LACK OF INFORMED CONSENT IN MEDICAL MALPRACTICE AND PRODUCT LIABILITY CASES: THE BURDEN OF PRESENTING EVIDENCE

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INTRODUCTION

In medical malpractice and product liability actions, one theory of liability often asserted is lack of informed consent. In a medical malpractice action, the plaintiff must allege that, had an adequate disclosure of risks been made by defendant-physician, plaintiff would have attached significance to the risk that in fact occurred, and thus would not have consented to the proposed procedure. In product lia-

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1. The doctrine of informed consent in medical malpractice imposes upon a physician a duty to disclose to his patient all relevant information concerning a proposed treatment, including the material risks involved, alternative treatments, and hazards if the condition is left untreated, so that the patient's consent to treatment will be an intelligent one based on complete information. See, e.g., Canterbury v. Spence, 464 F.2d 772, 780 n.15 (D.C. Cir.), cert. denied, 409 U.S. 1064 (1972). In the product liability context, the doctrine of informed consent imposes on a manufacturer, who should know that his product may be dangerous, a duty to warn potential users of the danger. Restatement (Second) of Torts § 401 (1965).

2. Those three elements must be satisfied whether the adequacy of the physician's disclosure is judged by the professional standard of disclosure or the so-called full-disclosure rule. In Woolley v. Henderson, 418 A.2d 1123 (Me. 1980), the court, after adopting the professional standard of disclosure, required that the plaintiff prove that, given an adequate disclosure, neither plaintiff nor a reasonable person in like circumstances would have consented to the proposed treatment. Id. at 1131-32. In Harnish v. Children's Hosp. Medical Center, 387 Mass. 152, 439 N.E.2d 240 (1982), the court, after adopting the full-disclosure rule, required that
bility cases arising under the failure to warn doctrine, the plaintiff
must allege that had an adequate warning been provided by defend-
ant-manufacturer, plaintiff would have read the warning and avoided
the injury-producing use of the product. In either type of action, a
basic question arises: Who should bear the burden of producing evi-
dence that, adequately informed, plaintiff would have avoided the
risk? A subsidiary question may also arise: What evidence should be
required to satisfy that burden of production? The manner in which
some of the courts have answered those questions in both types of
cases is somewhat surprising and not entirely satisfactory.

I. MEDICAL MALPRACTICE CASES

In a medical malpractice action predicated on lack of informed
consent, a significant number of jurisdictions have concluded that
the adequacy of the physician’s disclosure to the patient should be
judged not by the professional standard of disclosure, but rather by
a judicially fashioned standard. Typically, the latter standard re-
quires the physician to disclose all material risks incident to the pro-

the plaintiff prove that, given an adequate disclosure, neither plaintiff nor a reasonable person
in like circumstances would have consented to the proposed procedure. Id. at 158, 439 N.E.2d
at 243-44. See also Buzzell v. Libi, 340 N.W.2d 36 (N.D. 1983), where the court noted that
because the patient admitted that she would have consented to the operation if the material
risks had been disclosed, and thus failed to establish the necessary element of causation, it was
unnecessary to discuss whether an objective or subjective test should govern. Id. at 41 & n.3.

3. See Reyes v. Wyeth Laboratories, 498 F.2d 1264, 1281 (5th Cir.), cert. denied, 419
U.S. 1096 (1974) (a rebuttable presumption arises that plaintiff would have read a warning if
one were provided); see also Technical Chemical Co. v. Jacobs, 450 S.W.2d 602, 606 (Tex.
1972) (source of rebuttable presumption applied in Reyes).

4. The professional standard of disclosure is that amount of information a reasonable
physician practicing in the same branch of medicine would disclose under similar circum-
cstances. See, e.g., Woolley v. Henderson, 418 A.2d 1123 (Me. 1980).

1064 (1972); Cobb v. Grant, 8 Cal. 3d 229, 502 P.2d 1, 104 Cal. Rptr. 505 (1972); Logan v.
299 So. 2d 788 (La. 1974); Sard v. Hardy, 281 Md. 432, 379 A.2d 1014 (1977); Harnish v.
Children's Hosp. Medical Center, 387 Mass. 152, 439 N.E.2d 240 (1982); Plutshack v. Uni-
versity of Minn. Hosp., 316 N.W.2d 1 (Minn. 1982); Reikes v. Martin, 471 So. 2d 385 (Miss.
1985); Woods v. Brumlop, 71 N.M. 221, 377 P.2d 520 (1962); Nickell v. Gonzalez, 17 Ohio
St. 3d 136, 477 N.E.2d 1145 (1985); Scott v. Bradford, 606 P.2d 554 (Okla. 1979); Beauvais v.
Notre Dame Hosp., 120 R.I. 271, 387 A.2d 689 (1978); Wilkinson v. Vesey, 110 R.I. 606,
285 A.2d 676 (1972); Peterson v. Shields, 652 S.W.2d 929 (Tex. 1983); Small v. Gifford
Memorial Hosp., 133 Vt. 552, 349 A.2d 703 (1975); Smith v. Shannon, 100 Wash. 2d 26, 666
Co., 68 Wis. 2d 1, 227 N.W.2d 647 (1975).
posed therapy in order to secure an informed consent from the patient. The basic reason for supplanting the professional standard of disclosure with a standard requiring disclosure of all material risks is a judicial sensitivity to preserving the patient's right of self-determination. Yet, in most of the jurisdictions requiring disclosure of all material risks, materiality is judged by an objective standard. The courts ask whether the undisclosed risk would have been significant to a reasonable person in patient's circumstances in deciding whether or not to undergo the proposed therapy. Similarly and consistently, those jurisdictions also judge the consent or causation issue by an objective standard: Apprised of the material risk which occasioned the patient's injuries, would a reasonable person in patient's circumstances have consented to the procedure? If the reason for imposing the full-disclosure rule is to protect the patient's right of self-determination, why should materiality and consent be judged by an objective rather than a subjective standard? To the extent that a patient and a reasonable person in like circumstances might differ in their views on materiality and consent, the particular patient's right of

6. Canterbury v. Spence, 464 F.2d 772, 786-87 (D.C. Cir.) ("[T]he test for determining whether a particular peril must be divulged is its materiality to the patient's decision: all risks potentially affecting the decision must be unmasked."), cert. denied, 409 U.S. 1064 (1972). See also Crain v. Allison, 443 A.2d 588, 562 (D.C. 1982) ("The test for mandatory disclosure of information on treatment of the patient's condition is whether a reasonable person in what the physician knows or should know to be the patient's position would consider the information material to his decision.").

7. Crain v. Allison, 443 A.2d 558, 561 (D.C. 1982) ("The duty of a physician to inform the patient of the consequences of a proposed treatment stems from the right of every competent adult human being to determine what shall be done with his own body.") See also cases cited supra note 5.

In the cases considered in this Article, the duty to warn the patient relates to medically cognizable risks associated with the proposed therapy. For a discussion of the physician's duty to disclose errors already made, see Vogel & Delgado, To Tell the Truth: Physicians' Duty to Disclose Medical Mistakes, 28 UCLA L. REV. 52 (1980). For general discussions of the physician's duty to disclose and the appropriate role of the patient, see Seidelson, Medical Malpractice: Informed Consent Cases in "Full-Disclosure" Jurisdictions, 14 DUQ. L. REV. 309 (1976); Trichter & Lewis, Informed Consent: The Three Tests and a Modest Proposal for the Reality of the Patient as an Individual, 21 So. TEX. L.J. 155 (1980); Comment, Informed Consent: From Disclosure to Patient Participation in Medical Decisionmaking, 76 NW. U.L. REV. 172 (1981).


self-determination might fall outside judicial protection.

