d at 11

<sup>68</sup> *Id.* *Accord Canterbury*, 464 F 2d at 789 ("there is no obligation to communicate those [risks] of which persons of average sophistication are aware")

<sup>69</sup> *Cobbs*, 502 P 2d at 11 (citing HARRISON, *PRINCIPLES OF INTERNAL MEDICINE* 726, 1492, & 1510-14 (5th ed 1966)) Accordingly, definition of these terms herein is unnecessary

<sup>70</sup> *Getchell*, 489 P 2d at 956

obiter dicta: "A very small chance of death or serious disablement may well be significant; a potential disability which dramatically outweighs the potential benefits of the therapy or the detriments of the existing malady may summons discussion with the patient."<sup>71</sup> Thus, the courts have recognized that, in an informed consent decision-making setting, there must be a balancing of the benefits of treatment or diagnosis against the inherent risks embodied in those procedures.

The courts have been strained, however, to make these standards any more explicit. For example, although, some appellate courts have explicitly said in dicta that there is no obligation to disclose outcomes having small probabilities and relatively small consequences, no court has expressly said what "small" is. Given this vagueness, it cannot be known whether juries are applying the concepts espoused by the appellate courts in any meaningful manner. Nor has any court espoused a probability/consequence limit upon which physicians can rely, and no consistent rule has emerged in a review of the case law. As one commentator stated: "[E]ndless judicial rehearsal of these factors as general criteria by which the adequacy of particular disclosures would be judged neither helps physicians recognize the scope of their disclosure obligation nor aids courts in managing the inflow of informed consent suits."<sup>72</sup>

### 3. *Statutory Clarification and Modification of Disclosure Duties*

State legislatures have taken several approaches to defining the scope of the informed consent disclosure obligation. For example, several states specify in general terms what disclosure must be made. Louisiana raises a presumption of valid consent if information is provided in writing "setting forth in general terms the nature and purpose of the procedure or procedures, together with the known risks, if any, of death, brain damage, quadriplegia, paraplegia, the loss or loss of function of any organ or limb, or disfiguring scars associated with such procedure or procedures . . . ."<sup>73</sup> The Louisiana courts have interpreted this statute strictly, holding that consent forms reciting the statutory language above are valid.<sup>74</sup>

<sup>71</sup> *Canterbury*, 464 F.2d at 788.

<sup>72</sup> Schneyer, *Informed Consent and the Danger of Bias in the Formation of Medical Disclosure Practices*, 1976 WIS. L. REV. 124, 144-45. More bluntly, "the standard of what constitutes adequate disclosure for informed consent remains hazy at its best and virtually indecipherable to the medical community (and thus unworkable) at its worst." Note, *supra* note 57, at 869.

<sup>73</sup> LA. REV. STAT. tit. 40, § 1299:40 (West 1977 & Supp. 1989). See also Louisiana Medical Consent Law, *id.* § 1299:50; GA. CODE ANN. § 31-9-61 (1985); *supra* note 49 and accompanying text.

<sup>74</sup> *Hondroulis v. Schuhmacher*, 521 So. 2d 534, 536 (La. App.), writ denied, 522 So. 2d 571 (La.), *aff'd*, 531 So. 2d 450 (La. 1988). Accord *Hutton v. Craighead*, 530 So. 2d 101 (La. App. 1988); *Jones v. Levy*, 520 So. 2d 457 (La. App. 1988); *Leonhard v. New Orleans East Orthopedic Clinic*, 485 So. 2d 1008 (La. App.), writ denied, 489 So. 2d 919 (La. 1986); *Madere v. Ochsner Found*

If the consent form does not meet the statutory requirement, the judicially adopted materiality standard applies.<sup>75</sup>

The Iowa statute requires disclosure of the same potential consequences as Louisiana, and also requires disclosure of "the probability of each such risk if reasonably determinable,"<sup>76</sup> without setting any limit on how large probabilities must be to bear mention. It has been postulated that there is a substantial risk that in disclosing such a list to a patient, he or she would reject procedures that are inherently beneficial.<sup>77</sup>

Utah creates a defense if, absent fraud or duress in the inducement, the patient "executed a written consent which sets forth the nature and purpose of the intended health care and which contains a declaration that the patient accepts the risk of substantial and serious harm, if any, in hopes of obtaining desired beneficial results . . . ."<sup>78</sup>

Texas has implemented a disclosure system that has the potential for providing practitioners with substantial protection from liability. The legislature established the Texas Medical Disclosure Panel,<sup>79</sup> comprised of three attorneys and six physicians,<sup>80</sup> which is charged with "identify[ing] and mak[ing] a thorough examination of all medical treatments and surgical procedures . . . in order to determine which [of those treatments and procedures] do and do not require disclosure of the risks and hazards," and to "establish [and publish in the Texas Register] the degree of disclosure required and the form in which the disclosure will be made."<sup>81</sup> Disclosure must then be "in the form and to the degree required by the panel," and consent will be deemed to be effective if in writing, signed, and witnessed.<sup>82</sup> Such consent raises a rebuttable presumption of compliance with the disclosure requirements of the law. Conversely, failure to disclose in accordance with the section creates a rebuttable presumption of negligence.<sup>83</sup> Whether this procedure results in different or better forms is a matter of future research.

Similar to Texas' approach, Hawaii has charged its board of medical examiners with establishing standards for practitioners to follow "to insure

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Hosp. 505 So 2d 146 (La App 1987) In contrast, the Iowa courts have interpreted nearly verbatim statutory language as an enactment of the materiality standard. *Pauscher*, 408 N W 2d at 361

<sup>75</sup> *LaCaze v Collier*, 434 So 2d 1039 (La. 1983)

<sup>76</sup> IOWA CODE ANN § 147 137 (West Supp 1988)

<sup>77</sup> See Comment, *supra* note 28

<sup>78</sup> UTAH CODE ANN § 78-14-5(2)(e) (1987)

<sup>79</sup> Medical Liability and Insurance Improvement Act, TEX. REV. CIV. STAT. art. 4590i, § 6 01 (Vernon Supp 1989)

<sup>80</sup> *Id* § 6 03

<sup>81</sup> *Id* §§ 6 04(a) & (b)

<sup>82</sup> *Id* § 6 06

<sup>83</sup> *Id* §§ 6 07(a)(1) & (2)

that the patient's consent to treatment is an informed consent."<sup>84</sup> If the board promulgates standards "designed to reasonably inform a patient" of certain information, "then the standards shall be admissible as evidence of the standard of care required of the health care providers."<sup>85</sup>

Nevada places the least burden on the practitioner, where

[a] physician . . . has conclusively obtained the consent of a patient for a medical or surgical procedure if he has done the following: 1. Explained to the patient in general terms without specific details, the procedure to be undertaken; 2. Explained to the patient alternative methods of treatment, if any, and their general nature; 3. Explained to the patient that there may be risks, together with the general nature and extent of the risks involved, without enumerating such risks . . .<sup>86</sup>

The scope of this standard awaits judicial interpretation.

