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Introduction

Informed consent is the legal embodiment of the concept that each individual has the right to make decisions affecting his or her well-being. It is generally accepted that individuals should consider — that is, trade-off — the risks and potential benefits flowing from their decisions. To do so, decision-makers must have knowledge of those risks and potential benefits. The law protects the individual's right to give informed consent by requiring the disclosure of information by the party to whom consent is given. The right to information arises in three substantive areas: products liability - failure to warn, worker and community right-to-know, and medical informed consent. In each case, issues regarding the disclosure of *risks* are similar.

Risk may be defined as "exposure to a chance of an injury or loss."[1] It embodies two distinct factors: (1) *chance* relates to

1 Morgan, *Probing the Question of Technology-Induced Risk*, IEEE Spectrum

uncertain events — those that are not predictable in any single case, but for which a probability that an event will occur in any one case may be estimated; and (2) *injury or loss* includes any consequence for which the decision-maker has disutility. In each of the three areas identified above, the law places on one party a positive obligation to disclose information regarding risks to the party or parties who are "at risk," that is, those who will suffer injury if a chance event arises. The antecedent basis of these laws is the same, but their implementation has diverged. In each case, what it means to be *informed* and how *consent* is given varies.

Products liability law holds manufacturers and sellers of goods liable for damages resulting from the intended or foreseeable use of "unreasonably dangerous" — and therefore defective — products that they put into the stream of commerce. An "unreasonably dangerous" product is one for which the benefits are outweighed by the risks, or one which does not meet reasonable consumer expectations of safety.[2] As a means of safety regulation, this law tries to give manufacturers financial incentive to make their products "safe" or remove them from the marketplace.[3] On the borderline between strict liability for the marketing of a defective product and manufacturer negligence in creating or failing to discover a manufacturing flaw in a product is the failure to give adequate warning of risks inherent in the use of an otherwise useful product.[4] Generally, manufacturers and resellers have a duty to warn of risks known to them, or risks they

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58, 59 (Nov. 1981).

[2] *See generally* PROSSER AND KEETON ON TORTS (5th Ed. 1984).

[3] *See* G. CALABRESI, THE COST OF ACCIDENTS: LEGAL & ECONOMIC ANALYSIS (1970); Keeton, *Products Liability — Some Observations About Allocations of Risks,* 64 MICH. L. REV. 1329 (1966); Posner, *Strict Liability: A Comment,* 2 J. LEGAL STUD. 205 (1973).

[4] Comment, *Foreseeability in Product Design and Duty to Warn Cases — Distinctions and Misconceptions,* 1968 WIS. L. REV. 228, 234 (1968).

should have been aware of through the exercise of reasonable care, at the time the product left their control.[5]

In failure to warn cases, juries are empowered to determine whether a risk that transpired in that case was known and whether the warning, if any, was adequate to enable the reasonable consumer to avoid the risk either by not using the product or by taking appropriate precautions.[6] The scope of the disclosure obligation is uncertain, and, as two preeminent commentators noted:[7]

> This ground of negligence is probably the most difficult one for the manufacturer to manage on a satisfactory basis. Those who argue for warning as the judicial solution to latent design defects labor under a naive belief that one can warn against all significant risks. Too much detail can be counterproductive. A warning to be effective must be read and understood.

As in all other substantive areas of tort law, there must be a causal link between the defendant's failure to disclose the risk and the injury suffered by a plaintiff. In products cases, the law creates a rebuttable presumption that, had the warning been adequate, the plaintiff would have taken precautionary measures to avoid the risk — that is, it is presumed that the plaintiff would not have consented to the use of the product in the manner which gave rise to the transpired risk.[8]

Worker and community right-to-know laws are statutory

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5   *See generally* Keeton, *Products Liability — Inadequacy of Information*, 48 TEX. L. REV. 398 (1970); Twerski, Weinstein, Donaher & Piehler, *The Use and Abuse of Warnings in Product Liability — Design Defect Litigation Comes of Age*, 61 CORNELL L. REV. 495 (1976).

6   *See, e.g.,* Borel v. Fibreboard Paper Products Corp., 493 F.2d 1076 (5th Cir. 1973).

7   PROSSER AND KEETON, *supra* note 2, at 686.

8 . Petty v. United States, 740 F.2d 1428 (8th Cir. 1984) (affirming the district court's application of a rebuttable presumption of causation for inadequate disclosure in the mass immunization context, based on public policy grounds favoring compensation of those injured and on the basis of the hard-sell public relations campaign pursued by the government in the Swine Flu immunization program).

requirements to inform particular groups of the risks to which members of the group are, or may be, exposed. Employers are required to assess chemicals used in the workplace and to make information regarding physical exposures and any associated risks of those agents to their employees.[9] Similarly, under various state laws and federal law, manufacturers are required to publish information regarding various chemicals used in and released from their plants.[10] In each situation, it is expected that the group has the means to determine its members' exposures and any associated health risks, and that group members individually as well as collectively will take action to reduce their risks to acceptable levels.[11] If the individual worker does not quit and find a new job, or homeowners do not move away, or the union or community groups do not pressure management to lower exposures or emission levels, then consent may be implied by individual or group inaction.

As discussed more fully in the following section, medical informed consent law requires the disclosure of the risks of and alternatives to suggested medical procedures to enable patients to make knowledgeable decisions about the course of their medical care.[12] As under the failure

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[9]   *See generally* 29 C.F.R. § 1910.1200 (1990); Sussman, *An Overview of the OSHA Hazard Communication Standard and Key Issues of Interpretation*, 42 FOOD DRUG COSM. L. J. 307 (1987); Edwards, *Worker Right-to-Know Laws: Ineffectiveness of Current Policy-Making and a Proposed Legislative Solution*, 15 B. C. ENVTL. AFF. L. REV. 1 (1987); Comment, *The Extent of OSHA Preemption of State Hazard Reporting Requirements*, 88 COLUM. L. REV. 630 (1988).

[10]   *See generally* Haag, *Proposition 65's Right-To-Know Provision: Can It Keep Its Promise to California Voters?* 14 ECOLOGY L. Q. 685 (1987); Comment, *Will SARA Smile on Citizen Groups?* 6 TEMPLE ENVTL. L. & TECH. J. 97 (1987). These laws also serve to inform emergency personnel such as firefighters of plant inventories to allow planning for any special conditions that might exist.

[11]   Haag, *supra* note 10, at 688.

[12]   *See generally*, Merz & Fischhoff, *Informed Consent does not Mean Rational Consent: Cognitive Limitations on Decision-Making*, 11 J. LEGAL MED. 321 (1990) (providing an overview of the law as it has developed in all of the states and a critique thereof based on the cognitive and intellectual decision-making limitations of patients and physicians).

to warn laws, the obligation to inform placed upon physicians is unclear. Unlike the foregoing laws, however, the consent issue is resolved by looking to what the decision of the reasonable patient at the time of treatment would have been.

Each of these laws attempts to regulate the disclosure of risk information by one party to another. Risks are, however, highly subjective quantities. Research of how people perceive risks and make decisions in the face of uncertainty has shown that individuals exhibit biases in their perceptions.[13] Their decisions are often not the products of rigorous analysis but, rather, the result of simplified rules of thumb. These limitations militate against consistency and predictability in choices involving uncertainty. In the substantive areas of the law identified above, the courts are faced with cases involving issues of risk and decision-making. How consistently and predictably the courts resolve these issues will help measure the ability of the courts to regulate behavior.

While the perception of risk is subjective, there are fairly objective quantitative measures which may be used for risk and decision analysis purposes. To study how consistent and predictable the courts are when dealing with risk issues, this analysis of medical informed consent cases was undertaken. The analysis methodology and results presented below are very specific to the substantive and evidentiary law applicable to informed consent, and generalization to other substantive areas of the law should be made with caution.

Medical Informed Consent

Informed consent law developed from the intentional tort of battery, which protects the individual from an unwanted physical touching of the

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[13] For an introduction to this substantive literature, see JUDGMENT UNDER UNCERTAINTY: HEURISTICS AND BIASES (D. Kahneman, P. Slovic & A. Tversky eds. 1982).

body by one having neither express nor implied consent of the person touched nor a privilege to do so. Battery occurs in the medical setting when the physician performs a treatment without the consent of the patient,[14] performs a substantially different procedure than the one for which consent was given,[15] exceeds the scope of the consent,[16] or a different physician than the one to whom consent was given carries out the procedure.[17] As informed consent became a recognized basis for physician liability, the courts reasoned that any consent based on inadequate information was vitiated by the failure of the physician to disclose, and therefore that an unconsented touching occurred: to wit, a battery.

It did not take long for the courts to realize, however, that characterizing the tort in battery placed too great a burden on the medical

[14] *See, e.g.,* Lanford v. York, 457 S.W.2d 525 (Tenn. 1970) (unauthorized biopsy); Beck v. Lovell, 361 So.2d 245 (La. Ct. App. 1978) (unauthorized tubal ligation); Meretsky v. Ellenby, 370 So.2d 1222 (Fla. Ct. App. 1979) (physician operated on tip of nose against expressed wish of patient).

[15] *See, e.g.,* Maercklein v. Smith, 129 Colo. 72, 266 P.2d 1095 (1954) (consent to circumcision, not vasectomy); Lane v. United States, 225 F. Supp. 850 (E.D. Va. 1964) (surgery on wrong knee); Bobrick v. Bravstein, 116 A.D.2d 682, 497 N.Y.S.2d 749 (1986) (plaintiff expected knee surgery, not abdominal surgery); Arena v. Gingrich, 305 Or. 1, 748 P.2d 547 (1988) (physician explained two methods to repair hiatal hernia, employed third method).

[16] *See, e.g.,* Campbell v. Oliva, 424 F.2d 1244 (6th Cir. 1970) (consent to repair one condyle, not both); Jackson v. Julian, 694 S.W.2d 434 (Tex. Ct. App. 1985) (consent to remove one ovary, both were removed).

[17] Johnson v. McMurray, 461 So.2d 775 (Ala. 1984); Martin v. Southern Baptist Hosp., 444 So.2d 1309 (La. Ct. App. 1984) (barred by statute of limitations); Perna v. Pirozzi, 92 N.J. 446, 457 A.2d 431 (1983); *but see,* Forlano v. Hughes, 393 Mass. 502, 471 N.E.2d 1315 (1984) (plaintiff consented to one physician and made no objection before or during performance by different physician); Walstad v. University of Minnesota Hosp., 442 F.2d 634 (8th Cir. 1971) (same). The claim properly sounds in battery and not informed consent. Buie v. Reynolds, 571 P.2d 1230 (Okl. Ct. App. 1977) (plaintiff failed to state a battery count where surgeon permitted a resident to perform substantial portion of surgery); Guebard v. Jabaay, 117 Ill.App.3d 1, 72 Ill. Dec. 498, 452 N.E.2d 751(1983) (plaintiff withdrew battery count, could not recover under informed consent theory).

profession and, perhaps, did not emphasize enough the regulatory aspect of the law.[18] Currently, the courts nearly unanimously treat lack of informed consent as a matter of negligence of the physician to disclose necessary information to patients.[19] Negligence requires that four elements be established for liability of the defendant: (1) a duty of defendant to meet a particular standard of care; (2) failure to perform that duty; (3) a causal connection between defendant's failure and plaintiff's injury; and (4) an injury in fact, that is, one for which monetary compensation is adequate relief.

The prototypical informed consent case arises when a patient suffers an injurious, nonnegligently-caused outcome of a diagnostic or therapeutic medical procedure.[20] An outcome that is nonnegligently

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[18] The seminal case is Natanson v. Kline, 186 Kan. 393, 350 P.2d 1093 (1960), modified, 187 Kan. 186, 354 P.2d 670 (1961). *See also* Trogun v. Fruchtman, 58 Wis.2d 596, 207 N.W.2d 297, 312-13 (1973) (listing 5 reasons why assault and battery are inadequate in the informed consent setting).

[19] The exceptions are Pennsylvania and Tennessee. *See generally* Plant, *An Analysis of "Informed Consent"*, 36 FORDHAM L. REV. 639 (1968) (distinguishing the causes of action). *Cf.* Katz, *Informed Consent — A Fairy Tale? Law's Vision*, 39 U. PITT. L. REV. 137, 139 (1977); Gallub, *Assessing Culpability in the Law of Torts: A Call for Judicial Scrutiny in Comparing "Culpable Conduct" under New York's CPLR 1411*, 37 SYRACUSE L. REV. 1079, 1121-27 (1987).

[20] Several cases have applied the doctrine to the situation where the plaintiff had refused a recommended test or treatment, ostensibly without being warned of the possible consequences of that refusal. Truman v. Thomas, 27 Cal.3d 285, 611 P.2d 902, 165 Cal. Rptr. 308 (1980) (patient refused pap smears over a long time period and subsequently died from cervical cancer).