Canterbury v. Spence,10 a landmark decision in the medical malpractice area, addressed this issue directly and answered it precisely. Although conceding that "[o]ptimally for the patient, exposure of a risk would be mandatory whenever the patient would deem it significant to his decision,"11 the court rejected such a subjective standard for determining materiality because it would unfairly force the physician to second-guess his patient, whose ideas about materiality would be unknown to him. According to the court, a physician's liability for nondisclosure is based only on what he or she knew or reasonably should have known before the injury. Thus, liability should be imposed only if the physician's communication is deemed unreasonably inadequate.12

With regard to judging the consent or causation element, that is, whether or not consent would have been forthcoming had an adequate disclosure been made, Canterbury concluded that the subjective standard

places the physician in jeopardy of the patient's hindsight and bitterness . . . [and] places the factfinder in the position of deciding whether a speculative answer to a hypothetical question is to be credited. It calls for a subjective determination solely on testimony of a patient-witness shadowed by the occurrence of the undisclosed risk.13

In adopting an objective approach to the issue of causation, the Canterbury court reasoned that causation is shown if a prudent person in the patient's position would have declined treatment because of the undisclosed risks.14 The court noted:

The patient's testimony is relevant on that score of course but it would not threaten to dominate the findings. And since that testimony would probably be appraised congruently with the factfinder's belief in its reasonableness, the case for a wholly objective standard for passing on causation is strengthened. Such a standard would in any event ease the factfinding process and better assure the truth as its product.15

11. Id. at 787.
12. Id.
13. Id. at 790-91.
14. Id. at 791.
15. Id.
One may disagree with the ultimate wisdom of those conclusions, but one must recognize and applaud the precision of language with which the court framed and resolved each issue.

Given the court's conclusions, may a plaintiff enjoy a recovery if the jury ultimately determines that a reasonable person in plaintiff's circumstances would have considered the undisclosed risk which occurred significant and, apprised of the risk, would not have consented, but the actual plaintiff would either not have attached significance to the risk or, apprised of the risk, would have consented? I think the answer must be no. If the actual patient would not have considered the risk significant, or, apprised of its existence, would have consented anyway, then the actual patient's right of self-determination with regard to material risks incident to the proposed therapy would not have been frustrated by the physician's failure to disclose. The full-disclosure standard was fashioned to protect patient's right of self-determination, not the right of self-determination of some fictitious reasonable person in like circumstances.

We can attempt to prove that conclusion with a hypothetical cross-examination of plaintiff-patient. Assume that on cross-examination plaintiff concedes that, apprised of the undisclosed risk that caused his injuries, he still would have consented to the proposed therapy. If defense counsel moves for a directed verdict the motion should be granted. Plaintiff's concession demonstrates that defendant's failure to disclose did not in fact frustrate plaintiff-patient's

16. See Seidelson, supra note 7, at 318-27. In that Article, I proposed that both materiality and consent or causation should be judged subjectively. It is my belief that judging both issues subjectively better protects the actual patient's right of self-determination, does not impose unfairly on the physician, and creates no significant threat to the integrity of the judicial process. This proposal was adopted in Scott v. Bradford, 606 P.2d 554, 558-59 (Okla. 1979). Scott was applied in Smith v. Reisig, 686 P.2d 285, 288 (Okla. 1984), in which the Supreme Court of Oklahoma concluded that, contrary to the trial court's ruling, plaintiff's lack of informed consent case had been legally sufficient. In Smith, the plaintiff testified that had she been informed of an alternative therapy, she would not have consented to the surgery. Id. at 288.

17. In Scott v. Bradford, 606 P.2d 554, 559 (1979), the court noted that "[i]f a plaintiff testifies he would have continued with the proposed treatment had he been adequately informed, the trial is over under either the subjective or objective approach." Similarly, in Buzzell v. Libi, 340 N.W.2d 36, 41 (N.D. 1983), the court found that the plaintiff failed to establish causation because her testimony indicated that "[she] would have consented to the surgery if she had been advised of the material risks prior to the surgery." Therefore, it was unnecessary to determine whether an objective or subjective test should govern. Id. at 41 n.3.

18. See supra notes 2 & 17.


20. See supra note 17.
right of self-determination. Therefore, where materiality and consent are judged objectively, the real burden imposed on the plaintiff, both in terms of presenting evidence and ultimate persuasion, is that of demonstrating that both he and a reasonable person in like circumstances would have considered the risk significant, and, apprised of the risk, neither he nor a reasonable person in like circumstances would have consented. Indeed, the Court of Appeals of the District of Columbia has interpreted Canterbury in just this manner. Moreover, that court indicated that if at trial the patient, alive and able to testify, did not testify that, aware of the risk, he would not have consented, his case would be legally insufficient.

In Haven v. Randolph, a minor plaintiff sued to recover damages for paralysis which occurred after he underwent a retrograde femoral arteriogram. The minor plaintiff's parents asserted liability under the doctrine of lack of informed consent, inter alia, alleging that they had not been informed of any risk of paralysis before consenting to the procedure. The Haven court noted that in order to prove lack of informed consent, the parents would have to show that they would not have consented to the treatment if all the reasonable risks had been disclosed. Plaintiff's parents presented no such evidence, and the court accordingly directed a verdict for defendants.

The district court opinion in Haven is dated May 18, 1972, one day before Canterbury was decided. Obviously, the lower court opinion in Haven could not have been influenced by Canterbury. The appellate court's affirmance in Haven, decided in 1974, does not discuss the lack of informed consent theory of liability. Consequently, Haven, considered alone, provides little insight into the appropriate application of Canterbury. Both Haven and Canterbury, however, were explained and mutually related in Henderson v. Milobsky. Since the explanation is provided by the same judge who authored Canterbury, the language assumes an enhanced significance.

23. Id. at 657-58.
25. Id. at 541.
26. Id.
27. Id. at 543.
28. Id. at 544.
Henderson court determined that Haven added nothing novel to the Canterbury holding that causation cannot be proven merely by plaintiff’s hindsight assertion that he would not have consented to the treatment had he known of the risk.30 The court concluded that “Haven merely stands for the cognate proposition that when the claimant has not even made such an assertion, the issue of causation cannot possibly go to the jury.”31

In Henderson, plaintiff sought damages for paresthesia, a loss of sensation, in a half-inch square area of the face just below the lower right lip, allegedly caused by the extraction of an impacted wisdom tooth.32 One theory of liability asserted by the plaintiff was lack of informed consent.33 Plaintiff testified that he would have declined to proceed had he known of the risk of paresthesia.34 Nevertheless, two weeks after the injury-producing extraction, a time during which the paresthesia subsisted, plaintiff returned to the same dental surgeon to have a second impacted wisdom tooth extracted.35 Unable to reconcile plaintiff’s contradictory behavior, the Henderson court concluded that there could be “no more telling evidence of what [plaintiff] would have done had he been warned of the possibility of temporary paresthesia before the extractions began.”36

As for permanent paresthesia, the court found from the evidence presented at trial that it was likely to occur in less than one case in one hundred thousand.37 In light of the low statistical likelihood of such an injury, and its “troublesome but hardly disabling”38 nature, the court affirmed the ruling below that “no prudent juror could reasonably have considered the risk of permanent paresthesia material to a decision on whether to consent to the procedure . . . .”39 Consequently, the court affirmed a directed verdict for the defendant with regard to the lack of informed consent theory of liability.40 The result in Haven, as explained in Henderson,41 and the

30.  Id. at 657.
31.  Id. at 658 (emphasis added).
32.  Id. at 656.
33.  Id. at 658.
34.  Id.
35.  Id.
36.  Id. at 659.
37.  Id.
38.  Id.
39.  Id.
40.  Id.
41.  Id. at 657-58.
facts and result in *Henderson* itself, indicate that *Canterbury* contemplated imposing on the plaintiff a dual burden of providing evidence sufficient to justify a reasonable jury finding that (1) both plaintiff and a reasonable person in like circumstances would have considered the undisclosed risk significant, and (2) apprised of the risk, neither plaintiff nor a reasonable person in like circumstances would have consented to the proposed therapy. In addition, both *Haven*, as explained in *Henderson*, and *Henderson* itself, indicate that, in order for a plaintiff’s case to be legally sufficient, the patient, if able to testify at trial, must assert that he would have attached significance to the undisclosed risk and would not have consented if informed of such risk.