Three states have yet to adopt clearly a standard of disclosure. Alaska's informed consent statute<sup>87</sup> is silent on the issue of disclosure standard, requiring that the patient be informed of "the common risks and reasonable alternatives to the proposed treatment."<sup>88</sup> The most recent informed consent case in Alaska, *Poulin v. Zarman*,<sup>89</sup> favorably cited *Canterbury* and *Cobbs v. Grant* with respect to the proximate causation issue, but no appellate judicial interpretation of the statute has yet issued. Similarly, Hawaii adopted the professional standard in *Nishi v. Hartwell*,<sup>90</sup> but more recent appellate court decisions have shown a propensity to retreat from this position, although they have not settled the question.<sup>91</sup> Lastly, North Dakota has not adopted a standard, although, in holding the Medical Malpractice Act unconstitutional, its supreme court favorably recited the materiality standard and subjective causation.<sup>92</sup> The lack of direction provided by the

<sup>84</sup> HAWAII REV. STAT. § 671-3(a) (1985).

<sup>85</sup> *Id.* § 671-3(b). See *infra* notes 90 & 91.

<sup>86</sup> NEV. REV. STAT. § 41A 110 (1981) "[W]ithout enumerating such risks," *id.* is ambiguous, perhaps meaning providing a count of the risks or, more likely, quantifying the probabilities of the risks.

<sup>87</sup> ALASKA STAT. ANN. § 09 55 556 (1983).

<sup>88</sup> *Id.* § 09 55 556(a).

<sup>89</sup> 542 P.2d 251, 275 (Alaska 1976).

<sup>90</sup> 52 Haw. 188, 473 P.2d 116 (1970).

<sup>91</sup> See *Leyson v. Steuermann*, 5 Haw. App. 504, 705 P.2d 37 (1985) (interpreting HAWAII REV. STAT. § 671-3 (1985)); *Mroczkowski v. Straub Clinic & Hosp.*, 6 Haw. App. 563, 732 P.2d 1255 (1987) ("We do not answer the question whether the seriousness of the risk is to be answered from the point of view of the patient, the physician, or otherwise." *Id.* at 1259 n.1). See also Note: *Leyson v. Steuermann: Is There Plain Error in Hawaii's Doctrine of Informed Consent?*, 8 U. HAWAII L. REV. 569 (1986) (discussing the ambiguity in current Hawaii law, the appellate courts expressly failing to interpret the statute as affirming or undermining the professional standard as adopted in *Nishi*).

<sup>92</sup> *Arneson v. Olson*, 270 N.W.2d 125, 133 (N.D. 1978) (the law "changed from a subjective right of the patient to refuse consent to an objective determination of whether a reasonable prudent person

court may be seen in the ambiguous jury charge set forth in *Wasem v. Laskowski*,<sup>93</sup> which provides only that professional testimony is "relevant and material"<sup>94</sup> to the issue of whether there should have been disclosure.

## II. COMMUNICATION IN THE INFORMED CONSENT SETTING

Interestingly, no statutory or judicial standards have been promulgated for the determination of what information is necessary for making decisions,<sup>95</sup> nor the manner for providing such information so as to increase the likelihood that patients can make optimal decisions. Nor have there been any legal requirements for testing patients' comprehension or decision-making skills.<sup>96</sup> Two cases have been found, however, which indicate that the communication and comprehension aspects of informed consent may be a developing area of the law, arguably an area that raises many difficult questions about the informed consent setting.

### A. Disclosure, Comprehension, and Decision-Making

#### 1. Content of the Disclosure

One case has addressed the issue of how detailed information should be to ensure that the patient is *informed*. The trial court in *Nisenholtz v. Mt. Sinai Hospital*<sup>97</sup> granted a new trial after a hung jury on two special interrogatories on the informed consent issue. The plaintiff underwent surgical removal of his colon and rectum, and was rendered impotent. At trial, the plaintiff's expert testified that the "defendant's explanation of

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would have undergone the treatment had he been properly informed, and requiring information only to the extent that such information 'would normally be provided to the patient under like circumstances by health care providers' "

<sup>93</sup> 274 N.W.2d 219 (N.D. 1979)

<sup>94</sup> *Id.* at 226. In *Lemke v. United States*, 557 F. Supp. 1205, 1212 (D.N.D. 1983), the court, citing *Winkjer v. Here*, 277 N.W.2d 579 (N.D. 1979), noted that "[t]he North Dakota Supreme Court has not ruled on whether the standard by which [the physician's] duty is to be measured is 'the custom of the physician practicing in the community' or what is 'reasonable under the circumstances' "

<sup>95</sup> Sagan, *Beyond Risk Assessment*, 7 RISK ANAL. 1, 1 (1987), querying whether, when a physician told you that you need a coronary bypass, "would you only concern yourself with the various risks involved? Or, would you not also be asking yourself about benefits, about alternatives, and about whether or not you can trust this doctor, his skill and knowledge, his ethics, and his values?" See also Note, *Restructuring Informed Consent: Legal Therapy for the Doctor-Patient Relationship*, 79 YALE L.J. 1533, 1561 (1970) (discussing the impact of increased information communication on the physician-patient relationship)

<sup>96</sup> It is important to note that the vast majority of the early studies of patient attitudes, communications, and recall exhibited methodological weaknesses. Meisel & Roth, *supra* note 14. Any errors introduced into the present article from such questionable empirical results are negligible inasmuch as the desire to participate in the medical decision and the ability to recall technical information provided in the informed consent setting may be necessary but are not sufficient conditions for optimal decision-making.

<sup>97</sup> 126 N.Y. Misc. 2d 658, 483 N.Y.S.2d 568 (1984)

risks was inadequate to permit the patient to make a knowledgeable evaluation of the proposed surgery," and the court held that "it would be unwise . . . to hold that a physician need never provide more information than a mere identification of the risk and its likelihood of occurrence."<sup>98</sup> The court stated:

The risks of medical procedures vary depending upon a wide range of characteristics inherent to the patient, the physician, and the procedure. In order to adequately evaluate whether to submit to a procedure a reasonably prudent patient should be able to evaluate the interaction of these inherent characteristics—the 'mechanics' by which such could occur. A 'very slight' risk to the general population could become a substantial risk to a somewhat susceptible patient, being treated by a physician of less than average competence or experience, using a procedure with which the physician was unfamiliar.<sup>99</sup>

Such a requirement could easily be unbounded, for each consequence in the plethora of risks attendant upon even the simplest of procedures may have many "mechanisms" leading thereto.