A similar situation arose in Crisher v. Spak, 122 N.Y.Misc.2d 355, 471 N.Y.S.2d 741 (1983), where plaintiff refused surgical treatment of a pinched nerve in her leg, which turned out to be caused by a malignant tumor, necessitating subsequent amputation. The court avoided the statutorily mandated professional standard, opining, "[P]laintiff's claim here is not based on surgery without informed consent but, rather, on the negligent failure of the doctor to provide to his patient the information necessary to make an appropriate decision." 122 N.Y.Misc.2d, at 359. The opinion is specious and highly dependent upon perfect hindsight. The court found that "all Dr. Spak need have told his patient was: 'Mrs. Crisher we do not know what is wrong with your foot. It may be many things, including a tumor. It is important to your health that we find out. The only way to do that is to operate.'"

caused is one which arises in a certain percentage of cases regardless of the care of the physician, due to physiological differences from the norm or particular susceptibilities of a patient, or one that arises from an act or failure to act of the physician but such act or failure to act is within the standard of care.[21] In order to recover damages for that outcome, the

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122 N.Y.Misc.2d, at 358. This, even though the defendant "testified that . . . he did not even consider the possibility of a tumor." 122 N.Y.Misc.2d, at 356. If the failure to anticipate or diagnose a tumor as the cause of the pinched nerve does not rise to the level of negligence, then there is no duty to foresee that possibility, and only through hindsight can the court's proposed warning take place. If, however, the base rate (i.e., the rate in the population of patients presenting with the same symptoms) of tumor as a cause of a pinched nerve is high enough that the reasonable physician should have known of that possibility, then the cause of action sounds properly in negligence for failure to diagnose, not informed consent.

The court's emasculation of the informed consent law of New York is also in error, inasmuch as the action clearly sounds in informed consent. As the Federal Court of Appeal for the Third Circuit said: "The philosophy behind such theory of informed consent is that the patient has the right and responsibility to determine whether he wants to risk the suggested corrective surgery. If the patient's decision is to be a knowing and intelligent one, he must understand in addition to the risks of the suggested surgery, the possible results of the failure to chance it. A complete understanding of the consequences of foregoing the operation would seem necessarily to include a consideration of the alternative treatment for the patient's disease or condition." Dunham v. Wright, 423 F.2d 940, 944 (3d Cir. 1970). *Cf.* Scalere v. Stenson, 211 Cal. App.3d 1446, 1453, 260 Cal. Rptr. 152, 156 (1989) (recognizing that the appropriate action sounds in ordinary medical negligence for failure to diagnose).

[21] Meisel, *The Expansion of Liability For Medical Accidents: From Negligence to Strict Liability By Way of Informed Consent*, 56 NEB. L. REV. 51, 52-3 (1977). Because plaintiffs run the risk of failing to establish by expert testimony that their injuries were the result of their physician's negligence in diagnosing or carrying out a procedure, the informed consent claim has become a gratuitous appendage in malpractice litigation. Disclosure does not prevent frivolous claims, perhaps justifying more liberal use of sanctions. In Hondroulis v. Schuhmacher, 521 So.2d 534 (La. Ct. App. 1988) (en banc), *writ denied*, 522 So.2d 571, *aff'd*, 531 So.2d 450 (La. 1988), plaintiff sued after suffering leg numbness and loss of bladder control following a lumbar laminectomy, and testified "that she knew death, paralysis and loss of other bodily functions can result from surgery." 521 So.2d at 452; and in VanIperen v. VanBramer, 392 N.W.2d 480 (Iowa 1986), the jury found that disclosure occurred, and, on appeal, the plaintiff conceded that the possibility of hearing loss inherent in antibiotic use had been discussed with her. *See also,*

plaintiff must establish the elements of negligence, that: (1) the physician had a duty to disclose particular information to the patient; (2) disclosure did not occur; (3) (a) but for the nondisclosure, the tendered procedure would have been refused, and (b) that the tendered procedure was the cause in fact of plaintiff's injury; and (4) the plaintiff suffered a compensable injury.[22]

There are two dominant approaches to defining the standard of disclosure of information by which the physician's duty to their patients is measured.[23] A slim majority of states follow the "professional

Williams v. Menehan, 191 Kan. 6, 379 P.2d 292 (1963) (parents of boy who died during cardiac catheterization both testified that they knew there was a risk).

[22] PROSSER AND KEETON, *supra* note 2, at 189-93.

[23] For a recent review of the development of the law and the standards of disclosure throughout the United States, *see* Merz & Fischhoff, *supra* note 12. There are a small number of alternative standards, dictated by statute, that bring the disclosure duty outside of either standard discussed here. For example, Louisiana's statute requires the disclosure of known risks of death; brain damage; quadriplegia; paraplegia; the loss of or loss of function of bodily organ or limb; and disfiguring scars. 40 LA. REV. STAT. ANN. § 1299.40 (West 1977 & Supp. 1989). Consent forms that recite that these risks are associated with the procedure have been upheld by the courts as satisfying the statutory requirement. *See, e.g., Hondroulis,* 521 So.2d 534; Hutton v. Craighead, 530 So.2d 101 (La. Ct. App. 1988); Jones v. Levy, 520 So.2d 457 (La. Ct. App. 1988); Leonhard v. New Orleans East Orthopedic Clinic, 485 So.2d 1008 (La. Ct. App. 1986), *writ denied,* 489 So.2d 919 (La. 1986); and Madere v. Ochsner Foundation Hospital, 505 So.2d 146 (La. Ct. App. 1987). If the consent form doesn't meet the statutory requirement, the materiality standard applies. LaCaze v. Collier, 434 So.2d 1039 (La. 1983), *concurring op.,* 437 So.2d 869 (La. 1983).

An interesting comparison is with the informed consent law of Iowa, the standard of which reads nearly verbatim with the Louisiana statute. IOWA CODE ANN. § 147.137(1) (West Supp. 1988). The Iowa courts have read the statute as a codification of the materiality approach. Pauscher v. Iowa Methodist Medical Center, 408 N.W.2d 355, 361 (1987). *See also* Georgia Medical Consent Law, GA. CODE ANN. § 31-9-1 (1985).

In Oregon, physicians must disclose only in general terms the nature of the procedure and that there may be alternatives and risks. The physician must then ask the patient if a more thorough explanation is desired, and if so, all material risks and viable alternatives are to be disclosed. OREGON REV. STAT. ANN. § 677.097(2) (1989).

standard," requiring a physician to disclose information that other physicians possessed of the same skills and practicing in the same or a similar community would disclose in the same situation.[24] A large minority of courts apply the "materiality" or "prudent patient" approach, allowing the jury to decide whether risk or other information would have been considered significant by the reasonable patient in making a decision, therefore requiring disclosure.[25]

The courts recognize situations where a physician's nondisclosure will be excused.[26] Briefly, if a patient is incompetent to make a

In addition, the courts in several states apply both standards, as dictated by statute, Nelson v. Patrick, 326 S.E.2d 45 (N.C. Ct. App. 1985), or because the issue has not been finally decided in that forum, Martin v. Stratton, 515 P.2d 1366 (Okla. 1973); Poulin v. Zartman, 542 P.2d 251 (Alaska 1976); Lemke v. United States, 557 F. Supp. 1205 (D.N.D. 1983). Several courts have adopted the materiality approach as placing an *extra* disclosure obligation upon the physician, i.e., the physician must disclose that information other physicians would disclose under the same circumstances, and in addition must disclose information that would be material to the decision of the reasonable patient. Cobbs v. Grant, 8 Cal.3d 229, 104 Cal. Rptr. 505, 502 P.2d 1 (1972); Cornfeldt v. Tongen, 262 N.W.2d 684 (Minn. 1977), *modified*, 295 N.W.2d 638 (Minn. 1980). 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 219 (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). 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.

[24] The most influential decision rejecting the professional standard questioned whether a custom for disclosure in the medical profession truly exists. Canterbury v. Spence, 464 F.2d 772, 783–84 (D.C. Cir. 1972). *See infra* note 82.

[25] *Canterbury*, 464 F.2d at 787. At least one court construed the determination of materiality to be a subjective one, i.e., whether the *plaintiff* would have considered the information important in making the decision, Cowman v. Hornaday, 329 N.W.2d 422, 427 (Iowa 1983); VanIperen, 392 N.W.2d 480, but the issue has been settled in Iowa on an objective finding, Pauscher, 408 N.W.2d 355.

[26] *See* Meisel, *The "Exceptions" to the Informed Consent Doctrine: Striking a Balance Between Competing Values in Medical Decision Making*, 1979 WIS. L. REV. 413, 487 (1979).

reasoned decision, then disclosure to the patient may not be required.[27] Under the *therapeutic privilege,* the physician may withhold information if disclosure would be upsetting or otherwise would interfere with treatment or adversely affect the condition or recovery of the patient.[28] Finally, the emergency exception applies in situations where attempting to secure consent could detrimentally delay proper treatment.[29] More generally, physicians need not disclose risks of which the patient is already aware or risks which are commonly known.[30]

The causation element establishes the link between the physician's nondisclosure and plaintiff's injury upon which liability is predicated. In informed consent (as well as in products failure to warn), the element

[27] *See, e.g.,* Banks v. Wittenberg, 82 Mich. 274, 266 N.W.2d 788 (1978); Grannum v. Berard, 70 Wash.2d 304, 422 P.2d 812 (1967).

[28] Cases where the privilege was an issue include Ball v. Mallinkrodt Chemical Works, 53 Tenn.App. 218, 381 S.W.2d 563, 568 (1964); Roberts v. Wood, 206 F.Supp. 579 (S.D. Ala. 1962); Nishi v. Hartwell, 52 Haw. 188, 473 P.2d 116 (1970); Carmen v. Dippold, 63 Ill.App.3d 419, 20 Ill. Dec. 297, 379 N.E.2d 1365, 1370 (1978); Pardy v. United States, 783 F.2d 710, 712 (7th Cir. 1986). In North Carolina, exercise of the privilege may no longer be sufficient to obviate the duty to disclose all "material" information. Nelson, 326 S.E.2d at 52. *See also* Carnerie, *Crisis and Informed Consent: Analysis of a Law-Medicine Malocclusion,* 12 AM. J. L. & MED. 55 (1986).

[29] *See Dunham,* 423 F.2d 940; Stafford v. Louisiana State University, 448 So.2d 852 (La. Ct. App. 1984).

[30] *But see* Kissinger v. Lofgren, 836 F.2d 678 (1st Cir. 1988) (affirming a jury verdict for plaintiff, where plaintiff suffered painful damage to his left infraorbital nerve from surgical removal of a sinus tumor, even though plaintiff had been warned by two different physicians that the tricky or delicate part of the operation was avoiding damage to the infraorbital nerve, and plaintiff even sought out defendant to perform the procedure because of defendant's greater experience with the procedure); Kinikin v. Heupel, 305 N.W.2d 589, 595 (Minn. 1981) (affirming a verdict for plaintiff, where plaintiff suffered from post surgical skin necrosis, defendant argued unsuccessfully that plaintiff knew about this risk since she had experienced necrosis during her many abdominal operations by defendant); Crain v. Allison, 443 A.2d 558, 561 note 13 (D.C. App. 1982) (affirming a verdict for plaintiff, where plaintiff suffered an infection after receiving a cortisone injection to relieve her arthritis).

has two parts, which are often imprecisely and confusingly combined into a single causation question by trial and reviewing courts. First, plaintiff must establish what may be termed "decisional causation," that is, but for the nondisclosure by defendant, the procedure from which the injury arose would not have been accepted. In most jurisdictions, this issue is based on an objective finding that the reasonable person in the patient's position would have refused the tendered treatment had the information been disclosed.[31] A small minority have adopted a subjective approach, that is, that the *patient* would have forgone treatment if informed.[32] Pennsylvania alone has done away with the causation element, based on the continued characterization of the tort in battery.[33] The second "causation" element involved is the "physical

[31] *Canterbury,* 464 F.2d at 790-91.

[32] Wilkinson v. Vesey, 110 R.I. 606, 295 A.2d 676 (1972); Cunningham v. Yankton Clinic, P.A., 262 N.W.2d 508 (S.D. 1978); Scott v. Bradford, 606 P.2d 554 (Okla. 1979); McPherson v. Ellis, 305 N.C. 266, 287 S.E.2d 892 (1982). The subjective approach has been generally rejected because the courts are wary of the plaintiff's hindsight-biased testimony on this point. The hindsight problem is exacerbated by the patient's *propter hoc* optimism: "[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). For example, in 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."

[33] Sagala v. Tavares, 367 Pa. Super. 573, 533 A.2d 165 (1987), *allocatur denied,* 518 Pa. 626, 541 A.2d 1138 (1988); Jozsa v. Hottenstein, 364 Pa. Super. 469, 528 A.2d 606 (1987), *allocatur denied,* 518 Pa. 619, 541 A.2d 746 (1988); Gouse v. Cassel, 385 Pa. Super. 521, 561 A.2d 797 (1989); *allocatur granted,* 569 A.2d 1367 524 Pa. 608 (1989). The Supreme Court of Pennsylvania, which has not heard an informed consent case in 24 years, will have to address several issues arising from this approach. For example, can patients recover nominal damages for the technical battery even if no injury occurs? Are punitive damages available? Neither of these attributes of battery can be said to reflect desirable policy towards the medical profession. Nonetheless, resolution of these issues against plaintiffs would be inconsistent with general battery theory. If the courts are willing to recognize exceptions from normal battery law for nominal and punitive damages in the

causation" issue common in all negligence actions. The plaintiff must establish that the injury suffered was the result of the medical procedure tendered — that the risk which transpired was one known by the medical community to be associated with the procedure and that it arose in the instant case from the performance of that procedure.[34] Throughout this article, "causation" shall refer to "decisional causation" introduced here.