Several years later, however, in *Hartke v. McKelway*, the same court affirmed a judgment for plaintiff under the doctrine of lack of informed consent, despite the fact that she never testified that she would have foregone the treatment if advised of the risks. Plaintiff-patient, whose history of gynecological trouble was known to defendant-physician, sought sterilization. Defendant recommended a sterilization procedure to which plaintiff consented. After surgery was performed, plaintiff became pregnant, delivered a baby girl by Caesarian section, and, asserting lack of informed consent, inter alia, sued defendant. There was testimony at trial from which the jury could infer that the physician failed to disclose to plaintiff that the risk of subsequent pregnancy would be “one to three out of one thousand.” At no point, however, did plaintiff testify that she would have foregone the treatment if she had known of the risks. Nevertheless, the court affirmed a judgment for the plaintiff. In considering the role a patient’s testimony should play

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42. *Id.* at 659.
43. *Id.* at 657-59.
45. *Id.*
46. *Id.* at 1547.
47. *Id.*
48. *Id.*
49. *Id.*
50. *Id.* at 1549.
51. The court of appeals’ affirmance reads as follows:

    After a jury verdict for plaintiff on all claims, the District Court disallowed the award of childrearing expenses because it found the evidence clear that plaintiff had sought to be sterilized for therapeutic, not economic, reasons, and because she prized the child she bore. *Hartke v. McKelway*, 526 F. Supp. 97, 105 (D.D.C. 1981). The court also held that *in haec verba* testimony of causation is not required to get the issue of informed consent to the jury as long as there is otherwise suffi-
in determining causation, the court noted that it was precisely because of the distrust of such testimony that the subjective standard of causation had been replaced by an objective, reasonable person standard.\(^6\) The court concluded that a "jury certainly does not need the patient's testimony to decide what a reasonable person in that position would have done."\(^6\) 

_Canterbury_ had concluded that plaintiff must demonstrate two things. First, he must testify that had he been aware of the risk, he would have withheld consent. Even if believed by the jury, however, plaintiff's self-serving testimony would not alone be determinative.\(^5\) Plaintiff must also persuade the jury that a reasonable person, apprised of the risk, would not have consented.\(^6\) Both _Haven_ and _Hen-

\(^6\) Cient evidence from which the jury could infer that a patient would have declined the procedure had he or she known of the risks. _Id._ at 103. Finding such evidence, the court upheld the jury's award of damages for plaintiff's medical expenses, pain, suffering, and mental anguish resulting from the pregnancy and childbirth. _Id._

The court also held that a jury could have found that a reasonable person in plaintiff's somewhat unusual position would likely have attached significance to the undisclosed risk of subsequent pregnancy here (one to three out of one thousand). _Id._ at 102-03. We affirm.

707 F.2d at 1546-47.

With regard to plaintiff's right to recover the cost of rearing the unplanned child, the appellate court concluded from the evidence presented at trial that "the jury could not rationally have found that the birth of this child was an injury to this plaintiff." 707 F.2d at 1557. This matter-of-law conclusion was based on the "overwhelming" evidence that plaintiff sought sterilization "for therapeutic reasons: she desperately feared that serious complications or even death would result from pregnancy and childbirth." _Id._ at 1556. Since plaintiff's desire for sterilization had not been based on economic concerns, the court concluded that plaintiff could not recover for the cost of rearing the child. _Id._ at 1552-57.

Recognizing that its jurisdiction rested on diversity grounds, the court predicted that "the District of Columbia courts may well adopt" the view that, where sterilization is sought for economic reasons, recovery for the cost of rearing the unplanned child will be permitted. _Id._ at 1552. Just over a year later, the District of Columbia Court of Appeals held that, even when sterilization was sought for economic reasons, there could be no recovery for rearing the unplanned child. _Flowers v. District of Columbia_, 478 A.2d 1073 (D.C. 1984). In _Flowers_, the court characterized that holding as "in accord with recent decisions by the highest courts in Alabama, Arkansas, Delaware, Florida, Illinois, Iowa, Kentucky, New Hampshire, Pennsylvania, Wisconsin and Wyoming." _Id._ at 1075 n.2.

52. 707 F.2d at 1551. A similar conclusion was reached in _Reikes v. Martin_, 471 So. 2d 385 (Miss. 1985). After rejecting the subjective standard adopted in _Scott v. Bradford_, 606 P.2d 554 (Okla. 1979), the court adopted the objective standard, concluding that there had been no error in a jury instruction that would have allowed recovery "without any showing of [subjective] causation, i.e., that [plaintiff] would not have elected to undergo the treatment if she had been informed of the known risks." 471 So. 2d at 392.

53. 707 F.2d at 1551.

54. _See supra_ text accompanying note 15.

55. _Id._
derson seem to support that reading of Canterbury. In Hartke, however, plaintiff's potential testimony as to whether or not she would have consented is relegated to the category of "helpful" but not "need[ed]" in order for the jury to determine "what a reasonable person in that position would have done." What about what the plaintiff herself would have done? The language in Hartke suggests that, if the jury finds that a reasonable person, adequately informed, would not have consented, plaintiff may recover, whether or not the jury finds that the particular plaintiff would have withheld consent. In its effort to minimize the significance of plaintiff's testimony on that critical point, and, indeed, to demonstrate the lack of legal necessity for such testimony, the court employed language that eliminates the plaintiff's burden of demonstrating that, apprised of the risk, she would not have consented.

Such a radical change in the preexisting law was not necessary to support the court's conclusion that plaintiff's case was legally sufficient even without plaintiff's testimony that, aware of the risk, she would not have consented. The Hartke court could have sustained that conclusion by merely stating that the dual burden could be satisfied by evidence other than plaintiff's explicit testimony that she would not have consented. The adoption of such language would also have preserved the plaintiff's burden of persuading a jury that neither plaintiff nor a reasonable person in like circumstances would have consented. Instead, the court's language renders nugatory the actual patient's right of self-determination. Its language approves a judgment for the plaintiff based on lack of informed consent even though the plaintiff, informed of the risk, would have consented to the proposed therapy.

If the Hartke court had asked why Canterbury rejected the subjective standard in favor of an objective standard to resolve the consent issue, the answer would have been apparent from the Canterbury opinion. The subjective standard, in the view of Canterbury, puts the physician in danger of suffering from a patient's hindsight.