No court has ruled on the obligation to disclose risks using numerical rather than verbal expressions of frequency. Physicians have been found to favor the latter.<sup>100</sup> Nonetheless, a broad research base shows the imprecision and ambiguity inherent in words<sup>101</sup> and the context dependency of their interpretations.<sup>102</sup> Arguably, a patient could assert that, although a risk was disclosed, the use of a verbal expression having a wide interpretation was misleading, thereby vitiating the consent.<sup>103</sup> Conversely, if a physician dis-

<sup>98</sup> *Id.* at 662

<sup>99</sup> *Id.*

<sup>100</sup> The reasons for preferring verbal expressions may include the desire to avoid the appearance of precision where the frequency is highly uncertain, the lack of detailed knowledge of the medical literature on a particular procedure, or the hope of avoiding an explicit commitment. Kong, Barnett, Mosteller, & Youtz, *How Medical Professionals Evaluate Expressions of Probability*, 315 *NEW ENG J MED* 740, 743 (1986).

<sup>101</sup> Variability is rampant. One man's 'rarely' is another man's 'hardly ever'. 'Often' and 'rather often' have the same medians. 'Rather' is rather meaningless. 'Very seldom' is very seldom less than 'seldom'. Hakel, *How Often is Often?*, 23 *AM PSYCHOL* 533, 533 (1968); Kenney, *Between Never and Always*, 305 *NEW ENG J MED* 1097 (1981) (suggesting using words and numerical estimates together). Accord Nakao & Axelrod, *Numbers Are Better Than Words: Verbal Specifications of Frequency Have No Place in Medicine*, 74 *AM J MED* 1061 (1983) (showing that neither physicians nor laypeople have consistent numerical interpretations of word phrases). See generally Budescu & Wallsten, *Consistency in Interpretation of Probabilistic Phrases*, 36 *ORG BEH HUMAN DEC PROC* 391 (1985); Budescu, Weinberg, & Wallsten, *Decisions Based on Numerically and Verbally Expressed Uncertainties*, 14 *J EXPER PSYCHOL: HUMAN PERCEP. & PERF* 281 (1988).

<sup>102</sup> Parducci, *Often is Often*, 23 *AM PSYCHOL* 828 (1968).

<sup>103</sup> Indeed, failure to quantify the frequency at trial could result in the jury being empowered to assess their own frequency of occurrence from testimony provided. *Kissinger v Lofgren*, 836 F.2d 678 (1st Cir. 1988). Cf. *Precourt v Frederick*, 395 Mass. 689, 481 N.E.2d 1144 (1985) (reversing a jury verdict for plaintiff for lack of evidence of the frequency of aseptic necrosis of the femoral head from prolonged Prednisone use).

closes a numerical estimate of the frequency of a risk, and that estimate is lower than frequencies quoted in the medical literature, a plaintiff might assert a fraudulent misrepresentation of the risk.<sup>104</sup>

There has been very little study of how to communicate numerical frequencies or probabilities to patients. One example of the potential difficulties may be seen in a study where researchers used visual representations comprised of small dots printed on paper to convey the magnitude of risks. Student subjects were presented with a hypothetical choice of receiving an influenza vaccination or not. One group received frequencies of death from both the flu and the vaccination numerically, while a second group received the visual aid as well. Subjects receiving the combined presentation were more likely to accept vaccination.<sup>105</sup>

## 2. Form of the Disclosure

The law has generally deferred to the physician's discretion regarding "which mixture of pictures, words, and other media is adequate" to secure an informed consent.<sup>106</sup> Georgia's informed consent statute appears to be the only one that discusses specific media, endorsing "the use of video tapes, audio tapes, pamphlets, booklets, or other means of communication . . . ."<sup>107</sup> Other statutes require that the information be provided "in a manner permitting the patient to make a knowledgeable evaluation,"<sup>108</sup> or that the information be provided in a way that gives the reasonable individual a general understanding of the procedure, the alternatives, and the risks.<sup>109</sup> Most statutes, however, simply require that the patient have information disclosed,<sup>110</sup> supplied,<sup>111</sup> provided,<sup>112</sup> given,<sup>113</sup> or explained to him or her,<sup>114</sup> that the

<sup>104</sup> This raises the important issues of what comprises a known risk and the extent to which physicians have a duty to be aware of the medical literature, discussion of which is beyond the scope of this article.

<sup>105</sup> Kaplan, Hammel, & Schimmel, *Patient Information Processing and the Decision to Accept Treatment*, 1 J SOC BEH PERS 113 (1985).

<sup>106</sup> Halligan, *supra* note 41, at 38-39.

<sup>107</sup> GA CODE ANN § 31-9-6 1(c) (1985). For an excellent summary of the disclosure requirements under the various states' statutes, see Andrews, *Informed Consent Statutes and the Decisionmaking Process*, 5 J LEGAL MED 163 (1984). See also Meisel & Kabnick, *Informed Consent to Medical Treatment: An Analysis of Recent Legislation*, 41 U PITT L REV 407 (1980).

<sup>108</sup> VT STAT ANN tit 12, § 1909(a)(1) (Supp 1988).

<sup>109</sup> FLA STAT ANN § 766 103 (1988).

<sup>110</sup> IDAHO CODE § 39-4304 (1985); OHIO REV CODE ANN § 2317.54 (Baldwin Supp 1988); OR REV STAT § 677 097 (1989); N Y PUBLIC HEALTH LAWS § 2805-d 1 (McKinney 1985 & Supp 1989); TEX CODE ANN art 4590i, § 6 02 (Vernon Supp 1989).

<sup>111</sup> ARK STAT ANN § 16-114-206 (1987); DEL CODE ANN tit 18, § 6852 (Supp 1988); N H REV STAT ANN § 507-C:2 (1983); TENN CODE ANN § 29-26-118 (1980).

<sup>112</sup> NEB REV STAT § 44-2816 (1988).

<sup>113</sup> HAWAII REV STAT § 671-3 (1985).