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informed consent technical battery case, they would undermine the justification for doing away with the causation requirement. It would be inconsistent to assert that the informed consent technical battery is a battery and therefore causation need not be shown, while disallowing recovery of nominal and punitive damages on the basis that informed consent is only a technical battery. Further, it must be questioned how a defendant can be held liable for damages that he or she did not cause, within the due process constraints of the 5th and 14th Amendments to the U.S. Constitution. "[T]he framers of the constitution contemplated that instrument as a rule for the government of courts, as well as of the legislature." Marbury v. Madison, 5 U.S. (1 Brand) 49, 71 (1808). Finally, as argued more fully elsewhere, asking a jury to assess the "materiality" of a risk without consideration of the medical decision to be made with that information may produce a biased answer. Merz, *Musings on Materiality: A Decision-Theoretic Critique of the "Prudent Patient" Disclosure Standard for Informed Consent,* (forthcoming) (discussing the limitations of the formulation of the "materiality" issue from a decision-making point of view, and further developing the concept of decisional causation introduced here).

[34]   Because there cannot be a requirement to disclose risks which are not known to the medical community, this element places a limitation on the disclosure duty. *See Cornfeldt,* 295 N.W.2d at 640–41 (halothane hepatitis); Gordon v. Neviaser, 478 A.2d 292 (D.C. App. 1984) (shoulder injury worsened after surgery); Hartfiel v. Owen, 618 S.W.2d 929 (Tex. Ct. App. 1981) (stroke during chiropractic adjustment); Marshall v. Clinic for Women, P.A., 490 So.2d 861 (Miss. 1986) (Cu-7 IUD use preceded ectopic pregnancy and ovarian cysts); Nicholl v. Reagan, 208 N.J. Super. 644, 506 A.2d 805 (1986) (use of wire sutures versus catgut, suture protruded through skin); Parker v. St. Paul Fire & Marine Ins. Co., 335 So.2d 725 (La. Ct. App. 1976) (induced labor and amniotomy followed by postpartum hemorrhage, uterine atony, emergency hysterectomy); Reiser v. Lohner, 641 P.2d 93 (Utah 1982) (cardiac arrest occurred subsequent to amniocentesis).

   A good number of the cases arising from the Swine Flu vaccination program in the winter of 1976 were decided on this basis. Bean v. United States, 533 F. Supp. 567 (D. Colo. 1980) (foot drop); Freeman v. United States, 704 F.2d 154 (5th Cir. 1983) (adhesive capsulitis); Hasler v. United States, 718 F.2d 202 (6th Cir. 1983) (rheumatoid arthritis); Marneef v. United States, 533 F. Supp. 129 (S.D.N.Y. 1982) (peripheral neuropathy).

This overview identifies two dominant methods for delimiting the disclosure obligations of physicians. To summarize, the duty to disclose attaches — ex post — upon either the jury finding that there existed at the time of treatment a physician practice of disclosure, or the jury finding that a bit of information would have been "material" to the reasonable person in the patient's position at the time of treatment. Arguably, physicians will seek to disclose the more substantial risks of which they are aware. If so, then the two disclosure standards may converge — the lay and the professional views of risks that need to be disclosed to allow patients to make informed decisions may be the same.

The "materiality" jurisdiction courts have attempted to provide some guidance to physicians and jurors by indicating that the physician's duty to disclose risk information increases as the magnitude of the risk increases.[35] Further, some courts and commentators have expressed the idea that risks having severe consequences, e.g., of death or serious disability, are material and should be disclosed independent of the frequency.[36] "Severe risks (e.g., death, paralysis, loss of a sense) should always be disclosed, even when the probability of occurrence is almost negligible. Less severe risks which have a high incidence of occurrence likewise should always be disclosed. Nominal risks with little likelihood of occurrence need not be disclosed."[37] Not all courts place emphasis solely on consequences, recognizing that frequency is an important component of risk.[38] Indeed, one commentator interpreted

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[35] These courts uniformly fail to give explicit guidelines or to identify on what scale risks are to be measured. *See* Merz & Fischhoff, *supra* note 12, at 334.

[36] For example, one commentator felt that "[a]ny foreseeable risk is material to the medical consumer's decision, for it is the consumer, and not the physician, who bears the physical (and financial) brunt of the risk." Maldonado, *Strict Liability and Informed Consent: "Don't Say I Didn't Tell You So!"*, 9 AKRON L. REV. 609, 615 (1976).

[37] Note, *Malpractice: Toward a Viable Disclosure Standard for Informed Consent*, 32 OKLA. L. REV. 868, 886-87 (1979).

the cases as creating a frequency-based standard, finding a one percent threshold for liability.[39]

The courts stress that "full" disclosure, whatever is encompassed by that term, is not required. There are several reasons why full disclosure as a matter of course is unlikely in medical practice. First, the number of risks possible from even routine procedures is great. For example, in a footnote, the California Supreme Court recited some of the risks from having blood drawn: "[T]he risks . . . are said to include hematoma, dermatitis, cellulitis, abscess, osteomyelitis, septicemia, endocarditis, thrombophlebitis, pulmonary embolism and death, to mention a few."[40] Similarly, the Louisiana State Medical Society, in an amicus

[38] *Canterbury,* 464 F.2d at 788; Precourt v. Frederick, 395 Mass. 689, 481 N.E.2d 1144, 1148 (1985). Quantitative estimates of frequency are not always available, but this may not keep the issue of materiality from the jury. For example, when not quantifiable, the courts may rely solely on whether the risk was known or not. Hitchcock v. United States, 665 F.2d 354 (D.C. Cir. 1981), *aff'g* 479 F. Supp. 65 (D.D.C. 1979) (allowing recovery for a paralytic reaction to preexposure rabies vaccination). Other courts have expressly allowed the jury to assess their own frequency of occurrence from testimony provided. In *Kissinger,* the court found that: "The jury had evidence from which to find the likelihood of occurrence of the harm. There was ample evidence that the risk of injury to the nerve was substantial, 'a known risk,' . . . *Precourt* did not consider . . . whether the materiality analysis requires an expert to assess the risk of occurrence in terms of numerical data and we refuse to adopt such a rule." 836 F.2d at 681. The court continued in its footnote: "To accept a rule of that nature would be to glorify unduly the epidemiological statistician's art, and to foreclose meritorious suits in areas where precise statistics are yet unavailable." *Id.* One must question the use of the oxymoron "precise statistics." Statistics only provide a tool for quantitatively understanding uncertainty. If the uncertainty in the likelihood of a risk cannot be quantified, it may be questioned, first, whether the risk is one that is known and foreseeable to the medical community, and second, whether disclosure of a mere possibility of some outcome without any expression of the likelihood of that outcome transpiring can enable a person to make a reasonable decision based on the limited information.

[39] This interpretation is at best premature. Britain, *Product Honesty is the Best Policy: A Comparison of Doctors' and Manufacturers' Duty to Disclose Drug Risks and the Importance of Consumer Expectations in Determining Product Defect,* 79 Nw. U.L. Rev. 342, 386-98 (1984).

[40] *Cobbs,* 8 Cal.3d at 244, 104 Cal. Rptr. at 505, 502 P.2d at 11 (1972).

brief, identified 156 known risks associated with a laminectomy.[41] Second, the burden of identifying small consequence and diminishingly unlikely risks is too great upon the practitioner, and the resulting choice by the patient would likely be seriously impaired by such a listing. Indeed, many courts have recognized the bind placed by the law upon the physician, where the disclosure of too much information so as to lead the patient to refuse needed treatment could rise to the level of negligence.[42]

Despite the courts' pronunciations that "full" disclosure is not required, the courts have failed to enunciate clear limits on what must be disclosed. Given further that the bounds of the disclosure obligation are to be determined, if at all, on a case-by-case basis, then it takes no great leap of faith to conclude that no physician can absolutely avoid liability under the informed consent laws unless he or she discloses every known risk and alternative to every patient. Indeed, the California Supreme Court recently noted this uncertainty: "One cannot know with certainty whether a consent is valid until a lawsuit has been filed and resolved."[43] The present study was motivated to discover whether a consistent, reduceable *standard*[44] of disclosure is being delimited to

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[41] *Hondroulis,* 521 So.2d at 454.

[42] No cases have been found that were decided on this issue. *See, e.g.,* Collins v. Meeker, 198 Kan. 390, 424 P.2d 488 (1967); Miceikis v. Field, 37 Ill.App.3d 763, 768, 347 N.E.2d 320, 324 (1976); *and* St. Gemme v. Tomlin, 118 Ill.App.3d 766, 74 Ill.Dec. 264, 455 N.E.2d 294, 298 (1983) (defense counsel made this point to the jury in closing argument). A related issue is the possibility of parental liability for an "irrational" choice of treatment for a child, and possible professional negligence for not seeking a court order for the suggested treatment to override the parents' contrary choice. *See* Curlender v. Bio-Science Laboratories, 106 Cal.App.3d 811, 165 Cal. Rptr. 477 (1980) (in dicta, the court recognized a possible claim for wrongful birth against parents who made a conscience choice to proceed with pregnancy with knowledge of the child's likely condition; the legislature responded by relieving parents of liability).

[43] Moore v. Regents of the University of California, 51 Cal.3d 120, 165, 793 P.2d 479, 271 Cal. Rptr. 147, note 41 (1990). *See* Meisel, *supra* note 21.

which physicians may comport their behavior so as to avoid liability with certitude.[45]

Analysis Hypothesis

Inasmuch as the risk information provided in these cases is objective, that is, a given consequence may have a known frequency of occurrence from a particular medical procedure, then the duty to disclose a risk, represented by the proxy of a court outcome, may be modeled as a function of the frequency of an outcome and various conceivable measures of those consequences. If there is any clear demarcation between "material" and "immaterial" risks, then the model applied to the broad collection of informed consent cases may identify what risks need to be disclosed. Further, inasmuch as the plaintiff must establish "decisional causation," then it may be hypothesized that a legally-enforced disclosure duty is greater for "elective" medical procedures than for life saving procedures — because a nondisclosure is more

[44] A standard is "something that is established by authority, custom, or general consent as a model or example to be followed." WEBSTER'S THIRD NEW INTERNATIONAL DICTIONARY 2223 (1981). Query whether a "standard" that is to be determined on a case-by-case basis can ever meet this definition, especially in light of the fact that a jury's finding in one case will not bar a different jury from the opposite finding of fact. Indeed, the first jury's decision, if offered as evidence of the standard of care, would probably be ruled irrelevant and inadmissible, although an exception to the general rule could be justified to show the reasonableness of the defendant's behavior in light of trial outcomes. Merz, *supra* note 33, at 11-13. It is axiomatic that 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 so as 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 Refining Co., 267 U.S. 233, 239 (1925). *See also* Connolly v. General Constr. Co., 269 U.S. 385, 391 (1926).

[45] The curmudgeon's response is that nothing in life is certain. Nonetheless, the rule of law is without doubt undermined when the reasonable person cannot, even by exercising utmost care and diligence, avoid punishment. Perhaps this view helps explain physicians' frustrations with informed consent.

likely to be excused in the latter case.

Figure 1

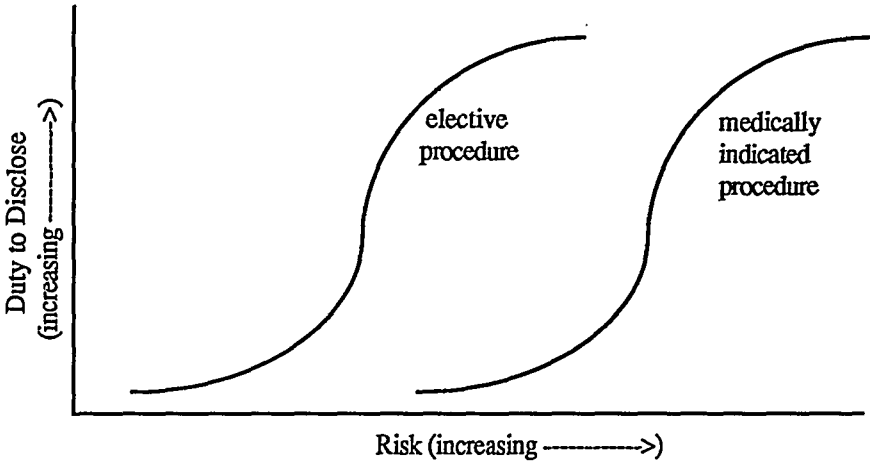**Hypothetical Functional Form of Duty to Disclose**

Figure 1 graphically presents the combined hypothesis — the probability of a plaintiff verdict should increase with increasing valuation of the nondisclosed risk and decrease with the degree to which treatment is medically necessary.