56. See supra text accompanying notes 24-31, 41-43.
57. 707 F.2d at 1551.
58. Id.
59. Id.
60. See supra note 51 and infra text accompanying note 61.
61. That seems to be precisely what the trial court did. See supra note 51.
62. If a plaintiff may recover whether or not he would have consented if adequately apprised of the risks, the plaintiff's right of self-determination becomes legally meaningless.
63. See supra text accompanying note 52.
and bitterness. Further, it requires the factfinder to determine causation solely by examining speculative responses to hypothetical questions made by self-interested patients. Consequently, *Canterbury* decided that fairness to the physician and preservation of the integrity of the judicial process militated against having the consent issue resolved solely on the self-serving testimony of the plaintiff. Yet, in *Hartke*, the court eliminated the necessity for such testimony, thereby favoring the plaintiff rather than assuring fairness to the physician, and depriving the jury of testimony that might better enable it to perform its function. The rationale of *Canterbury* seems to have been turned upside-down in *Hartke*.

What led the *Hartke* court to its conclusion? The court's opinion emphasizes the "distrust" of plaintiff's testimony that he would not have consented if apprised of the risk. There are, I believe, two elements which contribute to that distrust. First, the testimony is inherently self-serving. Of course, it is usually true that a litigant's testimony will be self-serving, and that fact will not generally lead to the legal conclusion that such testimony is insignificant. Rather, courts rely on the common sense of properly instructed juries to consider such self-interest in determining how much credibility to extend to the litigant-witness and what weight to afford his testimony.

Second, plaintiff's testimony that if informed he would not have consented is speculative. It should be remembered, however, that the underlying issue for the jury is itself inherently speculative, whether defined in pre-*Hartke* terms (apprised, would patient and a reasonable person in like circumstances have withheld consent?) or in post-*Hartke* terms (apprised, would a reasonable person in patient's circumstances have withheld consent?). Because the *Hartke* court concluded that the patient's testimony, while not necessary, "might be helpful," its denigration of such testimony based on distrust is not very persuasive.

In addition, the court recognized that it was exercising diversity jurisdiction and, therefore, should apply the *Erie* doctrine. Looking to the opinions of the highest appellate court in the District of Co-

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64. 464 F.2d at 790-91. *See also supra* text accompanying note 13.
65. Even the *Hartke* opinion conceded that such testimony would be "helpful" to the jury. 707 F.2d at 1551.
66. *Id.* at 1550.
67. *Id.* at 1551.
lumbia, the Hartke court discovered Crain v. Allison. According to Hartke, Crain "unequivocally adopted, albeit in dictum, the objective, prudent-person standard. Citing the Canterbury case, the court in Crain... wrote, '[T]he test of causation is objective. The test is what would a prudent person in the patient's position have decided if informed of all relevant factors...'."

Canterbury, however, did not negate the necessity for plaintiff's testimony that, informed of the risk, he would have withheld consent. Both Haven (as explained in Henderson) and Henderson read Canterbury as requiring the plaintiff to prove that, adequately informed, neither he nor a reasonable person in like circumstances would have consented. Moreover, in Crain, the plaintiff testified that she would not have taken the risk had she been aware of it. Crain clearly did not require the change in preexisting law that the Hartke language appears to have effected. Even Hartke noted that "[w]hat may eventually emerge is a standard of causation that requires the plaintiff to prove both that he or she would in fact have avoided the risk if informed of it and that a reasonable person would have done so." I believe the above standard emerged from Canterbury, was recognized by Henderson, and remained unchanged by Crain.

In further support of its conclusion that plaintiff's case was legally sufficient despite her failure to testify that she would not have consented if adequately informed, the Hartke court cited Sard v. Hardy. That case, like Hartke, arose out of a post-sterilization pregnancy, and the Maryland Court of Appeals, like the Hartke court, concluded that plaintiff's failure to so testify was not a legally fatal defect. By imposing the full-disclosure standard and judging

69. 443 A.2d 558 (D.C. 1982).
70. 707 F.2d at 1550 (quoting Crain, 443 A.2d at 563 n.14) (citation omitted).
71. See supra text accompanying notes 24-30, 41-43.
72. 443 A.2d at 563. A footnote relating to patient's testimony reads as follows: "Although the patient's testimony is relevant on the issue of causation, the test of causation is objective. The test is what would a prudent person in the patient's position have decided if informed of all relevant factors... See Canterbury v. Spence, 464 F.2d at 791." Id. at 563 n.14.
73. Since "[plaintiff] testified that she would not have agreed to the injections had she been aware of the risk of infection," id. at 563, the plaintiff's case in Crain would be legally sufficient if the consent issue were judged both objectively and subjectively.
74. 707 F.2d at 1551 n.6 (emphasis in original).
75. 281 Md. 432, 379 A.2d 1014 (1977), cited in Hartke, 707 F.2d at 1551.
76. 281 Md. at 451, 379 A.2d at 1025-26.
materiality and consent objectively, the Sard court concluded that plaintiff’s failure to negate her consent did not destroy her case.\(^7\) In making this finding, the court noted that a patient’s hindsight assertions as to what he or she would have hypothetically done, although useful to the court, are not determinative when applying the objective standard.\(^7\)

Apparently, the Sard court did not intend to eliminate the plaintiff’s dual burden of demonstrating that, apprised of the risk, neither he nor a reasonable person would have consented. At the outset of its discussion of causation, the court noted:

All courts recognizing the doctrine of informed consent require proof of proximate causation. The rule is that a plaintiff cannot recover under the doctrine unless he can prove by a preponderance of the evidence that he would not have given his consent to the proposed procedure had full and adequate disclosure been made at the time consent was originally given.\(^8\)

Consequently, to the extent that Sard influenced the Hartke court’s conclusion, the language used in the latter, apparently eliminating the requirement that plaintiff must establish that, adequately informed, he would not have consented, may have gone beyond the contemplation of the former. And, as we have noted,\(^8\) that language was not necessary to Hartke’s conclusion that plaintiff’s case was legally sufficient, even absent plaintiff’s explicitly negating consent. Sard seems to have accomplished that same result without eliminating plaintiff’s burden of proving he would not have consented.

Both Hartke and Sard, however, raise this basic question: Why, in a lack of informed consent case, would plaintiff fail to testify that, adequately informed, he would not have consented? The answer to that question should be instructive in determining the propriety of both courts’ conclusion that such testimony is not legally essential. There are, I think, three possible explanations for the absence of such testimony by the plaintiff: oversight on the part of plaintiff’s counsel,\(^8\) a “painfully honest” plaintiff, or a tactical decision made

\(^{77}\) Id. at 446, 450, 379 A.2d at 1022-23, 1025.
\(^{78}\) Id. at 451, 379 A.2d at 1026.
\(^{79}\) Id. at 450, 379 A.2d at 1025.
\(^{80}\) Id. at 448, 379 A.2d at 1024 (emphasis added).
\(^{81}\) See supra notes 51 & 61 and accompanying text.
\(^{82}\) In Hartke, 707 F.2d at 1550, the appeals court, referring to the district court’s opinion, wrote: “The court held that to require such testimony in such a case ‘would only set a trap for the unwary.’” (quoting 526 F. Supp. at 103). A fuller excerpt from the district court’s
by plaintiff's counsel to avoid adversely affecting plaintiff's general credibility.

How likely is the first explanation? Under the ongoing pressure of trial, I suppose counsel could overlook almost anything. Still, it does seem unlikely that counsel would overlook the direct testimony from the plaintiff that constitutes the gravamen of his complaint: "Had I known, I would not have consented." As to the second explanation, it could be that counsel believes that his client, if asked directly, would be unable to testify ingenuously that he would not have consented if informed. Finally, counsel might conclude that direct testimony from plaintiff on the subject of consent could unduly strain the jury's credulity, adversely affecting plaintiff's general credibility.