<sup>114</sup> IND CODE ANN § 16-9 5 1-1 (Burns Supp 1988); NEV REV STAT § 41A 110 (1981).

patient be informed thereof,<sup>115</sup> or only that the medical practitioner act in accordance with the accepted standard of the profession in obtaining consent from the information provided.<sup>116</sup>

In a Florida case, *Dandashi v. Fine*,<sup>117</sup> where surgical repair of a fractured orbital floor resulted in loss of vision, the court held that "the trier of fact is obligated to consider all the circumstances including . . . the adequacy and reliability of the means chosen to communicate the information to appellant, considering also the known language difficulty."<sup>118</sup> The additional emphasis here highlights the lack of specific guidance provided to physicians—or juries—for determining whether communications have been adequate. Indeed, allowing a lay jury to apply a nonexistent standard for such a complex issue is arguably a violation of due process.<sup>119</sup>

Generally, the courts and legislatures have not addressed the possibility that the complexity of medical decisions often means that simply providing information to a patient will not ensure that the patient comprehends the information well enough to use it in the decision-making task. Indeed, no case has been found where the argument has been advanced that consent, although given, was not effective because of the irrationality of the decision reached.<sup>120</sup>

There is, however, a growing research literature that can guide the courts and physicians in evaluating communications. For example, several studies have investigated how the format of communications can affect patients' recall of their contents. Other studies have identified barriers to physician-patient interactions, such as unwillingness or inability to disclose uncertainty,<sup>121</sup> or lack of interpersonal communication

<sup>115</sup> ALASKA STAT ANN § 09.55.556 (1983); ILL ANN STAT ch 110. ¶ 2-622 (Smith-Hurd Supp 1989); PA STAT ANN tit 40. § 1301.103 (Purdon's Supp 1988); UTAH CODE ANN § 78-14-5 (1987); WASH REV CODE ANN § 7.70.050 (Supp 1989)

<sup>116</sup> KY REV STAT ANN § 304.40-320 (Michie/Bobbs-Merrill 1987); ME REV STAT ANN tit 24. § 2905(B) (Supp 1988); N C GEN STAT § 90-21.13 (1985)

<sup>117</sup> 397 So 2d 442 (Fla App 1981).

<sup>118</sup> *Id.* at 446 (emphasis added) The cause of action really sounded in battery, inasmuch as plaintiff destroyed the first consent form and contended that he did not know that the second form he signed was a consent form

<sup>119</sup> Traditional notions of due process and fundamental fairness require that the law, whether judicially or legislatively created, give reasonable notice of prohibited conduct so that the average person may comport his or her behavior in order to avoid liability "As a matter of due process under the fifth amendment, reasonable notice must be given to the public of what conduct must be avoided. Whether in civil or criminal proceedings, it is unequivocally established that that basic right to notice applies." *A. B. Small Co. v. American Sugar Ref. Co.*, 267 U.S. 233, 239 (1925) See also *Connolly v. General Constr. Co.*, 269 U.S. 385, 391 (1926)

<sup>120</sup> See *Fain*, 479 So 2d at 1159 (Jones, J., dissenting) (characterizing as "absurd" the hypothetical argument that the putative consent of the plaintiff is vitiated because a reasonably prudent person would not have accepted treatment)

<sup>121</sup> Katz, *Why Doctors Don't Disclose Uncertainty*, 14 HASTINGS CENTER REP 35 (1984) But see Gutheil, Bursztajn, & Brodsky, *Malpractice Prevention Through the Sharing of Uncertainty*:

skills.<sup>122</sup> Despite these difficulties, most patients seem to prefer a physician as a source of information over written materials.<sup>123</sup> Other approaches to increasing recall include giving patients information well in advance of medical treatment,<sup>124</sup> giving written information followed by individual consultation,<sup>125</sup> testing patients for recall and comprehension,<sup>126</sup> and using videotapes.<sup>127</sup>

Written communications, such as hospital consent forms and patient package inserts (PPIs), have been analyzed by many researchers in an attempt to discover the nuances of this medium. For example, the readability of forms, based on the Flesch<sup>128</sup> and

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*Informed Consent and the Therapeutic Alliance*, 311 NEW ENG. J. MED. 49 (1984) (stressing the use of communication of uncertainty to build a therapeutic alliance)

<sup>122</sup> DiSalvo, Larsen, & Backus. *The Health Care Communicator: An Identification of Skills and Problems*, 35 COMM. EDUC. 231 (1986). See also Wu & Pearlman, *Consent in Medical Decision Making: The Role of Communication*, 3 J. GEN. INTERN. MED. 9, 9 (1988) (finding that clinicians seldom communicate the "four essential elements of informed decision making—rationale, risks, benefits, and alternatives")

<sup>123</sup> Fleckenstein, Joubert, Lawrence, Patsner, Mazzullo, & Lasagna, *Oral Contraceptive Patient Information: A Questionnaire Study of Attitudes, Knowledge, and Preferred Information Sources*, 235 J. A. M. A. 1331, 1336 (1976)

<sup>124</sup> Carnerie points out that up to a six-week delay in most procedures is not critical to survival, *supra* note 19, at 59. See also Morrow, Gootnick, & Schmale, *supra* note 19 (finding that patients given a form to take home for 1-3 days exhibited significantly improved recall over controls)

<sup>125</sup> Faden, *Disclosure and Informed Consent: Does It Matter How We Tell It?*, 5 HLTH. EDUC. MONOGR. 198 (1977). See also Applebaum, Roth, Lidz, Benson, & Winslade, *False Hopes and Best Data: Consent to Research and the Therapeutic Misconception*, 17 HASTINGS CENTER REP. 20, 24 (1987) (suggesting, in the research context, that a member of the Institutional Review Board meet with patients to review the disclosure "with a session in which the potential subject reviews risks and benefits with someone who is not a member of the research team"); H. BURSZTAJN, R. I. FEINBLOOM, R. M. HAMM, & A. BRODSKY, *MEDICAL CHOICES, MEDICAL CHANCES: HOW PATIENTS, FAMILIES AND PHYSICIANS CAN COPE WITH UNCERTAINTY* 218 (1981) (discussing patient advocates in the hospital setting); Gertson & McNamara, *Factors Influencing a Person's Reaction to Informed Consent*, 54 PSYCHOL. REP. 112 (1984) (finding that subjects were more likely to ask questions when information was provided orally and in writing versus in writing alone, although it is not clear from their article what opportunity was given to writing-only subjects to ask questions)

<sup>126</sup> Miller & Willner, *The Two-Part Consent Form: A Suggestion for Promoting Free and Informed Consent*, 290 NEW ENG. J. MED. 964 (1974) (incorporating comprehension tests into the consent process); Taub & Baker, *The Effect of Repeated Testing upon Comprehension of Informed Consent Materials by Elderly Volunteers*, 9 EXP. AGING RES. 135 (1981) (providing multiple trials with feedback); Williams, Rieckmann, Trenholme, Frischer, & Carson, *The Use of a Test to Determine that Consent Is Informed*, 142 MILITARY MED. 542 (1977) (using a test to verify communication to research subjects)