This hypothesis may be viewed as redefining the physician's duty to disclose risks as a function of both the negligence concept of "duty" with de facto limitations on that duty arising from the "decisional causation" element. Justification for this simplification is fourfold: (1) Court cases provide the primary means of feedback to medical practitioners of their legal obligations, and verdicts often take the form of general verdicts, where the jury will find for either party. Even if there were a method for systematically disseminating this information to the medical profession,[46] general verdicts favoring defendant do not identify the jury's reasoning for that decision; i.e., whether it is based

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[46] *See infra* notes 85-86 and accompanying text.

on the failure of the defendant to meet the appropriate standard of care in disclosing, or whether the plaintiff failed to establish decisional causation. It is egregious to place upon individuals a legal duty the limits of which cannot be ascertained with reasonable effort. (2) Nondisclosure of a risk in a situation where the reasonable patient would regardless agree to the tendered procedure "is legally without consequence."[47] Inasmuch as negligence law will not sanction nondisclosures where plaintiff fails to establish either the "duty" or "decisional causation" element, the distinction between them may be ignored for no legally enforced obligation is recognized unless both elements are satisfied. (3) With respect to the "materiality" determination, deciding whether any particular information is important to a decision requires assessment of the decision in which the information is to be used. Bifurcation of the "materiality" and "decisional causation" issues may confuse the finder of fact and prevent a complete assessment of these issues. If so, there should be one combined "materiality" and "causation" question, subsumed in the broader concept of duty defined here, for resolution by the jury.[48] (4) Within the medical profession, good practice may dictate that certain disclosures take place. While this may give rise to a "duty" and standard of care within the profession, in the absence of decisional causation, this duty is not enforced by the law, and the bounds of the legal duty may thus be interpreted to be narrower than those of the professional duty

For each of the above reasons, this analysis takes the more liberal view of a legal duty to disclose the risks of and alternatives to treatment. It is not asserted, however, that this legal duty bounds the physician's disclosure obligation — the physician must still inform his or her patient of the nature of the procedure and the expected course of therapy and, of

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[47] *Canterbury*, 464 F.2d at 790 (stated with respect to the necessity for an injury in fact).

[48] This idea is more fully developed in Merz, *supra* note 33.

course, must be truthful. Patients still have interests in information that are adequately protected by battery law — the factual and legal differences between the two theories of physician liability should be maintained steadfastly.[49]

Method

Logistic regression provides a technique whereby a dichotomous response variable, such as a court outcome (i.e., plaintiff or defense decision), may be explored for the effects thereon of categorical or continuous explanatory variables.[50] For the present analysis, over 450 reported decisions have been reviewed. These cases are predominantly appellate opinions, but include about 10 percent trial court opinions (verdicts by the court and opinions on motions). In addition, a data set comprised of summary information about trial court outcomes of informed consent cases has been acquired. Logistic regression will be used in this analysis to try to determine if the hypothesis presented above is supported by the cases.

I. Data and Preliminary Analysis

Two sets of data have been collected for this analysis. The first was developed by the author by reviewing over 450 published informed consent cases, comprising predominantly appellate decisions. All but 228 of these cases have been excluded from this quantitative analysis. The second is a set of 187 summaries of trial cases secured from Jury Verdict Research, Inc. (JVR). Cases not addressing the informed consent issue, those not presenting enough information for this

[49] Plant, *supra* note 19.

[50] The logistic in most general form represents the log odds of the modeled outcome as a linear function of the independent variables: $\log (p/1-p) = a + bX$, or $p = 1/(1 - e(a + bX))$, or the form given as Equation 1. For all X, p lies between zero and one, and is the estimated probability of the outcome given X. For a good description of this methodology, *see* S.E. FEINBERG, THE ANALYSIS OF CROSS-CLASSIFIED CATEGORICAL DATA (2d ed. 1979).

analysis, those decided on battery grounds, and those based on alternative disclosure standards[51] have been excluded from this quantitative analysis. The cases comprising the two data sets are exclusive.[52]

A. Reported Cases

The information derived from the case reports includes the complaint or illness of the patient seeking treatment, the type of treatment rendered, the consequences that subsequently transpired from that treatment, and the numerical estimate of the frequency of the transpired risk, when presented. Categorical factors in the cases that were recorded for analysis of their impact on court outcomes include: (1) disclosure standard, either professional or materiality;[53] (2) causation standard, either objective or subjective;[54] (3) whether the court has characterized

[51] *See supra* note 23.

[52] Only two cases appeared in both data sets, and both are included in only the reported data. Baltzell v. VanBuskirk, 752 S.W.2d 902 (Mo. Ct. App. 1988) (affirming a jury verdict for defendant); and Largey v. Rothman, 110 N.J. 204, 540 A.2d 504 (1988) (defendant verdict on remand).

[53] Some of the older cases did not clearly enunciate a standard. Some subjectivity in categorization was thus necessary. If the court deferred to the physician's judgment in deciding how much to disclose, this was treated as a professional standard case. Salgo v. Leland Stanford Jr. Univ. Board of Trustees, 154 Cal.App.2d 560, 317 P.2d 170 (1957); Mitchell v. Robinson, 334 S.W.2d 11 (Mo. 1960), *modified,* 360 S.W.2d 673 (Mo. 1962); *Ball,* 381 S.W.2d 563; Watson v. Clutts, 266 N.C. 153, 136 S.E.2d 617 (1964); Grosjean v. Spencer, 258 Iowa 685, 140 N.W.2d 139 (1966); Walstad v. University of Minnesota Hosp., 442 F.2d 634 (8th Cir. 1971); Bennett v. Graves, 557 S.W.2d 893 (Ky. Ct. App. 1977), Brigham v. Hicks,·44 N.C.App. 116, 260 S.E.2d 435 (1979). Several courts spoke in terms of reasonable disclosures, and were therefore categorized as materiality cases. Woods v. Brumlop, 71 N.M. 221, 377 P.2d 520 (1962); DiRosse v. Wein, 24 A.D.2d 510, 261 N.Y.S.2d 623 (1965); Gray v. Grunnagle, 423 Pa. 144, 223 A.2d 663 (1966); Sharpe v. Pugh, 270 N.C. 598, 155 S.E.2d 108 (1967); Koury v. Follo, 272 N.C .386, 158 S.E.2d 548 (1968).

[54] A number of courts discussed the element from a subjective viewpoint, and these cases were coded as applying a subjective standard, although it is doubtful that the jury was charged on subjective causation inasmuch as it is not the proper law in that jurisdiction. *See, e.g.,* Mallett v. Pirkey, 171 Colo. 271, 466 P.2d 466 (1970);

treatment as elective;[55] (4) whether the court discussed the availability

Holt v. Nelson, 11 Wash.App. 230, 523 P.2d 211 (1974); Hartfiel v. Owen, 618 S.W.2d 902 (Tex. Civ. App. 1981); Kranda v. Houser-Norborg Medical Corp., 419 N.E.2d 1024 (Ind. Ct. App. 1981); Doss v. Hartford Fire Ins. Co., 448 So.2d 813 (La. App.), *writ denied,* 450 So.2d 359 (La. 1984). Finally, a large number of cases did not discuss the causation element, usually because the issue was not reached.

There is always the potential problem that the standards enunciated in the appellate courts are not being implemented in jury charges, and the only way to verify this for this data set would be to contact the attorneys involved. Inasmuch as the causation standard does not appear to be an important predictor of outcome, this task would not be worthwhile. This study therefore assumes astute advocacy in preparing jury charges, timely objections, and appealing erroneous charges. But see Slater v. Kehoe, 38 Cal.App.3d 819, 113 Cal. Rptr. 790 (1974) (jury charged to subjective causation); Tenney v. Bedell, 624 F. Supp. 305 (S.D.N.Y. 1985) (same).

[55] "Elective" means different things to different courts. *See, e.g.,* Riedinger v. Colburn, 361 F. Supp. 1073, 1075-76 (D. Idaho 1973) (characterizing an anterior cervical excision treatment for whiplash: "the surgery . . . can be termed major 'elective' surgery. It is major in the sense that it is not without the same risks inherent in any operation involving an attack on body tissues under a general anesthetic. It is 'elective' in the sense that it is not necessary as a matter of life and death, but rather is a matter of choice to the patient depending upon his or her desire to try to eliminate problems of discomfort."); *Cowman,* 329 N.W.2d 422 (vasectomy for socioeconomic reasons "so optional that it would not qualify even as 'elective surgery' as defined by the *Riedinger* court." *Id.* at 424-25, fn. 1). Similarly, the court in Watkins v. Parpala, 2 Wash.App. 484, 469 P.2d 974, 976 (1970) opined that extraction of ten teeth for denture preparation was elective "in the sense that no immediate emergency existed, although the teeth were irregular, discolored and had some decay."; and the court in Rice v. Jaskolski, 412 Mich. 206, 313 N.W.2d 893, 893 (1981), characterized extraction of impacted wisdom teeth as "preventative."·*See also* Small v. Gifford Memorial Hosp., 133 Vt. 552, 349 A.2d 703, 704, 705, 706 (1975) (characterizing breast reduction surgery for a women having pendulous breasts that caused discomfort and affected her posture as elective), *Kinikin,* 305 N.W.2d 589 (reduction surgery on women suffering from extensive fibrocystic disease "prophylactic," *Id.* at 595, even though "good medical practice dictated removal of the fibrocystic diseased tissue." *Id.* at 593); Granado v. Madsen, 729 So.2d 866, 869 (Tex. Ct. App. 1987) (tonsillectomy); Hunter v. Brown, 81 Wash.2d 465, 502 P.2d 1194, 1196 (1972) (dermabrasion treatment of facial scars and dark patches (chloasma) elective treatment "for the attempted improvement of appearance only."); *Hitchcock,* 479 F. Supp. at 79 (preexposure rabies immunization for foreign service assignment); Ellis v. Smith, 528 N.E.2d 826, 828 (Ind. Ct. App. 1988) (foot surgery on muscular dystophy patient). The courts' characterizations appear broad enough that any procedure not performed in a life-saving emergency could be elective.

of alternative courses of treatment open to the patient;[56] (5) whether the court characterized the plaintiff as being specially susceptible to a particular risk;[57] and (6) whether the facts of the case were such that

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[56] Medically recognized "feasible and available" alternative treatments must be established by expert testimony, Thornton v. Annest, 19 Wash.App. 174, 574 P.2d 1199, 1203 (1978), and the alternatives need not be conservative treatments for submission of the case to the jury, Marino v. Ballestas, 749 F.2d 162 (M.D. Pa. 1984) (option of closed reduction of broken arm with involvement of radial nerve); Logan v. Greenwich Hosp. Assoc., 191 Conn. 282, 465 A.2d 294 (1983) (option of open renal biopsy under general anesthesia where closed needle biopsy under local anesthesia resulted in punctured gall bladder, necessitating removal).

[57] The frequency of a particular outcome in the patient's position might be higher than normal. For example, obesity places the patient at elevated risk of post-operative infection and incisional herniation, Harwell v. Pittman, 428 So.2d 1049 (La. Ct. App.), writ denied, 434 So.2d 1092, reconsideration denied, 436 So.2d 570 (La. 1983), and hemorrhage, Leiva v. Nance, 506 So.2d 131 (La. Ct. App. 1987), writ denied, 512 So.2d 1176 (La. 1987). Likewise, the chance is elevated for: hyperpigmentation in orientals from dermabrasion, Hunter, 502 P.2d 1194; keloid scarring in dark-skinned patients, Mastro v. Brodie, 682 P.2d 1162 (Colo. 1984); broncospasm from sodium pentothal in asthmatic patients, Siegal v. Mt. Sinai Hosp. of Cleveland, 62 Ohio.App.2d 12, 403 N.E.2d 202 (1978); stroke from epinepherine contained in xylocaine in artherosclerotic patients, LeBeuf v. Atkins, 28 Wash.App. 50, 621 P.2d 787 (1980); halothane-induced liver failure in patient presenting possible liver damage before surgery, Cornfeldt, 262 N.W.2d 684; infection from surgery in patient suffering from Crohn's Disease, Haley v. United States, 739 F.2d 1502 (10th Cir. 1984); and thrombosis from an arteriogram in a one year old child, Halley v. Birbiglia, 390 Mass. 540, 458 N.E.2d 710 (1983). But see Haven v. Randolph, 342 F. Supp. 538 (D.D.C. 1972), aff'd, 494 F.2d 1069 (D.C. Cir. 1974), where paraplegia resulted from transfemoral retrograde arteriogram on a two year old, the Court opined: "There is some doubt about the magnitude of the risk since Roy's extreme reaction to the Hypaque injection was apparently the first recorded instance of such a reaction to aortography in a child under nine years of age." Id., 494 F.2d at 1071, fn.1. Query how often such procedures are performed on children and if there is some reason why the frequency of such outcome would be less in a child under nine.