If counsel for the plaintiff does not ask that critical question during his direct examination of plaintiff, why does defense counsel not ask it on cross-examination? Again, one possible but unlikely explanation would be oversight. Another could be defense counsel's concern that, by asking the question, he may open the door to an undesirable answer ("Had I known, I would not have consented.") and thereby convert a potentially insufficient case into a legally sufficient one. There are, therefore, tactical explanations on both sides for not asking plaintiff the critical question. That, in turn, raises the ultimate question: Do those explanations justify the legal conclusion that it is unnecessary for plaintiff to testify explicitly that, adequately informed, he would not have consented?

Typically, where a litigant is deemed to have control over a particular witness or a particular piece of evidence, and, without explanation, fails to produce that witness or piece of evidence, an adverse inference may arise. Under that adverse inference, the court may instruct the jury that it may (but is not required to) infer that, had the witness been called or the evidence presented, the result would

opinion read as follows:

[P]laintiff's husband testified that had he known of the risks of pregnancy, he would have undergone a vasectomy. To require plaintiff herself to [testify that, apprised of the risk, she would not have consented,] in a case such as this when her husband testifies to this effect in her presence would only set a trap for the unwary.


The above can be read to imply that plaintiff's failure to give such testimony was the result of an understandable oversight occasioned by the testimony of her husband. I am inclined to think that testimony from the plaintiff that, informed of the risk, she would have foregone the sterilization procedure and have had her husband secure a vasectomy, would have been the perfect complement to the husband's testimony.

have been adverse to the nonproducing litigant. If that general rule were applied to plaintiff's failure to testify that, given adequate information, he would not have consented, it would be entirely appropriate for the court to conclude that plaintiff's failure was not a fatal defect. The rule generates only a permissible inference, one the jury is free to accept or reject. Should such permissibility be deemed applicable to plaintiff's failure to testify on the subject of informed consent? I think not.

Several unique aspects regarding that missing testimony should be noted. First, if plaintiff bears the burden of proving that, informed of the risk, neither he nor a reasonable person would have consented, the missing testimony goes directly to the first part of that dual requirement for a legally sufficient case. As we have noted, such testimony would be at the very core of the plaintiff's complaint. Second, one person alone is the world's foremost authority on that critical point: the plaintiff. No one else can know as well as he whether, informed of the risk, he would have consented. These two considerations lead me to conclude that if plaintiff fails to offer such critical testimony, his case should be deemed legally insufficient. I do not suggest, however, that if defense counsel's adroit maneuverings or plaintiff's own stress under cross-examination cause him to make the improvident concession that, informed of the risk, he would have consented anyway, plaintiff's case must fail. In those circumstances, appropriately helpful redirect examination by plaintiff's counsel could be expected to produce contrary testimony by the plaintiff. Then, the matter would become an appropriate question of credibility for the jury to resolve. Rather, I suggest that where plaintiff fails to address the particular question of informed consent, his case should fail as a matter of law. Or, if on cross-examination, plaintiff willingly concedes that, informed, he would have consented, his case should also fail, absent his contrary testimony on direct or redirect examination. In short, I believe that the plaintiff, alleging an actionable frustration of his right of self-determination, should not reach the jury if he fails to testify that, informed, he would not have consented.

84. Id. at 805-07.
85. Id. at 807.
86. See supra text accompanying notes 21, 27, 30.
87. Id.
88. E. Cleary, supra note 83, at 786.
89. Id.
Given the three possible explanations for that failure, oversight, ingeniousness, or fear of straining credibility, is the suggested result unfair to plaintiff? If plaintiff's failure to offer the critical testimony is the result of oversight on the part of plaintiff's counsel, two possibilities arise. The court, sensitive to the need for such testimony, could, at side-bar, draw counsel's attention to the oversight. Should the court, as well as counsel, overlook the necessity of such testimony, the result would be that which usually follows plaintiff's counsel's failure to present legally essential evidence: a directed verdict for defendant. Of course, when defense counsel moves for the directed verdict, the attention of both the court and plaintiff's counsel will be drawn to the oversight. At that point, the court, in the exercise of its discretion, could grant plaintiff permission to reopen his case in order to present the overlooked testimony. Should plaintiff's counsel decline to do so, the court's granting of the directed verdict would hardly be the product of mere oversight on the part of counsel.

If plaintiff's failure to offer the critical testimony is the result of plaintiff's candor, his case should fail, since in such circumstances the defendant's failure to inform would not have frustrated patient's right of self-determination. If plaintiff's failure to offer the critical testimony is the result of counsel's tactical decision that such testimony would adversely affect plaintiff's general credibility, two possibilities exist: Either counsel recognizes the inherent incredulousness of such testimony, or counsel has made a poor tactical decision. Whichever more appropriately describes counsel's decision, the trial court, cognizant of the unasked question, can suggest to counsel that the question be asked. If counsel persists in declining to ask the question, the trial court may ask it. If the court does, and the plaintiff answers that he would not have consented if informed, he will have given the critical testimony. If he answers, however, that he would have consented anyway, plaintiff's case should fail.

If the trial court neglects to suggest that plaintiff's counsel ask the question, and defendant moves for a directed verdict, the court could exercise its discretion and offer plaintiff's counsel the right to reopen plaintiff's case to ask the critical question. Should plaintiff's counsel decline to do so, because of his belief that a favorable answer would strain the jury's credulity, plaintiff's case should fail. If a favorable answer would, in fact, be inherently incredible, plaintiff's right of self-determination is not likely to have been frustrated. If counsel's belief that a favorable answer would be incredible is not
well-founded, but counsel persists in his refusal to ask the question, plaintiff's case should still fail. After all, a failure by plaintiff's counsel to present legally required evidence, whether a tactical decision or otherwise, usually results in a directed verdict for defendant. Finally, as an ultimate protection against injustice, the highest appellate court of the jurisdiction, assuming that it eventually holds that plaintiff's explicit negation of his consent is legally essential, could impose that requirement prospectively, making it applicable only to cases not yet tried.

Do the possible explanations for defense counsel's failure to ask the critical question on cross-examination justify a different result? I do not think so. If the failure is attributed to oversight, that explanation would not justify treating the plaintiff's case as legally sufficient. The absence of essential evidence in plaintiff's case is not generally cured by defense counsel's failure to explore the area on cross-examination, as long as defendant makes a timely motion for directed verdict. If the failure is attributed to defense counsel's concern about converting an insufficient case into a legally sufficient one, that also would not justify treating the plaintiff's case as legally sufficient. Plaintiff's burden of making a legally sufficient case is not generally shifted to the defendant. Whether defense counsel's failure is at-

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90. E. Cleary, supra note 83, at 947, 952-56.
91. Cf. Scott v. Bradford, 606 P.2d 554 (Okla. 1979) (Oklahoma court, holding for the first time that materiality and causation were to be judged by a subjective standard, mandated that its opinion be applied prospectively).
92. Suppose the [litigant] who had the initial burden of offering evidence in support of the alleged fact, on pain of an adverse ruling, does produce evidence barely sufficient to satisfy that burden, so that the judge can just say, "A reasonable jury could infer that the fact is as alleged, from the circumstances proved." If the proponent then rests, what is the situation? Has the duty of going forward shifted to the adversary? Not if we define that duty as the liability to a peremptory adverse ruling on failing to give evidence, for if at this juncture the original proponent rests and the adversary offers no proof, the proponent will not be entitled to the direction of a verdict in his favor on the issue, but rather the court will leave the issue to the decision of the jury. But it is frequently said that in this situation the duty of going forward has shifted to the adversary, and this is unobjectionable if we bear in mind that the penalty for silence is very different here from that which was applied to the original proponent. If he had remained silent at the outset he would irrevocably have lost the case on this issue, but the only penalty now applied to his adversary is the risk, if he remains silent, of the jury's finding against him, though it may find for him.