<sup>127</sup> Compare Tymchuk, Ouslander, & Rader, *supra* note 10 (finding no effect of videotape of storybook enactment) with Barbour & Blumenkrantz, *Videotape Aids Informed Consent Decision*, 240 J. A. M. A. 2741 (1978) (finding a positive effect)

<sup>128</sup> Flesch, *A New Readability Yardstick*, 32 J. APPLIED PSYCH. 221 (1948) (promulgating the readability formula  $RE = 206.835 - 846 * wl - 1.015 * sl$ ; where  $wl$  is the average number of syllables in several 100-word samples, and  $sl$  is the average number of words per sentence in those samples. The score falls between 0 and 100, where the higher scores indicate easier readability)

Fry<sup>129</sup> readability scales,<sup>130</sup> has been varied with mixed success on recall.<sup>131</sup> In general, these materials are hard to read,<sup>132</sup> and clear guidelines are lacking for how to simplify them.

### 3. The Decision

Research has found that most patients express a strong desire for a great deal of information with respect to their ailment and treatment.<sup>133</sup> Yet, many studies also have shown patients' limited ability to recall such information.<sup>134</sup> Recall is important for both decision-making, where information is assembled and a choice made, and for recovery, where, for example, procedures may need to be followed and contraindicated substances

<sup>129</sup> Fry. *A Readability Formula that Saves Time*. 11 J. READING 513 (1968) (introducing a measure similar to that of Flesch, but including a scale for estimating the level of education necessary to read the material)

<sup>130</sup> See generally Grundner. *Two Formulas for Determining the Readability of Subject Consent Forms*. 33 AM PSYCHOL 773 (1978) (recommending the use of the Flesch and Fry tests in preparation of such documents)

<sup>131</sup> Compare Bradshaw, Ley, & Kinsey. *Recall of Medical Advice: Comprehensibility and Specificity*. 14 BR J SOC & CLIN PSYCHOL 55 (1975) (nonsignificant improvement with easier readability) and Tymchuk, Ouslander, & Rader. *supra* note 10 (finding an improvement by shortening the length of the document, reducing words per sentence from 22.9 to 13.8, reducing the number of low frequency words from 70 to 29, and changing verbs from active to passive form) with Taub, Baker, & Sturr. *supra* note 10 (finding mixed effectiveness of increased readability as a function of subject age)

<sup>132</sup> Morrow. *How Readable Are Subject Consent Forms?*. 244 J A M A. 56, 57 (1980) (finding the readability of 60 forms from five regional cancer clinics to be difficult. "comparable to material in an academically oriented journal")

<sup>133</sup> See, e.g., Cassileth, Zupkins, Sutton-Smith, & March. *Information and Participation Preferences Among Cancer Patients*. 92 ANNALS INT MED 832, 835 (1980) ("most patients want to know as much as possible about their illness and treatment, and most prefer to participate in decisions about their care"); Morris & Kanouse. *Consumer Reactions to Differing Amounts of Written Drug Information*. 14 DRUG INTELLIGENCE CLINICAL PHARMACY 531 (1980) (describing recall and preferences for four various-length PPIs); Morris, Mazis, & Gordon. *A Survey of the Effects of Oral Contraceptive Patient Information*. 238 J A M A. 2504 (1977) (finding that patients preferred and tended to retain the more elaborate manufacturer's booklets over PPIs); Roling, Pressgrove, Keeffe, & Rafkin. *An Appraisal of Patients' Reactions to "Informed Consent" for Peroral Endoscopy*. 24 GASTROINT ENDOSCOPY 69 (1977) (finding that a majority of patients believed that disclosure of risks was helpful in decision-making) The desire for information does not necessarily mean that the patient desires to make or participate in the therapeutic decision. Blanchard, Labrecque, Ruckdeschel, & Blanchard. *Information and Decision-Making Preferences of Hospitalized Adult Cancer Patients*. 27 SOC SCI MED 1139 (1988) (finding that about 92% of their subject lung cancer patients desired a great deal of information, and that about 25% of those wanting information preferred to have the physician make the decision)

<sup>134</sup> Priluck, Robertson, & Buettner. *What Patients Recall of the Preoperative Discussion after Retinal Detachment Surgery*. 87 AM J OPHTHALMOLOGY 620 (1979) (57% recall, measured on average 4.2 days after surgery); Robinson & Merav. *Informed Consent: Recall by Patients Tested Postoperatively*. 22 ANNALS THORAC SURG 209 (1976) (20 patients exhibited poor recall four to six months after coronary surgery); Leeb, Bowers, & Lynch. *Observations on the Myth of "Informed Consent"*. 58 PLASTIC RECONSTR SURG 280 (1976) (35% recall within seven days, with significantly better recall exhibited for those with more high school education and for those who characterized

avoided. It must be stressed that recall is only a proxy for comprehension, the latter requiring assimilation of new information with other knowledge.

From a legal viewpoint, as long as patients make a choice and can explain some rationale for their decision,<sup>135</sup> then further inquiry is not made into the rationality or appropriateness of the decision.<sup>136</sup> While some writers assert that the physician may try, through legitimate means such as education, argument, persuasion, wheedling, and cajoling, to change a patient's mind if the patient's decision is viewed as being wrong,<sup>137</sup> the dividing line between coercion and such persuasion may be difficult to discern.

## B. Limitations on Decision-Making Skills

A good deal of research has been performed over the last 30 years regarding the cognitive processes of decision-making in the face of uncertainty.<sup>138</sup> It applies to patients in informed consent settings just as it does to people making any risky decision. Such decisions involve choices between alternative treatments, each having different chances of success, different side effects, and different collateral risks. In the decision-making process, patients must understand these risks, assess their values for the potential

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themselves as being "very nervous"); Leonard, Chase, & Childs. *Genetic Counseling: A Consumers' View*. 287 *NEW ENG J MED* 433 (1972) (post-birth counseling of families of children with cystic fibrosis, phenylketonuria, and Down's syndrome; half had a good grasp of the material, a quarter learned something, and a quarter learned little)

<sup>135</sup> In most settings, patients are not required to give an explanation for their decision, except when competency is at issue. Nonetheless, "[r]efusals [of treatment] may be used as a justification for challenging the capacity of the citizen to decide what is best for himself. A finding of incompetence which deprives him of authority to decide for himself results from a successful challenge and constitutes the ultimate disregard of his human dignity." Goldstein. *For Harold Lasswell: Some Reflections on Human Dignity, Entrapment, Informed Consent, and the Plea Bargain*. 84 *YALE L J* 683-691 (1975)