Conversely, the magnitude of a particular possible consequence might be overriding to a particular patient for a reason that was known or that should have been known to the physician. Hartke v. McKelway, 707 F.2d 1544 (D.C. Cir.), cert. denied, 464 U.S. 983 (1983) (laparoscopic tubal ligation failed, pregnancy presented serious risk to plaintiff although no injuries resulted); Clark v. Miller, 378 N.W.2d 838 (Minn. App. 1986) (plaintiff, a dancer, was primarily concerned with scarring, which resulted following knee surgery).

the claim should have sounded in battery, but the case was treated as one for lack of informed consent.[58]

Preliminary analysis of the reported data set indicates that the plaintiff has won significantly more appeals in materiality jurisdictions than in professional jurisdictions. This is not at all indicative of plaintiff's chances with a jury, however, inasmuch as a high number of the materiality courts' decisions are not final, the cases being remanded for trial. Generally, the materiality courts have been more apt to discuss and adopt an objective causation standard, which reflects the fact that the professional standard courts often do not reach the causation issue due to the failure of plaintiff to establish a duty to disclose. The materiality courts have placed more reliance than professional standard courts on the elective nature of treatment, the availability of alternative treatments, and the special susceptibility of the plaintiff to the particular risk which transpired. This may be the product of the courts' more detailed reviews in justifying remand for trial and, in some cases, adoption of a new (i.e., materiality) disclosure standard in that state. Finally, the cases which might have been categorized as battery are more prevalent in the materiality courts. This might be the result of the fact that it is easier to get to the jury in the materiality jurisdiction on the informed consent claim,[59] and because it might be easier to confuse the causes of action

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[58] In some states, the statute of limitations for intentional torts such as battery is shorter than for negligence, providing an incentive for a plaintiff to try to characterize his or her action as one for lack of informed consent.

[59] In the materiality jurisdictions, plaintiff may have the case submitted to the jury for a finding of fact after establishing, by expert testimony, that the risk suffered is a known risk of treatment. In the professional jurisdictions, expert evidence must also establish the existence of a duty to disclose. In most of the professional standard courts, failure to offer such evidence results in a summary judgment for defendant. The exceptions are Kansas, *Natanson*, 186 Kan. 393, 350 P.2d 1093 (1960), *modified*, 187 Kan. 186, 354 P.2d 670 (1961); and Colorado, Hamilton v. Hardy, 37 Colo.App. 375, 549 P.2d 1099 (1976); which, upon plaintiff alleging that no disclosure took place, shift the burden to the physician to establish that nondisclosure complies with the practice in the profession.

where expert testimony on disclosure practices is not offered.[60]

B. Trial Cases

The data represent cases identified in JVR's data base as lack of informed consent cases or containing "failure to inform" or "failure to warn" in the text summary, and which were disposed of in the trial courts between January 1986 and June 1989, inclusive.[61] From the summary provided by JVR, the case name, jurisdiction, and year of disposition were derived. The data set comprises the following information: (1) the illness suffered, the treatment, the consequences, and the amount of the verdict, if any;[62] (2) whether the facts presented

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[60] Cases that appeared to be battery-type actions were largely excluded from this analysis. Those cases retained had informed consent issues, usually that a collateral risk arose from a procedure to which, the patient contends, consent was not given. *See infra* note 73. These cases should be resolved solely on the battery claim, inasmuch as there reasonably cannot be a duty imposed to disclose risks of and alternatives to treatment, where the patient contends that the nature or extent of the treatment was not even disclosed. *See Lipscomb,* 733 F.2d 332 (physician performed a Nissen fundoplication of plaintiff's stomach to treat her hiatal hernia where consent was given only for gall bladder surgery, defendant liable for failure to inform of at least a 60% chance of constriction of the esophagus).

[61] The data are collected by various court clerks, attorneys, and others, and verified with the litigating attorneys for accuracy. JVR collects the data for the compilation of jury verdicts for valuation of personal injuries for litigation purposes. It is not an exhaustive collection of all trial court outcomes, but is represented as an unbiased sample for jury verdict evaluation purposes. The author acknowledges the contribution of Jury Verdict Research to the present work in subsidizing in part the trial court data base and in assistance in using the Valuation Handbooks. Subsequent to the performance of this analysis, counsel for about five percent of the cases were contacted, and it was found that the characterization of some cases as informed consent cases was in error. These represent a small fraction of the data set and should not affect the results.

[62] Due to variation in the reporting of summary information, not all of this information was consistently provided. For example, the indicator variable for disclosure represents those cases where the summary reports that the physician contended that disclosure was made or that the patient's consent was informed. Not every summary reported on this fact, and these cases were coded as no disclosure being made. Similarly, whether plaintiff's informed consent action was joined with a malpractice action may have been inconsistently reported. The impact of these reporting inconsistencies on the results is uncertain.

a battery-type of action;[63] (3) whether the informed consent claim was joined with a negligent treatment claim; and (4) whether the physician contended that disclosure had been made. The disclosure standard applicable to the case was assumed to be that of the state at the time of disposition of the case.[64] Settlements before verdict were excluded from this analysis, as were instances in which insufficient facts were available for analysis.

Summary analysis of the trial court data indicates that: (1) while plaintiffs have fared better in professional standard jurisdictions, there is no significant difference in the likelihood of a plaintiff verdict based on the law applied, that is, professional or materiality disclosure standard;[65] (2) actions sounding solely in informed consent are more

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[63] The actions may indeed have sounded in battery but were reported in the data base as lack of informed consent cases. Lack of consent cases in the data were excluded from this analysis.

[64] There may be some error due to this assignment because the law in Hawaii, Alaska, and Nebraska is in limbo. *See* Merz & Fischhoff, *supra* note 12. Any impact should be negligible due to the small number (n = 3) of cases from these courts.

[65] $P = 0.16$ by test of proportions. It was hypothesized that there might be a possible selection bias toward higher dollar value cases involving more serious injuries or cases having a higher likelihood of success in the professional jurisdictions due to possibly higher expenses of litigation (for example, from increased costs for experts), causing attorneys to be more selective in choosing cases. However, a Kolmogorov-Smirnov two-sample test of the cumulative jury verdict distributions over the 3-1/2 year period indicates that it cannot be concluded that the verdicts are drawn from different underlying distributions (Pr < 0.70). Combined with the nonsignificant difference in the chance of success of plaintiff's claim, the hypothesis is unsupported. Plaintiff has won about 32% of the cases in the professional standard jurisdictions and about 26% in the materiality jurisdictions. Although not a significant difference, the sign is in the right direction, i.e., that plaintiffs are bringing claims that are more justifiable and are therefore succeeding more frequently. Nonetheless, one-way analysis of variance of mean verdict valuation of the claims across the two types of jurisdictions shows a small and nonsignificantly greater mean value of claim in the *materiality* jurisdictions, clearly contrary to the hypothesis. This result is not totally surprising due to the fact that, in jurisdictions applying either disclosure standard, expert evidence is necessary to

prevalent in materiality jurisdictions than in professional jurisdictions; this may be the result of the lower burden required in terms of expert testimony in the materiality courts; (3) there is a significant association between a verdict favoring plaintiff and an uncontested nondisclosure, although this could be explained in part by the inconsistent reporting in the data set; this is a sensible result inasmuch as, ceteris parabus, liability is predicated upon the additional issue of physician veracity; and (4) the battery characterization of the action is significantly associated with actions brought without concurrent negligence claims, which is further evidence that the suits involve breakdowns in communication and lack of consent, and not necessarily risks of treatment (informed consent) or negligent treatment by the physician.

From the above analysis, several features of the cases have been identified which yield insight into what is happening in the trial courts and in appellate court reasoning. A logistic regression model will now be used to explore whether the disclosure obligation is related to the magnitude of the risk.

II. Logistic Regression Analysis

The purpose of this analysis is to try to discover whether the disclosure obligation increases with increasing risk of treatment. Not only is a positive relationship between these factors of interest, but, more importantly, a dividing line which separates "material" from "immaterial" risks, both for physicians in professional standard jurisdictions and lay jurors in materiality standard jurisdictions. The methodology is logistic regression analysis, modeling the probability of a plaintiff's verdict as a function of various predictor variables.

A. Model Development

In addition to the independent predictor variables identified in

establish the risks of treatment, and experts are also necessary (except in rare cases) for trying the negligent treatment claims which are often joined with the lack of informed consent claims.

Section I above, variables addressing the underlying risks and the choice of treatment have been identified for modeling purposes. First, four continuous measures of risk were utilized in the present analysis: (1) the frequency of occurrence of a particular outcome from a given treatment;[66] (2) mean jury verdicts for personal injuries of the type suffered by the plaintiff, as summarized in Table 1;[67] (3) a quality of life measure,[68] comprised of a subjectively assigned value to the

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[66] The frequencies have been taken only from the case law; no secondary sources have been utilized. In some cases, these frequencies have been applied to like cases in which the frequencies were not reported. With respect to uncertainty, generally a single figure is quoted in the cases, usually reflecting physician testimony. In the few instances, ranges have been presented and the midpoint of that range has been used. When a frequency has been characterized solely as being "less than" some upper bound, that upper bound has been utilized. Barclay v. Campbell, 683 S.W.2d 498, 501 (Tex. Ct. App. 1985), rev'd and rem'd, 704 S.W.2d 8 (Tex. 1986); Ficklin v. MacFarlane, 550 P.2d 1295, 1296 (Utah 1976). In addition, when erroneous or ambiguous frequency information was presented to the jury, that value is used. E.g., in Gray, 223 A.2d 663, the court recited a 15-20% conditional probability of worsening plaintiff's condition, given one of several causes of that condition, as the frequency of paraplegia resulting from a laminectomy. Other cases have recited the frequency of nerve damage to be about 1%. Canterbury, 464 F.2d at 778. See Merz, The Informed Consent Doctrine in Pennsylvania: Lack of Supreme Court or Legislative Direction Leaves Law Limping, 137 PITT. LEGAL J. 223 (1989) (discussing the failure of the Gray court to recognize and properly use conditional probabilities).

[67] The mean values were derived from the Personal Injury Valuation Handbooks published by Jury Verdict Research, Inc. All values were estimated in 1989 dollars. Use of median values and/or upper and lower quartiles were considered for this analysis, but the mean was chosen as most representative of the expected value of a jury verdict and because the consistent use of mean values provides a relative scale of consequences. Furthermore, all data was rounded off to one significant figure for subsequent analyses. Finally, it was felt that the wide distribution of verdicts reflects too many variables, such as specific extent of injury, type of injury within the data set, and regional effects on verdicts, so as to render the data of questionable value beyond the relative scaling used here.

[68] There are several different quality of life indices that have been developed in the last thirty years for the purpose of evaluation of health programs. See generally QUALITY OF LIFE ASSESSMENTS IN CLINICAL TRIALS (B. Spilker ed., 1990). See also, Hiltbrunner and Breitsprecher, Pharmaceutical Risk and the Quality of Life, supra, at 19. These methods are too detailed to work with the summary information provided in the legal cases. For example, the Sickness Impact Profile (SIP) provides a

outcome, as summarized in Table 2;[69] and (4) the classic measure of risk, the frequency multiplied by the mean dollar valuation for the resulting consequences. While risk is technically the chance of an unfavorable outcome, the frequencies and the outcomes themselves, independent of each other, provide a measure of risk.[70]

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percentage index based on a series of 136 statements regarding activities, physical impairment, and psychosocial factors. Bergner, Bobbitt, Carter & Gilson, *The Sickness Impact Profile: Development and Final Revision of a Health Status Measure,* 19 MED. CARE 787 (1981). Therefore, it was necessary to generate a simple scale based only on physical outcomes. Death as the most severe outcome is not a fixed feature of these scales, Torrance, Thomas & Sackett, *A Utility-Maximization Model for Evaluation of Health Care Programs,* 1972 HLTH SERV. RES. 118, 119 (describing a von Neuman-Morganstern gamble and time trade-off elicitation for preferences between health states), but in this case presented an interesting comparison with the verdict valuation, under which death is far from the "worst" outcome.

[69] This scale was developed based on outcomes presented in the body of case law analyzed in this study, and its general applicability may therefore be limited. The scale is highly correlated with the mean verdict values as applied to both the reported and trial data sets (Spearman Rank Correlations: reported r = 0.746, trial r = 0.435, p = 0+). The author and an independent rater applied the scale to the consequences in the two data sets, with inter-rater reliability of 0.85. Inter-rater reliability was calculated by the number of cases that were rated the same divided by the total number of cases rated. This somewhat low reliability appears to be impacted by the lack of knowledge of medical terminology by the second rater, but also reflects the lack of detail in the reports of injuries suffered. The scale is also extremely similar to another "Severity Scale" developed in the 1970's for assessment of medical malpractice issues. *See, e.g.,* Daniels & Andrews, *The Shadow of the Law: Jury Decisions in Obstetrics and Gynecology Cases,* in MEDICAL PROFESSIONAL LIABILITY AND THE DELIVERY OF OBSTETRICAL CARE, VOL. II 177 (V.P. Rostow & R.J. Bulger, eds. 1989). The two scales applied to the reported data set are highly correlated (Spearman Rank Correlation r = 0.938, p = 0+).

[70] The logarithmic transformations of jury verdicts, the risk, and the frequency were also explored.