E. Cleary, supra note 83, at 954-55 (footnotes omitted; first emphasis in original, second emphasis added). See P. Carrington & B. Babcock, Civil Procedure 133 (3d ed. 1983) ("[T]he plaintiff . . . has the burden of producing evidence on each of the elements of his prima facie case.").
93. See supra note 92.
tributable to oversight or concern, absence of the testimony becomes
critical only when challenged by a motion for directed verdict.\textsuperscript{94} As
previously noted, when confronted with such a motion the court
could, in the exercise of discretion, grant plaintiff permission to reo-
pen his case to present the critical testimony.\textsuperscript{95} Ultimately, the
highest appellate court of the jurisdiction, concluding that such testimony
was essential, could make its determination prospectively applicable
and thus avoid an unfair imposition on the present plaintiff.\textsuperscript{96} There-
fore, whichever reason might explain defense counsel's failure to in-
quire on cross-examination, there will be little fear of plaintiff's be-
ing "sandbagged."

Why did neither \textit{Hartke} nor \textit{Sard} inquire as to the reasons un-
derlying plaintiff's failure to testify that, informed, she would not
have consented? With \textit{Hartke}, the answer may lie in the manner by
which the court, whether intentionally or not, changed the require-
ments of a legally sufficient case which had been spelled out in \textit{Can-}

\textsuperscript{94} Id.

\textsuperscript{95} In virtually every jurisdiction, the court may exercise its discretion to grant a liti-
gant's motion to reopen his case after the parties have rested, either for the purpose of present-
ing evidence, the legal significance of which was not recognized, or for the purpose of present-
ing newly discovered evidence. \textit{See}, e.g., Hancock v. City of Montgomery, 428 So. 2d 29 (Ala.
361, 362 P.2d 737 (1961); Johnson v. Johnson, 64 Ariz. 368, 172 P.2d 848 (1946); Kennedy v.
Kennedy, 243 Ark. 773, 421 S.W.2d 611 (1967); Walker v. State, 240 Ark. 441, 399 S.W.2d
672 (1966); People v. Carter, 48 Cal. 2d 737, 312 P.2d 665 (1957) (en banc); Bruner v.
Bruner, 240 Ga. 159, 240 S.E.2d 48 (1977); Iverson v. Gordon Farming Co., 103 Idaho 527,
650 P.2d 669 (1982); Dixon v. Indus. Comm'n, 60 Ill. 2d 126, 324 N.E.2d 393 (1975);
Anthony v. State, 274 Ind. 206, 409 N.E.2d 632 (1980); Stanford v. Iowa State Reformatory,
279 N.W.2d 28 (Iowa 1979); City of Wichita v. Unified School Dist. No. 259, 201 Kan.
110, 439 P.2d 162 (1968); State v. Colony, 407 A.2d 1115 (Me. 1979); Custody of a Minor, 375
Mass. 733, 379 N.E.2d 1053 (1978); Shannon v. Polish Falcons of America Nest No. 86, 348
Mich. 92, 82 N.W.2d 523 (1957); State v. Berg, 326 N.W.2d 14 (Minn. 1982); Hahn v.
Diamond Iron Works, Inc., 221 Minn. 33, 20 N.W.2d 704 (1945); Nelson v. Home Ins. Co.,
353 So. 2d 763 (Miss. 1977); Fireman's Fund Am. Ins. Co. v. Webber, 112 N.H. 466, 298
A.2d 745 (1972); People v. Turesik, 34 N.Y.2d 985, 318 N.E.2d 605, 360 N.Y.S.2d 414
(1974); State v. Jungling, 340 N.W.2d 681 (N.D. 1983); Johnson v. Johnson, 674 P.2d 539
(Okla. 1983); Hiestand v. Wolfard, 272 Or. 222, 536 P.2d 520 (1975); \textit{In re} J.E.F., 487 Pa.
455, 409 A.2d 1165 (1979); Pozzolan Portland Cement Co. v. Gardner, 668 P.2d 569 (Utah
1983); Goslant v. Goslant, 130 Vt. 210, 290 A.2d 22 (1972); Ferguson v. Colonial Pipeline
S.E.2d 539 (1961); Ertman v. City of Olympia, 95 Wash. 2d 105, 621 P.2d 724 (1980) (en
banc); Jimco Supply Co. v. Neal, 277 S.E.2d 626 (W. Va. 1981); Wisconsin \textit{ex rel} Lewandow-
ski v. Callaway, 118 Wis. 2d 165, 346 N.W.2d 457 (1984); Gifford v. Casper Neon Sign Co.,
618 P.2d 547 (Wyo. 1980).

\textsuperscript{96} \textit{See supra} note 91 and accompanying text.
The language in the Hartke opinion suggests that use of an objective standard to judge causation makes the particular patient’s decision concerning consent, given an adequate disclosure, legally insignificant. Once a patient’s reaction to an adequate disclosure is relegated to legal insignificance, there is not much point in inquiring why such testimony was not offered. In Sard, although the court did not so characterize the patient’s informed decision, it did conclude that, given an objective standard to judge consent, such testimony was unessential. There is a latent ambiguity lurking in that conclusion. It is one thing to say that plaintiff’s self-serving testimony will not alone be determinative; it is quite different to say that it is not legally required. The Sard court seems to have said both. Had its reasoning and language been more precise, perhaps noting that use of the objective standard did not necessarily eliminate the need for patient’s testimony regarding response to an adequate disclosure, the court might have speculated why plaintiff had failed to offer direct testimony on such a significant point. Had either the Hartke or Sard court bothered to ponder the reasons for the omission, I suspect that both would have reached the same explanations as I have: counsel’s oversight, a “painfully honest” plaintiff, or a tactical advantage sought by plaintiff’s counsel. I am also inclined to think that both courts might have concluded, as I do, that none of those explanations constitutes an acceptable justification for the absence of such testimony.

It should be noted that plaintiff’s burden of testifying that, adequately informed, he would have withheld consent, is neither particularly onerous nor a reward for the physician-defendant’s neglect. In other factual settings, it might be unfair to require a plaintiff’s testimony that, but for defendant’s failure, the injuries would not have occurred. For example, if plaintiff alleges that a defendant-common carrier failed to exercise reasonable care to protect its employees or passengers from injuries at the hands of criminals, it would be inappropriate to require him to testify that reasonable care would have prevented the injuries. Because of the defendant’s failure to

97. See supra text accompanying notes 13-14.
98. See supra text accompanying notes 30, 33-36.
99. See supra notes 70-73 and accompanying text.
100. See supra notes 62-63 and accompanying text.
101. See supra text accompanying note 79.
102. See supra text accompanying notes 79-80.
utilize available safety devices, it would be impossible for anyone to testify explicitly that those devices would have prevented the injury-producing criminal conduct. All that is or should be required of plaintiff is sufficient evidence to justify a reasonable jury finding that use of such devices would have prevented the injuries.\textsuperscript{106}

In the context of a medical malpractice action based on the lack of informed consent, however, the available patient-plaintiff does have the capacity to testify that, adequately informed, he would not have consented to the procedure. That testimony goes to the very core of plaintiff's complaint: the frustration of his right of self-determination.\textsuperscript{106}

What about the plaintiff who simply is not certain how he would have reacted to an adequate disclosure? Would it be an undue imposition to require his direct testimony that, given adequate information, he would not have consented? It should be sufficient for such a plaintiff to testify that he does not think he would have given consent. We do not want to penalize the candid plaintiff who, although unable to state emphatically that he would not have consented, is able to testify that he believes he would not have done so.