<sup>136</sup> For example, the *Cooper* court stated that the "primary interest" is in "having the patient informed of all the material facts from which he can make an intelligent choice as to his course of treatment, regardless of whether he in fact chooses rationally." *Cooper*. 286 A 2d at 650. Indeed, "[t]o assign to supervising courts the function of determining whether an individual citizen's consent is informed or intelligently made is to attribute to such decisionmakers a capability they do not have." Goldstein *supra* note 135, at 686

<sup>137</sup> Arras. *A Philosopher's View*. 11 *GENERATIONS* 64, 65 (1987)

<sup>138</sup> *JUDGMENT UNDER UNCERTAINTY: HEURISTICS AND BIASES* (D. Kahneman, P. Slovic, & A. Tversky eds. 1982) (provides an introduction to and overview of this substantial literature) [*JUDGMENT UNDER UNCERTAINTY*]; Andrews. *supra* note 107, at 180-201, reviewed the cognitive psychology literature and early risk communication literature. She concluded that a rational decision may be enabled by providing probabilistic information in consistent percentage form, and by providing information about alternatives, benefits, risks, and side effects by like attributes to ease comparisons. This is an extremely optimistic view of the efficacy of communications and decision-making under uncertainty, and requires empirical validation. See also Mazur. *Why the Goals of Informed Consent Are Not Realized: Treatise on Informed Consent for the Primary Care Physician*. 3 *J GEN INTERN MED* 370 (1988); Mazur. *Informed Consent: Court Viewpoints and Medical Decision Making*. 6 *MED DECIS MAKING* 224 (1986)

outcomes, and discount each value by the probability of its occurring. If people lack these intellectual skills, then their decision-making will suffer. The research has shown a mixed picture.

One area where individuals exhibit difficulty is in the intuitive assessment of uncertain events.<sup>139</sup> As mentioned, in the absence of explicit training, people often resort to the use of simplified decision rules, known as heuristics. Reliance on these rules can be useful. However, it often leads to suboptimal decisions.<sup>140</sup> For example, people may estimate the frequency of an event by the ease with which they can remember instances of it happening. That sensible strategy will lead them astray when instances are differentially memorable, or when occurrences are differentially observable. For example, in one study, subjects assessed the frequency of dying from various causes. Homicide was judged to be about as frequent a cause as fatal stroke, while about 11 times more people die of strokes. Homicides often get extensive publicity, while deaths from stroke may only be publicized when the victim is well known. In general, researchers found that "overestimated causes of death were dramatic and sensational, whereas underestimated causes tended to be unspectacular events, which claim one victim at a time and are common in nonfatal form."<sup>141</sup>

Thus, risks may be exaggerated when individuals have had some salient, available experiences with them. Conversely, risks with which a patient has no familiarity may be subjectively underestimated, leaving the patient unhappily surprised when the risk transpires. Indeed, individuals

<sup>139</sup> The biases and limitations on individual decision-making skills discussed in this section apply equally to jurors and jurists. The potential impact of such limitations on the ability of materiality-jurisdiction juries to apply the law is beyond the scope of the present article. A comprehensive review of the judicial decisions under the two bodies of law currently is being performed to discover if the "prudent patient" courts are establishing a definitive standard by which practitioners might guide their behavior. It may be assumed that the patient-based standard requires greater disclosure than does the professional standard in a given situation. For example, in *Cooper*, where the plaintiff's stomach was perforated during a gastroscopic examination, such perforation having an incidence rate of less than 1/2500 or 0.0004 (the court mistakenly recited this as ".0004%," *Cooper*, 286 A.2d at 648), the court decided that the appropriateness of failing to disclose this risk was an issue for the jury. In stark comparison and perhaps result (the actual outcome of *Cooper* on remand is not reported), the court in *Mason v. Ellsworth*, 3 Wash. App. 298, 474 P.2d 909 (1970), where an endoscope punctured the patient's esophagus, the frequency of which was estimated at 0.0025 to 0.0075 (or roughly an order of magnitude greater than the risk in *Cooper*), held as a matter of law that the risk was not reasonably foreseeable and need not have been disclosed.

<sup>140</sup> E.g., Fleckenstein, et al., *supra* note 123, at 1335 (identified a group of oral contraceptive users who believed that the benefits of preventing unwanted pregnancy did not outweigh the risk to their health; their beliefs are inconsistent with the findings of physicians and regulators concerning the reasonableness of the risk). See also Kaplan, Hammel, & Schimmel, *supra* note 105.

<sup>141</sup> Slovic, Fischhoff, & Lichtenstein, *Facts Versus Fears: Understanding Perceived Risk*, in JUDGMENT UNDER UNCERTAINTY, *supra* note 138, at 467. See generally Tversky & Kahneman, *Availability: A Heuristic for Judging Frequency and Probability*, 5 COG. PSYCHOL. 207 (1973).

have been observed to be overly optimistic about events with which they have little experience, thinking that "it can't happen to me."<sup>142</sup>

Even when probabilities are perceived accurately, how potential outcomes are presented (or "framed") to a patient may still affect the decision.<sup>143</sup> Individuals have been found to be risk-averse when potential consequences are presented as gains (for example, in terms of lives saved) and risk-seeking when the same options are presented as losses (for example, in terms of deaths unavoids). For example, the risk from general anesthesia may be framed as a 0.0002 chance of death or a 0.9998 chance of living. In a close decision, the former presentation might tip the decision away from surgery, while the latter presentation tips it toward.<sup>144</sup> There is an acute need to explore the effects of such nuances of communication in the context of informed consent decisions, so that physicians have guidance about how to present information most fairly.

In the light of these cognitive limitations, the legal rhetoric of informed consent appears unreasonably optimistic about the ability of information alone to ensure that patients will make decisions in their own best interests. As one commentator summed up:

These judgmental difficulties have several implications for the optimality of decision making in informed consent cases. One is that people's intuitions are not to be trusted. It cannot be assumed that information about risks is common knowledge, nor that the obligation to inform people is served simply by depositing technical information on their doorsteps.<sup>145</sup>

Many courts have recognized that the informed consent laws place physicians at the mercy of unhappy patients, who, enlightened by perfect hindsight, assert that their decision to accept treatment was in error.<sup>146</sup>

<sup>142</sup> Slovic, Fischhoff, & Lichtenstein. *supra* note 141, at 468 "[O]ptimism is greatest for hazards with which subjects have little personal experience, [and] for hazards rated low in probability . . . ." Weinstein. *Optimistic Biases About Personal Risks*. 246 *SCIENCE* 1232, 1232 (1989) See, e.g., *Contreras v St Luke's Hosp*, 78 Cal App 3d 919, 923, 144 Cal Rptr 647, 650 (1978) (plaintiff was nonsuited where the defendant had told him: "In one out of a hundred operations, infection was one of the complications," to which plaintiff had replied: "Doctor, you say it's one out of a hundred. Then I'm not going to be the one").