Table 1

Mean Jury Valuation of Consequences (1989 $ Millions)

Injury	Valuation	Injury	Valuation
Death	0.81	Quadriplegia	8.1
Paraplegia/Hemiplegia	4.0	Minor Spinal Injury	0.43
Spinal Disc Damage	0.49	Vertebra Fracture	0.44
Vertebra Damage	0.11	Severe Brain Damage	5.9
Moderate Brain Damage	1.6	Minor Brain Damage	0.82
Minor Cerebral Damage	0.18	Bilateral Leg Amputation	4.7
Leg Amputation	1.9	Leg Tissue Damage	0.059
Leg Nerve Damage	0.22	Leg Vascular Damage	0.18
Lower Leg Fracture	0.3	Femur Fracture	0.21
Foot Amputation	0.7	Foot Tissue Damage	0.15
Toe Amputation	0.36	Arm Amputation	1.3
Arm Nerve Damage	0.59	Upper Arm Tissue Damage	0.074
Upper Arm Fracture	0.1	Forearm Tissue Damage	0.02
Forearm Fracture	0.11	Carpal Tunnel Syndrome	0.13
Wrist Tissue Damage	0.043	Hand Amputation	0.46
Multi-finger Amputation	0.86	Finger Amputation	0.26
Hand Tissue Damage	0.58	Hand Fracture	0.21
Blindness	5.7	Loss of One Eye	0.92
Visual Impairment	0.41	Total Loss of Hearing	0.65
Partial Loss of Hearing	0.4	Hair Damage	0.34
Skull Fractures	0.092	Facial Fractures	0.13
Mouth Damage	0.14	Teeth Damage	0.1
Facial Nerve Damage	0.17	Facial Scars	0.052
Throat Damage	0.24	Abdominal Damage	0.21
Bladder	0.72	Spleen	0.98
Liver	0.43	Gallbladder	1.2
Loss of Kidney	1.6	Minor Kidney Damage	0.056
Lung Damage	0.18	Serious Heart Damage	0.19
Minor Heart Damage	0.084	Breast Damage	0.15
Chest Tissue Damage	0.052	Hip Replacement	0.26
Hernia	0.099	Miscarriage	0.36
Hysterectomy	0.098	Female Minor Genital Damage	0.17
Female Sexual Dysfunction	0.2	Wrongful Conception	0.18
Male Loss of Genitals	0.66	Male Minor Genital Damage	0.35
Male Sexual Dysfunction	0.24		

Table 2

Quality of Life Index	
Index	*Physical State*
1	Infection, pain
2	Wrongful conception
3	Scars, tissue damage
4	Damage to bodily part requiring further treatment
5	Partial or temporary paresthesia, loss, or loss of use of bodily part with no residual impairment
6	Paresthesia, loss, or loss of use of bodily organ with residual impairment
7	General paresthesia, loss, or loss of function of limb, eye, ear, minor brain damage
8	Paraplegia, hemiplegia, moderate brain damage, stroke, loss of two limbs, blindness, deafness, birth defects
9	Quadriplegia, severe brain damage
10	Death

The final aspect of model development was to address the causation issue, which shields the actual reasoning for a defense verdict. For the reported data, a description of the complaint or illness suffered by the patient exists. To model how strongly a medical procedure is indicated for a patient, a three value scale of the severity of the patient's condition was developed: [1] represents an elective or optional situation, where treatment is not medically necessary — where lack of treatment would in no way threaten life or normal (i.e., pre-illness) lifestyle; [2] represents

non-life threatening situations where treatment is necessary to avoid impairment of normal lifestyle; and [3] represents severe, disabling, or life threatening conditions, where diagnosis and treatment are strongly indicated.[71] This variable does not reflect the appropriateness of the actual treatment rendered, nor the availability of alternative courses of therapy. While the patient's decision necessarily would include consideration of alternatives, and the risks of alternatives can impact the "materiality" or significance of risks associated with a given procedure, insufficient information was provided in the reports to model this feature. Thus, the present model reflects only the refusal of treatment as an alternative to the tendered procedure.

B. Regression Results

Each set of data was fitted to a logistic function modeling the probability of a verdict in plaintifff's favor. The model in general form is:

[1] $\Pr(\text{plaintiff wins}) = e^{(b_0 + S\ b_i * X_i)}/(1 + e^{(b_0 + S\ b_i * X_i)})$

where X_i represents each predictor variable. Step-wise logistic regression was performed with all non-risk measure predictor variables and one risk measure, and the regression was iterated for each risk measure. This full model was also estimated with all and with various subsets of the independent variables, with no difference in result.

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[71] Coding of the appellate data was performed with this scale by the author and an independent lay rater, with inter-rater reliability of 0.82 (with omission of the first 30% of cases due to the second rater's initial difficulty in understanding the code). That this code was applied by lay raters instead of physicians might interject some error into the analysis. Nonetheless, it is lay jurors who must assess whether the patient would have accepted treatment, albeit aided by physician testimony and more detailed information than is available for the present analysis. Application of this scale showed a significant association with whether the court characterized treatment as elective (Spearman Rank Correlation $r = -0.337$, $p = 0+$). The low reliabilities of both scales might have been contributed to by the fact that, from having read all of the cases, the author coded the data with knowledge of more of the facts related to condition, treatment, and outcome than was presented in the summary table provided for the independent rater's use.

1. Reported Cases

For the reported case data set, interaction terms were included to analyze differences in response to the various risk measures between the two types of disclosure standards, causation standards, and the index of severity of the patient's affliction. All interaction terms were not statistically significant and were dropped from the model. Significant parameter estimates were found for the final model having the variables identified in Table 3.

Importantly, a significant relationship appeared with respect to the log of the mean verdict valuation of the consequences suffered by the plaintiff. The causation standard and severity index variables were analyzed with indicator variables, and estimation yielded clearly nonsignificant parameter estimates for causation standard and a significant estimate for one of the latter variable indicators. Inasmuch as the difference between cases where treatment is indicated and those that are strongly indicated is just significant ($p = 0.05$), this variable has been left in the model.

The variables that appear important to decisions favoring plaintiff from this model yield insight into what is important to appellate courts reviewing these cases. Most of these important variables may be treated independently of the risk-based analysis that comprises the purpose of this study, that is, to determine if a disclosure obligation attaches as a function of risk.

Table 3

Final Model Parameters — Appellate Data — All Jurisdictions

Independent Variable	Coefficient	Z-score	95% Confidence Interval[72]
Disclosure Std	1.082	3.31	[.44; 1.72]
Alternative Treatment	1.134	3.28	[0.46; 1.81]
Battery	·2.641	2.34	[0.43; 4.85]
Severity (1)	−0.296	−1.10	[−0.82; 0.23]
Severity (2)	−0.528	−1.96	[−1.06; 0.00]
Log(mean jury verdict)	0.669	2.03	[0.02; 1.32]
Special Risk	1.792	2.51	[0.39; 3.19]

The courts' discussions of the availability of alternative treatments in many cases was a critical factor in the decision.[73] Further, the handful

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[72] n = 217.

[73] Cases where the court relied particularly on the nondisclosure of alternative treatments include: Archer v. Galbraith, 18 Wash.App. 369, 567 P.2d 1155 (1977) (thyroid tumor, hemithyroidectomy performed where observation, drug treatment, and biopsy were available); Bowers v. Talmage, 159 So.2d 888 (Fla. Ct. App. 1963) (diagnostic arteriogram given to child for "spells," psychiatric treatment available); Brown v. Dahl, 41 Wash.App. 565, 705 P.2d 781 (1985) (local or regional anesthesia alternatives to general); Sauro v. Shea, 257 Pa. Super. 87, 390 A.2d 259 (1978) (same); Cornfeldt, 262 N.W.2d 684 (delay due to test results indicating liver damage); Creasey, 617 P.2d 1377 (therapeutic treatment instead of surgery); Cress v. Mayer, 626 S.W.2d 430 (Mo. App. 1981) (exercise and physical therapy instead of surgical correction of thoracic outlet syndrome); Rook v. Trout, 113 Idaho 652, 747 P.2d 61 (1987) (same); Davis v. Caldwell, 54 N.Y.2d 176, 445 N.Y.S.2d 63, 429 N.E.2d 741 (1981) (availability of biopsy to confirm mammogram results before mastectomy); Dewes v. Indian Health Service, Inc., 504 F. Supp. 203 (D.S.D. 1980) (traction of fractured elbow versus open reduction); Doss, 448 So.2d 813 (use of pad in shoe instead of surgery); Eichelberger v. Barnes Hosp., 655 S.W.2d 699 (Mo. App. 1983) (venous cutdown versus subclavian stick catheterization); Festa v.

of cases which appeared to be battery-type actions often involved issues such as proper communication of the course of treatment in addition to risk considerations.[74] Lastly, it is clear that the courts consider it very

Greenberg, 354 Pa. Super. 346, 511 A.2d 1371 (1986) (various methods of sterilization); *Hartke,* 707 F.2d 1544 (same); Sard v. Hardy, 379 A.2d 1014 (Md. 1977) (same); Gates v. Jensen, 92 Wash.2d 246, 595 P.2d 919 (1979) (tests available to diagnose glaucoma); Hales v. Pittman, 118 Ariz. 305, 576 P.2d 493 (1978) (subtemporal rhizotomy and RF coagulation alternatives to phenol injection treatment of trigeminal neuralgia); Holland v. Sisters of Saint Joseph of Peace, 270 Or. 129, 522 P.2d 208 (1974) (reduced dose and increased number of treatments of radiation therapy); ZeBarth v. Swedish Hospital Medical Center, 81 Wash.2d 12, 499 P.2d 1 (1972) (same); Hood v. Phillips, 554 S.W.2d 160 (Tex. 1977) (oxygen or drugs to help breathing in patient suffering from emphysema versus carotidectomy); Jacobs v. Theimer, 519 S.W.2d 846 (Tex. 1975) (abortion availability to pregnant patient who contracted rubella fever); Jeffries v. McCague, 242 Pa. Super. 76, 363 A.2d 1167 (1976) (superpubic or transurethral versus retropubic prostatectomy); Keogan v. Holy Family Hosp., 95 Wash.2d 306, 622 P.2d 1246 (1980) (availability of tests to diagnose angina); *Kissinger,* 836 F.2d 678 (intranasal anthostomy instead of Caldwell-Luc surgical removal of sinus tumor); *Lipscomb,* 733 F.2d 332 (availability of drug treatment for sliding hiatal hernia where physician performed Nissen fundoplication procedure for combination paraesphageal and sliding hernia); *Marino,* 749 F.2d 162 (broken arm immobilization instead of open reduction); *Poulin,* 542 P.2d 251 (two methods of incubator oxygen regulation to premature baby); Salis v. United States, 522 F. Supp. 989 (M.D. Pa. 1981) (drug regimen not followed by plaintiff before angiogram); Smith v. Karen S. Reisig, M.D., Inc., 686 P.2d 285 (Okla. 1984) (hormonal therapy instead of hysterectomy); Steele v. St. Paul Fire & Marine Ins. Co., 371 So.2d 843 (La. App. 1979) (pap smear monitoring instead of hysterectomy); *Tenney,* 624 F. Supp. 305 (delay); Trapp v. Cayson, 471 So.2d 375 (Miss. 1985) (CAT scan or posterior fossa myelogram instead of vertebral arteriogram); and *Wilkinson,* 295 A.2d 676 (availability of biopsy to confirm lymphoma before extensive X-ray treatment).

[74] The cases which were categorized as batteries in the first analysis were: *Clark,* 378 N.W.2d 838 (treatment unauthorized unless arthritis or knee cap malalignment were found); *Cross,* 294 S.E.2d 446 (consent to cystoscopy, resection performed); DeFulvio v. Holst, 272 Pa. Super. 221, 414 A.2d 1087 (1979) (consent to biopsy, not parotidectomy); *Dewes,* 504 F. Supp. 203 (incompetence of patient); Gravis v. Physicians & Surgeons Hosp. of Alice, 427 S.W.2d 310 (Tex. 1968) (plaintiff's husband signed consent form, capacity to consent a jury question); *Gray,* 223 A.2d 663 (consent to exploratory laminectomy, physician cut dentate ligaments to relieve pressure on spinal cord); *Kinikin,* 305 N.W.2d 589 (consent to adenomammectomy, not nonradical mastectomy); and *Lipscomb,* 733 F.2d 332 (consent to gallbladder surgery, not hiatal hernia repair).

important if the patient is in a high-risk group for a particular outcome.[75] Inasmuch as the presence of these factors in the cases appears, in many instances, to drive these decisions, all observations exhibiting these factors were removed and the analysis reperformed. The result is a more highly significant relationship of the response variable with the illness severity indicator variable and with the log of the mean jury verdicts. Again, interaction terms were nonsignificant, and were omitted from the model. The resulting logistic fit for this reduced data is presented in Figure 2. The estimate of the parameter for the elective severity index is not significant, indicating that for model purposes the estimated response is not different than for the alternative severity values. This parameter nonetheless has been left in the plotted model because it shows a large difference in the probability of a plaintiff judgment in the elective treatment cases, which is something that this model should reflect, if addressing the causation issue implicit in the data consistently with the main hypothesis.[76]

There is thus a definite increase in the probability of a verdict for plaintiff as the mean jury verdict valuation of the consequences suffered increases. In addition, the measure of how strongly treatment is indicated for the patient's condition or ailment appears to be explaining

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[75] *See* the cases listed *supra* at note 57. Importantly, none of these cases presented a *quantitative* estimate of the frequency of the risk. Analysis of base rates and differential risks due to special risk factors would be important in determining whether the increased risk was important to the decision to accept treatment.