But suppose the plaintiff, despite an awareness of his litigation posture, is so uncertain of how he would have reacted to an adequate disclosure that he can say no more than, "I don't know." Should his case be deemed legally sufficient? I think not, for a few reasons. First, such an unenlightening answer indicates that the plaintiff is unable to assert even that his right of self-determination was violated. Since the essence of the cause of action is a frustration of the plaintiff's right of self-determination, the inability to assert even a probable violation seems to destroy the crux of the action. Also, since the one person in the world who should best know how he would have reacted to an adequate disclosure has given an unenlightening response, permitting the jury to consider the issue would be an exercise in undue speculation. Rejecting the "I don't know" response does not unduly impose upon an "honest" plaintiff; rather, it bases the distinction between a case which is legally sufficient and one which is not on the presence or absence of critical testimony from the "world's foremost authority" on the subject. If all the plaintiff can say is, "I don't know," perhaps counsel erred in taking the case and initiating the action.

\textsuperscript{105} In Kenny, the Third Circuit reversed the trial court's granting of judgment n.o.v., and reinstated the jury's verdict in favor of the plaintiff. 581 F.2d at 356.

\textsuperscript{106} See supra text accompanying notes 86-87.
II. PRODUCT LIABILITY CASES

The issue of informed consent is also significant in product liability cases. In *Reyes v. Wyeth Laboratories*,\(^\text{107}\) the minor plaintiff contracted paralytic poliomyelitis from defendant’s live polio vaccine which was administered to her at a health clinic.\(^\text{108}\) Included with each vial of the vaccine was a package insert provided by defendant-manufacturer to warn doctors, hospitals, and other purchasers of the potential dangers of ingesting the drug.\(^\text{109}\) The warning mentioned the possibility of contracting polio from the vaccine, but that possibility was not explained to the minor plaintiff’s mother.\(^\text{110}\) Plaintiff based her claim, inter alia, on strict liability.\(^\text{111}\)

Wyeth asserted that it had a right to rely on the dispensing physician or authorities to convey the warning to plaintiff’s mother be-

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107. 498 F.2d 1264 (5th Cir.), cert. denied, 419 U.S. 1096 (1974). In *Reyes*, as in the other cases considered in this Article, the product risks were either known or knowable to the sellers. For discussions of the sellers’ obligation with regard to “unknowable” risks, compare Page, *Generic Product Risks: The Case Against Comment k and for Strict Tort Liability*, 58 N.Y.U. L. Rev. 853 (1983) (supporting the imposition of strict liability on manufacturers of generic products even though the risks were unknown at the time of sale), with Owen, *Rethinking the Policies of Strict Products Liability*, 33 Vand. L. Rev. 681 (1980) (explaining and criticizing the accepted policies behind strict liability in tort), and Shapo, *A Representative Theory of Consumer Protection: Doctrine, Function and Legal Liability for Product Disappointment*, 60 Va. L. Rev. 1109 (1974) (theorizing that products liability must be determined upon consideration of a variety of factors, particularly the way a product is portrayed by the seller).


108. 498 F.2d at 1270.

109. Id.

110. Id.

111. Id. According to the Restatement (Second) of Torts:

There are some products which, in the present state of human knowledge, are quite incapable of being made safe for their intended and ordinary use. These are especially common in the field of drugs . . . . Such a product, properly prepared, and accompanied by proper directions and warning, is not defective, nor is it unreasonably dangerous . . . . The seller of such products, again with the qualification that they are properly prepared and marketed, and proper warning is given, where the situation calls for it, is not to be held to strict liability for unfortunate consequences attending their use, merely because he has undertaken to supply the public with an apparently useful and desirable product, attended with a known but apparently reasonable risk.

**RESTATEMENT (SECOND) OF TORTS** § 402A comment k (1965).
cause the vaccine was a prescription drug. Concluding from the evidence presented that a reasonable jury could find that Wyeth knew or should have known that the vaccine would be administered outside a private physician-patient relationship, the Fifth Circuit held that Wyeth had no matter-of-law right to rely on a learned intermediary's conveying notice of the risk to the mother.\textsuperscript{112} In effect, plaintiff asserted that her mother had not given an informed consent to have plaintiff receive the vaccine since no one apprised her mother of the risk.

Although plaintiff's mother testified at trial that she was not warned of any possible danger in taking the vaccine,\textsuperscript{113} she failed to testify that, apprised of the risk, she would not have consented to her daughter's receiving it.\textsuperscript{114} The court concluded that this failure did not destroy the plaintiff's case.\textsuperscript{116} Rather, the court held that "[w]here a consumer . . . is injured by a product sold without a required warning, a \textit{rebuttable presumption} will arise that the consumer would have read any warning provided by the manufacturer, and acted so as to minimize the risks."\textsuperscript{116} That language goes beyond

\begin{footnotesize}
\begin{enumerate}
\item 498 F.2d at 1276-78.
\item \textit{Id.} at 1270.
\item \textit{Id.} at 1281-82.
\item \textit{Id.}
\item \textit{Id.} at 1281 (emphasis added).
\end{enumerate}
\end{footnotesize}
Sard, where the court held, in effect, that the jury could infer such a conclusion from evidence other than the plaintiff's explicit negation of consent. In Reyes, that permissible inference was elevated to a rebuttable presumption resting on no specific evidence. Why?

Reyes was a diversity case. The Fifth Circuit, applying Texas law and relying significantly on "crucial dicta" in Technical Chemical Co. v. Jacobs, concluded that the mother's failure to testify that she would not have consented if adequately informed, would be cured under Texas law by a rebuttable presumption to that effect.

In Jacobs, plaintiff was injured by the explosion of a can of freon manufactured by the defendant. At the time of the explosion, plaintiff was attempting to inject the freon into his automobile's air conditioning compressor. He had apparently attached the can to a valve on the "high" side of the compressor rather than on the "low" side, so that pressure built up in the can until it burst. Plaintiff's theory of liability was that the product was defective and unreasonably dangerous because the directions for use printed on the can failed to warn of the danger of attaching it to the wrong side of a compressor. The plaintiff's problem was the introduction of evi-

expressly approved of a proximate cause burden shifting presumption in swine flu vaccination cases . . . . Such a rebuttable presumption was appropriate for three reasons: (1) in a mass immunization setting without the advice of a doctor, warnings would not have been very helpful; (2) public policy favors placing the risk of loss on the manufacturers, not on the consumers; and (3) the government's "hard sell" of the swine flu program minimized the impact of any warning . . . .

Here, the [trial] court, although conceding that the first factor was not present, used the presumption because it found that the third factor was the most important in this particular case. While this extension of Petty II presents another close question, in view of the deference with which we review a court's predictions of state law, we uphold the court's use of the presumption.

Id. at 1359-60.

I confess that I do not understand why the government's "hard sell" of the swine flu vaccine should have the effect of shifting the burden of presenting evidence from the plaintiff to the defendant. Presumably, that "hard sell" would make it all the easier for the plaintiff to testify convincingly that he would not have consented to the vaccination if apprised of the risks.

117. See supra text accompanying notes 79-80.
118. See supra note 116 and accompanying text.
119. 498 F.2d at 1280.
120. 480 S.W.2d 602 (Tex. 1972).
121. 498 F.2d at 1281-82.
122. 480 S.W.2d at 602.
123. Id. at 603-04.
124. Id. at 604.
125. Id.
ference that he had failed to read the printed directions before attempting to use the product. Moreover, plaintiff apparently never testified that he had either read the directions or would have observed a warning had one been provided. The jury thus refused to find that defendant's failure to warn was "a producing cause" of plaintiff's injuries.