<sup>143</sup> R. DAWES, *RATIONAL CHOICE IN AN UNCERTAIN WORLD* 34-7 (1988).

<sup>144</sup> See, e.g., McNeil, Pauker, Sox, & Tversky, *On the Elicitation of Preferences for Alternative Therapies*. 306 *NEW ENG J. MED.* 1259 (1982) (finding a framing effect from presentation of survival rates as probabilities of dying versus living) For a discussion of risk aversion, risk seeking, and utility theory, see generally Kahneman & Tversky, *Prospect Theory: An Analysis of Decision under Risk*. 47 *ECONOMETRICA* 263 (1979)

<sup>145</sup> Fischhoff, *supra* note 7, at 177

<sup>146</sup> The subjective causation standard enunciated by a small number of prudent-patient courts. see *supra* note 37, has been criticized on the basis that "patient hindsight" will tend to decrease the uncertainty under which the decision was made, in light of the subsequently gained knowledge. Note, *supra* note 57, at 883

Juries, too, can fall prey to this bias. This concern has been studied extensively by cognitive researchers, concluding:

In hindsight, people consistently exaggerate what could have been anticipated in foresight. They not only tend to view what has happened as having been inevitable, but also to view it as having appeared "relatively inevitable" before it happened. People believe that others should have been able to anticipate events much better than was actually the case. They even misremember their own predictions so as to exaggerate in hindsight what they knew in foresight.<sup>147</sup>

This research does not imply that hindsight is a knowing misrepresentation of fact, for individuals will be truthful in their hindsight recall. The hindsight bias arises from cognitive limitations on people's ability to recall past perspectives accurately.<sup>148</sup> The potential for hindsight bias in treatment decisions was foreseen by the Utah legislature: "In determining what a reasonable, prudent person in the patient's position would do under the circumstances, the finder of fact shall use the viewpoint of the patient before health care was provided and before the occurrence of any personal injuries alleged to have arisen from said health care."<sup>149</sup> The research literature on this phenomenon can be useful here in at least three ways: (1) documenting the existence and magnitude of the bias, perhaps to sensitize the trial judge and jury to its impact on the findings of fact; (2) developing procedures for retrieving foresightful perspectives; and, (3) creating defensible records of what perceptions motivated decisions at the time they were made.

### III. IMPROVING COMMUNICATIONS

The clearest conclusion arising from this review is that further research is needed to determine how cognitive barriers to rational decision-making affect the legal concept of informed consent—after more intensively reviewing the extensive literature.

One direction for such research is through better analysis of informed consent decisions. Patients face a flood of information, frequently without

<sup>147</sup> Fischhoff. *For Those Condemned to Study the Past: Heuristics and Biases in Hindsight*. in JUDGMENT UNDER UNCERTAINTY. *supra* note 138. at 341 (citing Fischhoff & Beyth. "I knew it would happen"—Remembered Probabilities of Once-Future Things. 13 ORG BEH HUMAN PERF 1 (1975)). See also Fischhoff, *Hindsight ≠ Foresight: The Effect of Outcome Knowledge on Judgment Under Uncertainty*. 1 J EXPER PSYCHOL: HUMAN PERCEP & PERF 288 (1975) Research indicates that the bias is difficult to overcome. Fischhoff. *Debiasing*. in JUDGMENT UNDER UNCERTAINTY. *supra* note 138. at 427 (suggesting possible means for overcoming the bias)

<sup>148</sup> R. DAWES. *supra* note 143. at 119-20

<sup>149</sup> UTAH CODE ANN § 78-14-5(1)(f) (1987) Cf. *Jozsa v Hottenstein*. 364 Pa Super 469. 474. 528 A 2d 606, 608 (1987) (court operationalized the jury's hindsight. stating. "it is the role of the jury to decide whether that type of harm if it occurs. is a risk which a reasonable patient would consider in deciding on whether to undergo or reject the procedure" (emphasis added))

the skills for identifying what the information means or how to use it. Indeed, it is nontrivial for even a formal decision analysis to determine what information is important. One way that such analysis proceeds is through value-of-information analysis. In such analyses, the costs of providing additional information are set against the expected contribution of that added information to the decision-maker.<sup>150</sup> Indeed, value-of-information analysis may be seen as offering an operational definition of otherwise vague standards of disclosure. Specifically, physicians could be required to provide all information that might change the patient's identification of the optimal choice.<sup>151</sup> This provides a standard for what information should appear and how precisely it must be presented.<sup>152</sup>

A second direction for research is developing ways to help people with the unusual task of making explicit decisions involving hard tradeoffs among quantitatively expressed costs and benefits. Much research is being conducted to understand how people understand physical and biological processes, such as gravity, electricity, toxicity, and fertility.<sup>153</sup> These studies have found that individuals rely on mental structures, called mental models, schemas,<sup>154</sup> or situation models,<sup>155</sup> when they learn and use information. People who lack basic structures have difficulty understanding communications. People who have inappropriate structures may misconstrue accurate communications. For example, it has been found that the most important variable in the recall of medical information is prior knowledge of medical terminology.<sup>156</sup> Also, one study of people suffering from hypertension found that subjects believed they could tell when their blood

<sup>150</sup> Fischhoff, *supra* note 7, at 176-77. Another analysis (one which could be criticized for being cold and calculating, but not outside the normal risk management process of companies and insurers alike) is to evaluate disclosures from the viewpoint of the practitioner's potential liability. Each undisclosed health risk creates some financial risk. De minimis expected values of financial risks associated with the nondisclosure of a particular medical risk might be acceptable to practitioners and their insurers, as a matter of course. Thus, standards for disclosure could be developed where the expected value of nondisclosure of a particular risk is less than some small value (for example, \$1 00), or some calculated value representing the physician's time spent in the informed consent disclosure setting, assigned as a "cost" of disclosure.

<sup>151</sup> The *Canterbury* court expressly rejected a standard of disclosure based on risks that would lead the reasonable patient to forego the treatment recognizing that, while one risk might not change a decision, several might. *Canterbury*, 464 F.2d at 788 n 89. This is proper for disclosure purposes, but not valid for defining the set of risks, attendant to a particular medical procedure, that should be disclosed. Analysis of all risks in a decision analysis framework to identify those that could potentially alter the decision may yield a consistent, reduceable standard of materiality.