[76] Nonsignificance may be the result of the small number of cases coded as elective (n = 7). Indicating that there is indeed some difference between these illness severity groups, analysis of variance of verdict valuations of the claimed injuries within each causation group shows that injuries sustained vary significantly with the measure of the severity of the patient's condition ($F^* = 4.73$ with 2,214 df, $p = 0.01$). This reflects that the risks of treatment increase with the severity of the illness suffered, in accord with empirical hospital experience. Larson, Oram & Hedrick, *Nosocomial Infection Rates as an Indicator of Quality*, 26 MED. CARE 676 (1988); Britt, Schleupner & Matsumiya, *Severity of Underlying Disease as a Predictor of Nosocomial Infection*, 239 J.A.M.A. 1047 (1978).

some of the variation in the data, reflecting the causation requirement and the fact that higher risks of treatment will be accepted by patients facing more severe consequences of their illness.[77]

Figure 2[78]
Logistic Fit — Reported Cases
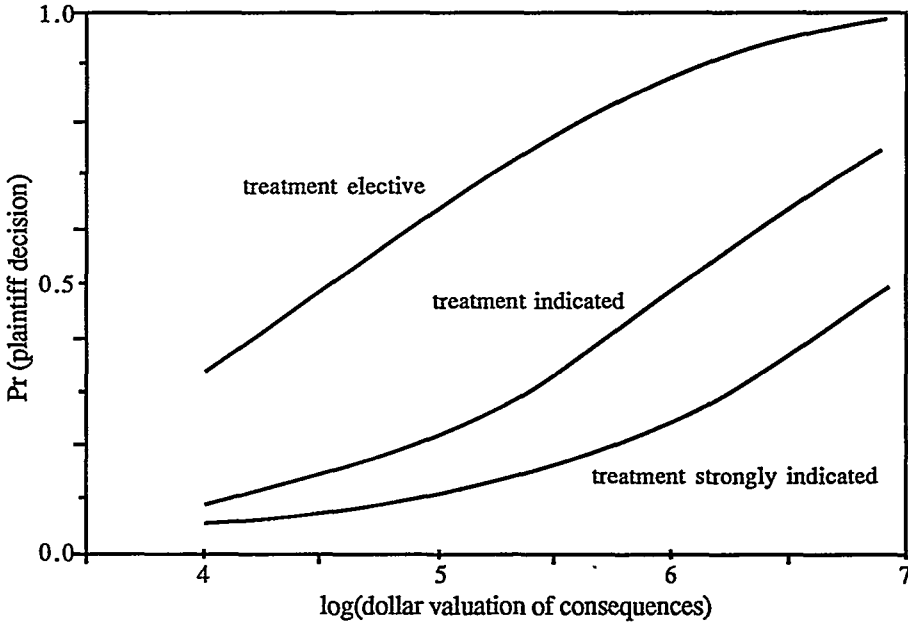
Despite the nonsignificant interactions found between disclosure standard and consequence measures above, the data were separated by professional and materiality disclosure standard, and the logistic regression model fitted to each data set. The results of the step-wise regression are presented in Table 4. These results indicate that the reported case results in the professional standard jurisdictions may be

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[77] This provides support for the idea that the materiality determination is not independent of how strongly treatment is indicated for the patient. A de minimis risk to one suffering a terminal illness might be significant to one facing a choice of elective treatment. *See* Merz, *supra* note 33.

[78] $Pr = 1/(1+ \exp(7.63^{\dagger} + 0.26 \times Severity1 + 1.39^{\dagger} \times Severity2 - 1.28^{\dagger} \times \log(consequences)))$. [† $p < 0.002$].

explained by a significant relationship with mean verdict values of consequences, and that the parameter estimates for all other risk measures are nonsignificant. Interestingly, in the materiality courts, no significant parameter estimates were found for any of the risk measures.

Table 4

Final Reduced Model Parameters — Appellate Data
Materiality versus Professional Jurisdictions

Jurisdiction	Independent Variable	Coefficient	Z-score	95% Confidence Interval
P[79]	Alternate treatment	0.645	2.47	[0.13;1.16]
	Severity (1)	-0.683	-1.64	[-1.50; 0.13]
	(2)	-0.581	-1.48	[-1.35; 0.19]
	Disclosure made	-0.886	-2.15	[-1.69; -0.07]
	Special risk	1.109	1.68	[-0.19; 2.40]
	Mean jury verdict	0.00024	1.77	[-0.00003; 0.00050]
M[80]	Alternate treatment	0.556	2.31	[0.08; 1.03]
	Battery	1.532	2.00	[0.03; 3.03]
	Disclosure made	-0.906	-1.54	[-2.06; 0.25]
	Special risk	0.718	1.74	[-0.09; 1.53]

Again, parameter estimates for all risk measures had the right signs. Failure to find a significant relationship appears to be caused by the nonfinal nature of these decisions, where the courts are not making the materiality judgment but are remanding the case for trial to allow a jury to make that factual finding. The feature of the combined data sets that

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[79] Professional; n = 119.
[80] Materiality; n = 98.

, yielded a significant relationship with the log of the verdict measure may reflect that different approaches to determining physician liability are at work. No plot of these results is provided.

None of the above models explains a significant amount of the variation in the data, which is to be expected given the large variation in fact situations, subjective characteristics of the parties, attorney and judge competence, and jury composition, all unmeasurable factors which potentially affect case outcomes. Nonetheless, the significant estimates of the parameters for the variables give some indication that the probability of a decision favoring plaintiff, and thus the disclosure obligation, is related to the verdict valuation measure of consequences.

Importantly, no significant model parameters were found for frequency of occurrence of the risk, for the product of the frequency and the monetary valuation of the outcome, or for the alternative quality of life measure (minimum $p > 0.06$), although the signs were in the right direction. This result in the frequency and risk instances might be the product of limited data availability, where less than 100 cases in the data set had associated frequencies. With respect to the quality of life measure, this result may be the product of treating a crude categorical scale as a quasi-continuous variable. That the signs without exception are in the right direction nonetheless provides evidence that the mean verdict valuation of consequences has some correspondence with personal perceptions of the severity of injuries. Besides the range and relative differences between categories over which the jury verdict scale and the quality of life measures vary, the major difference between these measures is the fact that death is by far not the worst outcome on the former scale, while it is the ultimate outcome on the latter. While jury verdicts reflect different types of damages in the calculation of awards, the values may fortuitously reflect that the subjective disutility of a debilitating injury is greater than that for death, which position has some

intuitive appeal.[81]

2. Trial Cases

Of more interest is the trial court data, inasmuch as greater insight directly into the jury box might be attained from this source. The limited information available from the data summaries prevented analysis of the causation issue in these cases. The trial data was fit by step-wise reduction to a logistic function, with the resulting significant parameters . of the final two reduced models presented in Table 5. The estimates of parameters for battery and negligence were nonsignificant, and were dropped from the model. Significant relationships with both consequence measures were attained for the data from the combined professional standard and materiality jurisdiction cases.[82] Unfortunately, the variables that appeared to be important to the appellate courts, that is, discussion of available alternative treatment and special susceptibility of the patient, were not available in the summary information provided on the trial cases. Further information on alternative treatments and special risk susceptibilities of the plaintiff as presented in these trial cases might help explain the jury decisions.

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[81] The implications of this finding to the development of quality of life measures is obvious: viewing death as the ultimate state may be improper, depending upon context. The implications with respect to environmental risk analysis are not as clear, inasmuch as debilitating but nonfatal outcomes are rarely modeled, nor are outcomes such as brain or spinal damage (except perhaps for teratogenic effects) or losses of limbs generally foreseeable consequences of personal exposures to chemical and radiological environmental insult. Using a categorical scale to approximate a continuous variable may be inappropriate, inasmuch as the difference between adjacent categories cannot be represented as constant. The rank order of the scale appears to be valid, so the error introduced by this approximation should be limited.

[82] Only one summary in the trial court data base included the frequency of outcome. No effort was made at this point to fill in frequencies. This effort is left to a more detailed analysis of this data.

Table 5

Model	Independent Variable	Coefficient	Z-score	95% Confidence Interval [83]
1	Disclosure standard	-0.357	-2.16	[-0.68; -0.03]
	Disclosure made	-0.876	-2.56	[-1.55; -0.21]
	Mean jury verdict	0.00019	1.73	[-0.00002; 0.00041]
2	Disclosure standard	-0.707	-2.00	[-1.40; -0.01]
	Disclosure made	-0.905	-2.40	[-1.64; -0.17]
	Quality of life index	0.148	1.76	[-0.02; 0.31]

Model Parameters — Trial Data — All Jurisdictions

Again, in the trial courts, whether the physician contends that disclosure was made is an important factor in determining outcome. The negative coefficient of the disclosure standard variable indicates that plaintiffs won more often in the professional standard jurisdictions. Interaction terms were analyzed and were nonsignificant. Unlike in the reported data, significant parameter estimates were found here for both measures of consequences. To learn more about what is driving these results, the data were separated into professional standard and materiality court cases, and logistic models fit to these reduced data sets. The final reduced model variables having significant parameter estimates for the materiality and professional standard jurisdictions are presented in Table 6.

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[83] n = 186.

Table 6

Final Reduced Model Parameters —Trial Data
Materiality versus Professional Standard Jurisdictions

Jurisdictional Standard	Independent Variable	Coefficient	Z-score	95% Confidence Interval
M[84]	Mean jury verdict	0.000316	2.22	[0.00004; 0.00060]
P[85]	Disclosure made	-0.844	-3.19	[-1.36; -0.33]

The dependence of the probability of a plaintiff verdict on physician disclosure is now seen to be important only in the professional standard jurisdictions,[86] while the parameter estimate for mean verdicts is negative and nonsignificant, and for the quality of life measure positive and not significant. Conversely, a significant estimate of the parameter for mean verdict values is found in the materiality jurisdictions, but, again, not with the quality of life index.[87] The fitted model for

[84] Materiality; n = 112.

[85] Professional; n = 87.

[86] $P < 0.001$. Analysis of the contingency table of plaintiff verdicts in professional jurisdictions on whether disclosure is asserted by the defendant shows that plaintiff has a significantly greater chance of winning when defendant does not contest nondisclosure ($c2 = 6.56$, 1df, $p < 0.02$). Due to the uncertainty in data reporting on this variable, this result, while intuitively satisfying, should be considered preliminary, pending the availability of more detailed information on the trial data cases.

[87] $P > 0.09$. Further, one-way analysis of variance of mean verdict valuation of claims shows a significantly greater mean valuation of injuries in cases won by plaintiff than cases lost in the materiality courts ($F* = 6.70$ with 2,112 df, $p = 0.011$). This outcome reflects the fact that, of eight cases having consequences valued in excess of $2 million in these jurisdictions, plaintiffs won five of them. This finding is consistent with the concept developed above that physical disability can be viewed as a more severe outcome than death, independent of frequency.

materiality jurisdictions is graphed in Figure 3.

Figure 3

Logistic Fit - Trial Cases - Materiality Jurisdictions
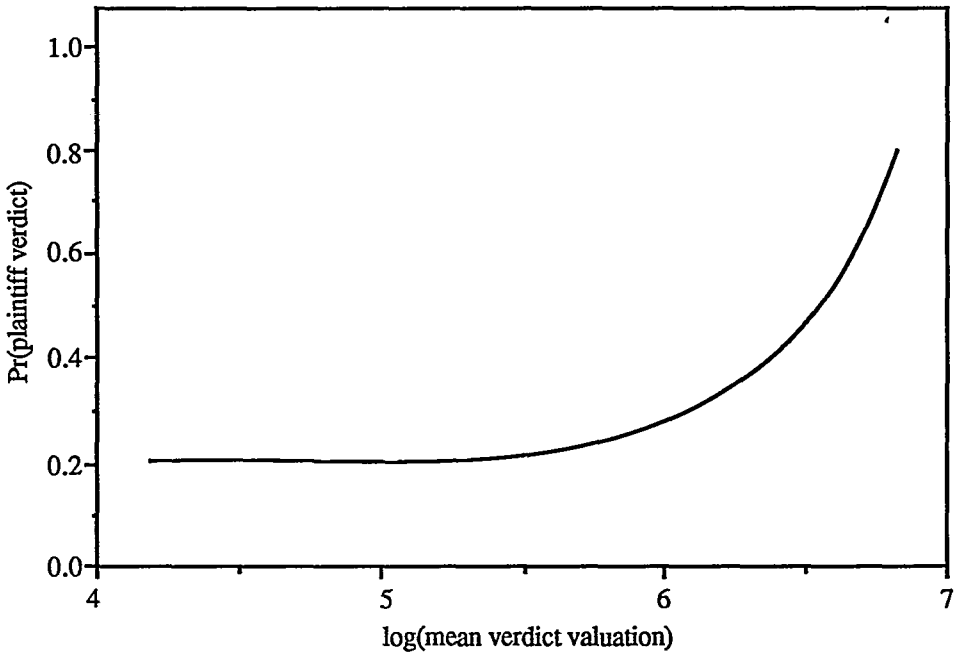
These results provide limited evidence that, perhaps, the juries in the materiality jurisdictions are applying a more consequence-based standard to the disclosure obligation than are physicians. Without analysis of frequencies in these cases, this conclusion cannot be drawn with much certainty. The results found with respect to the quality of life measure, that is, nonsignificant parameter estimates were found for all of the models except for the combined jurisdiction trial data analysis, but in all cases the sign was correct, evince that this index may indeed be a robust measure of consequences.