<sup>152</sup> Fischhoff, *supra* note 7.

<sup>153</sup> For a thorough introduction to this literature, see MENTAL MODELS (D. Gentner & A. L. Stevens, eds, 1983).

<sup>154</sup> Jungermann & Thuring, *The Use of Mental Models for Generating Scenarios*, in JUDGMENTAL FORECASTING (G. Wright & P. Ayton, eds, 1987). See also Jungermann, Schutz, & Thuring, *Mental Models in Risk Assessment: Informing People About Drugs*, 8 RISK ANAL. 147 (1988).

<sup>155</sup> Kintsch, *Learning from Text*, 3 COGNITION & INSTRUCTION 87 (1986).

<sup>156</sup> See, e.g., Plaja, Cohen, & Samora, *Communication Between Physicians and Patients in Outpatient*

pressure was elevated, even though this is not regarded as being medically possible, and they would alter their behavior consistently with how they felt.<sup>157</sup> Although most patients have some familiarity with their malady and some of the basic issues involved in testing, diagnosis, and treatment, that need not mean that the patient knows or can assimilate the information required to ensure informed consent. As a result, any attempt to inform must begin with a detailed understanding of what patients already believe.

Physicians, presumably, attempt to make such assessments of their patients. Research has shown, however, that finding out what people know is far from trivial, meaning that physicians may misread their audience. Physicians might find it useful to have research summarizing what lay people typically know about particular treatment decisions and how to elicit and test the understanding of particular patients.

Most discussions of informed consent assume that, given their technical knowledge, individual physicians are adequate sources of information, even if they may not know how to make the most effective presentations. Yet, treatment decisions require not just facts, but also values, if one is to reach a sensible decision. As the *Cobbs* court noted: "The weighing of . . . risks against the individual subjective fears and hopes of the patient is not an expert skill" possessed by physicians.<sup>158</sup> Such decisions must depend on the values and circumstances of the patient, which may not be known by the physician. Unless physicians realize how different their patients are, they risk imposing their values on patients.<sup>159</sup> Moreover, even if physicians know what is important to their patients, absent training in decision theory, there is no reason for them to be particularly adept at assimilating this information into the decision process. Thus, there may be a need to train physicians in decision-making.<sup>160</sup> Alternatively, the medical system might be adapted to incorporate experts skilled in decision analysis per se in order to work with and recommend optimal courses of action to patients.

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*Clinics*. 46(2) MILBANK MEM FUND Q 161. 170 (1968) (working with low SES patients in Colombia) For a review of studies showing some effect of SES and education, see McIntosh, *Processes of Communication, Information Seeking and Control Associated with Cancer: A Selective Review of the Literature*, 8 SOC SCI. & MED 167, 172-73 (1974)

<sup>157</sup> Meyer, Leventhal, & Gutmann, *Common-Sense Models of Illness: The Example of Hypertension*, 4 HEALTH PSYCHOL 115 (1985)

<sup>158</sup> *Cobbs*, 502 P.2d at 10 See generally Kassirer, *Adding Insult to Injury: Usurping Patients' Prerogatives*, 308 NEW ENG. J. MED 898 (1983) (discussing the need for patient input and participation in the therapeutic decision process).

<sup>159</sup> It is possible that patients seek physicians who exhibit the same or similar values in their discussions and possibly in the physicians' decisions

<sup>160</sup> This is mindful of the substantial efforts already taken, for example, by the Division of Clinical Decision Making at the New England Medical Center Hospital and by the publishers (and authors) of the *Journal of Medical Decision Making*. Such efforts are needed on a more global scale. See generally A. ELSTEIN, L. SHULMAN, & S. SPRAFKA, *MEDICAL PROBLEM SOLVING: AN ANALYSIS OF CLINICAL REASONING* (1978)

For example, one study, using a well-developed elicitation method, found that a group of lung cancer patients was fairly risk averse, in the sense of preferring the better chance of short term survival and higher quality of life associated with radiation therapy over a higher five year survival probability associated with lung extirpation.<sup>161</sup> The accepted medical practice was surgery, reflecting a discrepancy between the physicians' values and patients' preferences.

While there are potential difficulties and expenses of providing patients with needed help in decision-making, such a service might be desirable. As the *Canterbury* court noted, in rejecting a rule requiring that patients ask questions: "Physicians and hospitals have patients of widely divergent socio-economic backgrounds, and a rule which presumes a degree of sophistication which many members of society lack is likely to breed gross inequities."<sup>162</sup> Before accepting such inequities as inevitable, a research and development effort seems justified to assess whether this vital service can be delivered at a reasonable price.

## CONCLUSION

Twenty years ago, Waltz and Scheuneman wrote an article that helped shape the development of the materiality disclosure standard and the objective causation approach, writing:

At this juncture, it can be concluded that the set of concepts surrounding the doctrine of informed consent are slippery and complex. Dealing as they do with such broad areas as medical judgment, scientific knowledge and human communication, there can be little wonder that doctors have been concerned and courts have been less than precise.<sup>163</sup>

This now may be repeated, for at *this* juncture, no improvements and many new questions have arisen with respect to the doctrine.

After reviewing the state of informed consent in the legal community, the present article raises the generally neglected problem of whether people have the cognitive abilities needed to use the information provided in order to secure informed consent. If they do not, then patients who receive the information required under the informed consent laws still will not be able to make informed decisions. To understand and manage this threat, more

<sup>161</sup> The study was performed after the patients had a lung surgically removed. McNeil, Weichselbaum, & Pauker, *Fallacy of the Five-Year Survival in Lung Cancer*, 299 NEW ENG J MED 1397 (1978). See also McNeil, Weichselbaum, & Pauker, *Tradeoffs Between Quality and Quantity of Life in Laryngeal Cancer*, 305 NEW ENG J MED 982 (1981) (finding that about 20% of volunteer subjects would prefer radiation treatment of carcinoma of the larynx to surgery, despite better long-term survivability associated with the surgery).

<sup>162</sup> *Canterbury*, 464 F.2d at 783 n 36.

<sup>163</sup> Waltz & Scheuneman, *supra* note 37, at 649.

detailed knowledge is needed about how patients and experts intuitively make decisions, leading to an understanding of how communications can be developed to improve that decision-making. Such research also may be useful in other situations where people must act on the basis of risk information. Thus, the present line of analysis is pertinent to the legal issues associated with product labeling and worker or community right-to-know contexts.