III. Limitations on the Analysis

There are two major limitations on this analysis. First, there is a possibility of a selection bias in the reported data base toward cases that

were more easily reduceable by the reviewing court to important issues such as quantifiable risks or alternative treatments, or those that presented novel issues of law or difficult fact issues which necessitated resolution. This highlights the major shortcomings in this type of analysis of court cases, where potential limitations stem from: (1) court processes and procedure, where cases are often decided on procedural grounds or where counsel adopt tactical positions or commit errors which compromise the case; (2) the nonfinality of cases remanded for trial, due to the fact that most of these cases are lost to analysis after remand — they are either settled or subsequent verdicts are not appealed;[88] the appellate court's decision is thus usually the last information available regarding the case; (3) a selection bias in the data towards more serious injuries because of a higher likelihood of suit being brought against a physician; (4) selective appeals and reporting of cases; (5) the strong incentives to insurers to settle good claims which are therefore not litigated; and (6) the significant danger that what appears in trial transcripts is transformed in the appellate process by the numerous hands of judges, clerks, and zealous advocates. Nonetheless, judges make law and adopt policy, as embodied in their common law decisions, based on precedent and on their perceived notions of fairness and equity. Precedent is embodied solely in the case reports used as the foundation of this analysis. Inasmuch as judges draw on this body of precedent in their decision-making and the medical community must rely on this information to guide their disclosure practices, a critical review of the policy may be based properly on the same information available to the policy-makers.

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[88] For example, if *Largey* is not appealed, there will be no public record of the final result except for this article. Similarly, authorities cite *Canterbury* for the proposition that a physician can be held liable for a one in one hundred risk of nerve injury inherent in a spinal laminectomy, while defendant received a favorable verdict on remand. Murphy, *Canterbury v. Spence — The Case and a Few Comments*, 11 FORUM 716 (1976).

Second, the use of a plaintiff decision as a proxy measure for the disclosure obligation may be a source of error in the analysis. It is recognized that there are several reasons why a verdict may be returned for the defendant, and the lack of special interrogatory use by the courts and litigants shields this analysis from more detailed insight into jury rationale. Defendant verdicts may reflect that: (1) disclosure occurred; (2) there was no duty to disclose the information; (3) the reasonable patient would have proceeded with treatment even if the information was disclosed, that is, there is no decisional causal link between the putative nondisclosure and the outcome; or (4) the tendered medical procedure did not cause plaintiff's injury. Verdicts for plaintiff also may be ambiguous, in that a general verdict could be based on success on the informed consent claim or, if both informed consent and negligent treatment claims are tried together, success on the latter cause and failure on the former. Verdicts for plaintiff are nonetheless more diagnostic for analysis of the risks, because each element of each cause of action must have been established. It is only the confounding negligence claim that obscures the data. In this regard, the reported data is more detailed, giving the appellate court's rationale and decision on the informed consent claim, although in some cases the appellate court must also guess at the rationale for the jury's finding. In most reported cases, however, the informed consent issues were explicitly addressed by the reviewing court. As precedent on the informed consent law, as argued above, these decisions are justifiably used in this analysis. The uncertainty in the basis for the juries' findings is greater in the trial cases. Nonetheless, for this analysis, the assumption is made that the action sounds in informed consent and any confounding negligent treatment claim is ignored.

IV. Implications of the Results

This analysis provides evidence that the obligation to disclose risk

information increases with increasing severity of the potential consequences. Importantly, however, no clear demarcation has been found separating risks which must be disclosed from those which need not be disclosed. Physicians may minimize their financial risk arising from the informed consent laws by disclosing high consequence risks, and by making more complete disclosures to patients when medical treatment is not necessary to save the patient's life. How complete a disclosure should be is still not determinable.

The analysis of trial cases provides evidence that juries might be applying a "materiality" standard that places emphasis on outcomes. Combined with the result from the analysis of professional standard trial cases, which showed no such positive relationship between verdict valuation of consequences and the probability of a plaintiff verdict, and the result from analysis of the professional standard reported cases which showed a marginally significant positive relationship, the preliminary conclusion might be drawn, by discounting the appellate results for being one step removed from the jury, that the disclosure practices of the medical profession are based on criteria different than relied upon by materiality court juries.[89] Juries in the materiality courts appear to be applying a consequence-based decision rule, but, again, more information on these cases must be collected and analyzed to

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[89] For example, the nondisclosure of risks occurring less than one percent of the time, *Granado,* 729 So.2d at 874 (Halothane anesthesia resulted in liver failure and death); or risks deemed to be too remote to mention, *Sagala,* 533 A.2d 165 (pulmonary embolism, death following foot surgery); *Largey,* 540 A.2d at 505 (1988); or risks which could be self-inducing, *Pardy,* 783 F.2d 710 (anaphylactic shock reaction to IVP agent Conray 60). Some judges have suggested ruling as a matter of law that there is no obligation to disclose "minimal" risks, such as those having a frequency of less than one in one hundred. *Ficklin,* 550 P.2d at 1298 (Crockett, J., concurring specially) (where hemiparesis resulted from bypass surgery). Several researchers have indeed found that physicians tend to disclose high frequency risks and not low probability events, even if the potential consequences of those low frequency risks are severe. Faden, Lewis, Becker, Faden & Freeman, *Disclosure Standards and Informed Consent,* 6 J. HLTH. POL. POL'Y. & L. 255, 277 (1981).

confirm this observation.[90]

The reported case analysis failed to show a significant relationship between the probability of a decision favoring plaintiff and the frequency of occurrence of the risk ($p > 0.06$). To explore this further, Figure 4 presents a plot of plaintiff and defendant decisions on a log frequency — log verdict valuation risk-space.[91]No pattern of decisions favoring plaintiff is evident, providing additional evidence that frequency may not be an important variable in assessment of risks. Nonetheless, an approach to defining a standard for disclosure could be adopted with this type of playing-off consequences against frequencies of occurrence.

For example, a standard might be expressed as the line D — D in Figure 4, where disclosure would be required for risks lying above and to the right of the line. Due to the subjectivity in assessing values for consequences and difficulty in determining frequencies for low probability risks, this approach may have limited usefulness.[92] It is nonetheless valuable for understanding and framing the disclosure problem.

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[90] What has been coined the availability heuristic may help explain this result, inasmuch as the subjective assessment of the frequency of occurrence might be swayed by the severity of the injury sustained by the plaintiff. *See* Merz & Fischhoff, *supra* note 12, for a discussion of this and other cognitive biases which may affect patient and jury decision-making. Issues of communications of risks may have applicability in the courtroom, inasmuch as measures taken by counsel to help the jury understand the risks can help them make their decision. At least one court has mentioned that testimony may be received from "any witness with knowledge of the particular inquiry, such as . . . whether the average patient would consider the risk in making a decision." Miller v. Kennedy, 11 Wash.App. 272, 522 P.2d 852, 861 (1974), *aff'd per curiam*, 85 Wash.2d 151, 530 P.2d 334 (1975), thus arguably opening the witness stand to expert decision analysts.

[91] Defendant's and plaintiff's decisions at the same location are shown, but the plot does not indicate multiple decisions for either.

[92] Further development of this approach is beyond the scope of the present article, but could be a fruitful area for further research.

Figure 4
Risk - Space Plot - Reported Cases
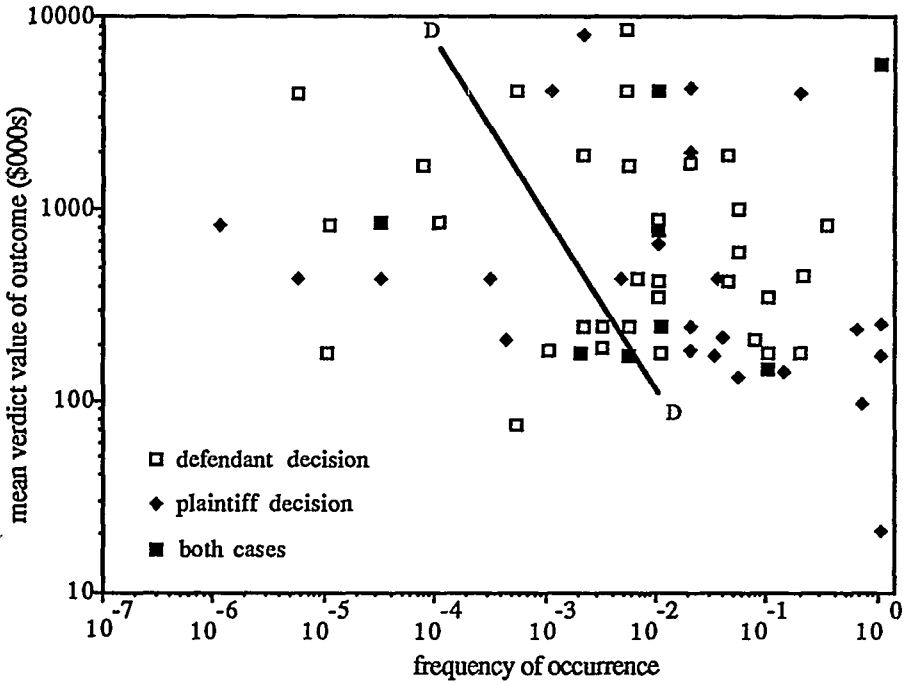
Apart from risks, the appellate courts have focused on various issues embedded in the informed consent claims such as the availability of alternative treatments and whether the patient was especially susceptible to a particular risk or outcome. Physicians should thus disclose the medically recognized alternative courses of treatment for a patient's condition, and special physiological risk factors that could impact outcomes.

In the trial courts in professional standard jurisdictions, the single most important predictor appears to be whether the physician contends that disclosure was made. If the defendant contends that disclosure occurred, the jury, in order to return a verdict for the plaintiff, must find

that the physician is being untruthful. If disclosure did not occur, the jury may be free to simply choose between the viewpoints of opposing experts. The defendant and his or her expert witnesses will assert that there was no obligation to disclose, while plaintiff must produce physicians who testify that it is the practice of like practitioners to disclose.

Conclusions

The informed consent law is still in a development stage, and despite an extensive literature on the subject, many questions remain unanswered, providing a fruitful area for research that can contribute to the policy of the law and its implementation in the courts, and to physician-patient communications and decision-making. This analysis presents a regression model which helps explain outcomes of medical informed consent cases. This is an important factor in implementation of the informed consent laws, which developed in recognition of patient autonomy, but which impose unclearly defined obligations on the medical profession. Indeed, this study provides firm evidence that there is no fine line separating risks which must be disclosed from those which need not be disclosed.

As the limited availability of useful information for this study shows, a more efficient feedback mechanism to physicians regarding the limits of their obligation is required. Further research involving the identification of trial court cases, contacting the attorneys involved, and the collection of more specific information regarding jury findings could help refine the analysis performed herein. However, the most direct and equitable resolution of this issue may be the adoption by state legislatures of laws requiring the use of special interrogatories in every informed consent case.[93] Such an act could require that copies of trial

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[93] This requirement might further lead to less informed consent claims being gratuitously added to malpractice suits, to avoid the use of special verdict forms.

transcripts or a summary thereof be provided to a clearing house.[94] Undoubtedly, enabling greater information flows will facilitate physician awareness of their disclosure obligations, and will promote a more "informed discussion of informed consent."[95]

More generally, this study presents an example of using somewhat objective quantitative measures of risk to explain court outcomes. Such quantitative measures have not found their ways into the courtroom, but they could be used to help the fact finder address risk issues. Further, risks find their way into court in failure to warn and right-to-know contexts. While this study provides limited evidence that juries are somewhat capable of handling the risk issues inherent in the decision regarding medical treatment, how well juries and others do this in failure to warn and right-to-know contexts is a question worthy of future research. Issues of risk perception and decision-making in the jury box may become even more important in the coming years in toxic tort and community right-to-know contexts, and the legal community should aggressively undertake to understand how these issues may affect court outcomes.

Special verdict forms also can help clarify the issues for the fact finder, especially since the jury is in essence asked to carry out a risk analysis and make a decision. These forms can hypothetically be formulated to lead the jury through the problem. Further work on this is left to the future.

[94] The American Medical Association, American Dental Association, medical insurers, or other organizations could provide the resources for data collection, analysis, and dissemination.

[95] Meisel & Roth, *Toward an Informed Discussion of Informed Consent: A Review and Critique of the Empirical Studies,* 25 ARIZ. L. REV. 263 (1983).