In the course of its opinion, the Supreme Court of Texas noted:

We recognize the problems of proving causation in such a case as this. If the user of the product dies from its use, testimony whether he did or did not read the label may be impossible. If the label is inadequate, whether he would or would not have read an adequate label may be speculative. On the other hand, proof that the defect was the cause of the injuries should, on logic, be required as it is in other cases.

This excerpt elicits several reactions. First, where the user of the product dies, there will obviously be no direct testimony from him as to whether or not he had read the label. Plaintiff in the wrongful death action has the perfect explanation for the lack of such testimony: its absolute unavailability.

That was not the case in Jacobs. There, the injured victim was able to testify at the trial. In fact, it was plaintiff's testimony that suggested he had not read the directions. Second, while there will always be speculation about whether an adequate label would have been read, the user, alive and able to testify at trial, might have the burden of explaining why he would have read an adequate label. For example, plaintiff might testify that, had the label contained a prominent "WARNING" or "DANGER," he probably would have seen and read the warning. The jury would then determine how much credibility to extend to the plaintiff and what weight to give his testimony. Finally, it seems entirely logical to conclude that proof that inadequate directions were the cause of plaintiff's injuries "should . . . be required as it is in other cases." Again, the one person most competent to offer that proof would be the injured but availa-

126. Id. at 603-04, 606. Jacobs had first testified that he was preparing to read the directions when the explosion occurred. When confronted by eyewitness testimony to the contrary, however, he admitted that he was probably wrong about his original version of the facts.

127. Id. at 606.

128. Id. at 603.

129. Id. at 606.

130. See supra note 126 and accompanying text.

131. See supra text accompanying note 129.
ble victim.

What about the rebuttable presumption applied in *Reyes* and evoked by *Jacobs*? Immediately following the excerpt quoted above, the *Jacobs* court wrote that “[i]t has been suggested that the law should supply the presumption that an adequate warning would have been read.”\(^{132}\) In support of this reasoning the court immediately quoted section 402A comment j of the Restatement (Second) of Torts: “Where warning is given, the seller may reasonably assume that it will be read and heeded[.]”\(^{133}\) I am not sure, however, that “assumption” and “presumption” are synonymous.\(^{134}\) More significantly, the language of comment j speaks to the situation where an adequate warning was provided.\(^{135}\) In *Jacobs*, there was no adequate warning. This would suggest that both comment j and the court’s language were mere dicta.

The court additionally cited a Note that had been written in response to the intermediate appellate court’s opinion in *Jacobs*, after the Supreme Court of Texas had granted review but before it decided the case,\(^{136}\) which suggests that, in failure-to-warn cases, a “presumption of causation . . . might be a better vehicle for minimizing problems of proof.”\(^{137}\) One of the problems contemplated in the Note was the situation where the victim is “unable to testify because of death or injury.”\(^{138}\) It has been noted that that problem did not exist in *Jacobs*, and that, where it does exist, the plaintiff would have an appropriate explanation for the absence of direct testimony from the victim.\(^{139}\) The Note states that, under the suggested presumption, “[s]ince the jury would presume that a truly adequate conspicuous enough to attract the user’s attention, the plaintiff would not be required to testify that he would have acted differently if a warning had been given.\(^{140}\)

\(^{132}\) 480 S.W.2d at 606 (emphasis added).

\(^{133}\) *RESTATEMENT* (SECOND) OF TORTS § 402A comment j (1965) (emphasis added).

\(^{134}\) “Assumption” is not a word of legal art. Consequently, “assumption” could be intended to mean a permissible inference, a rebuttable presumption, or a conclusive presumption. Where adequate warning to prevent injury is given, and “the seller may reasonably assume that it will be read and heeded,” it may well be that the “assumption” becomes a conclusive presumption precluding liability as a matter of law.

\(^{135}\) *RESTATEMENT* (SECOND) OF TORTS § 402A comment j (1965).


\(^{137}\) *Id.* at 581.

\(^{138}\) *Id.*

\(^{139}\) See supra text accompanying notes 129-30.

\(^{140}\) Note, *supra* note 136, at 581 (footnote omitted).
But if the victim is alive and able to testify at trial, why should he not be required to so testify? If the reason is that such testimony would be inherently incredible, it should not be supplanted by a rebuttable presumption of the same unbelievable conclusion. If it is counsel's desire to achieve a tactical advantage by sparing plaintiff from giving testimony that will adversely affect his general credibility, such an edge should not be granted by a rebuttable presumption that would equally strain credulity. If the answer is counsel's oversight, it would be a novel proposition to reward such oversight with a favorable rebuttable presumption. Finally, it should be mentioned that the opinion which prompted the Note was reversed by the Texas Supreme Court, to the extent that the intermediate court would have entered judgment for the plaintiff despite his own testimony that he had not read the directions.\footnote{1}

In its opinion, however, the Texas Supreme Court noted that the presumption that an adequate warning would have been read favors the manufacturer.\footnote{2} In Jacobs, where there was no warning, the presumption would work in favor of the plaintiff,\footnote{3} but could be rebutted by the manufacturer, who could demonstrate that a warning would not have been heeded.\footnote{4} When an adequate warning is given, there is a rational basis for giving the manufacturer the benefit of such an "assumption" (the language of comment j) or "presumption" (the court's language): the manufacturer has no readily available method of proving that the user read the warning. But the court would also apply a similar presumption to a case where no adequate warning is given. In that situation, the user will not need the benefit of such a presumption. If he is alive and able to testify at the trial, he can either say that because he read the instructions provided he would have read an adequate warning had one been included, or that, although he did not read the instructions, he would have read a conspicuously marked "WARNING."

In effect, what the court did was to convert the comment j "assumption" into a rebuttable presumption which could be applied both for the benefit of the manufacturer (when an adequate warning is given and the manufacturer cannot demonstrate that the user read it), and also for the benefit of the user (where no adequate warning

\footnote{1} Jacobs, 480 S.W.2d at 606.  
\footnote{2} Id.  
\footnote{3} Id.  
\footnote{4} Id. The manufacturer might produce evidence, for example, that the user was blind, illiterate, intoxicated, irresponsible, or lax in judgment. Id.
is given and the user can testify that he would have read one if it were provided). The court not only suggested such a rebuttable presumption in the latter situation, but also imposed one in *Jacobs*.

Although the Texas Supreme Court reversed that portion of the intermediate appellate court's opinion which would have directed a judgment for the plaintiff, it affirmed the "alternative holding" of the intermediate court that "the jury's refusal to find for Jacobs on the causation issue was against the great weight and preponderance of the evidence." How could a jury finding that defendant's failure to warn was not "a producing cause" of the plaintiff's injuries be against the weight of the evidence, given plaintiff's own testimony that he had not read the instructions and the absence of testimony that he would have read an adequate warning? The only answer is the court's application of a rebuttable presumption favoring the plaintiff.

*Jacobs*, then, was the primary source of the rebuttable presumption applied by the Fifth Circuit in *Reyes*. As previously indicated, that presumption in *Jacobs* was fashioned from comment j's "assumption." Since *Reyes* was a diversity case applying Texas law, it is understandable that the Fifth Circuit, in compliance with its *Erie* obligation, would apply the holding of the Texas Supreme Court in *Jacobs*. Consequently, even though the minor's mother in *Reyes* failed to testify that she would not have consented if apprised of the risk, she became the beneficiary of a rebuttable presumption which cured the defect.

In a lack of informed consent case where the victim is unable to testify at trial, the absence of testimony explicitly negating consent

145. 480 S.W.2d at 606. It seems to have been such a rebuttable presumption that led the Texas Supreme Court to "remand the cause to the trial court in accord with the alternative holding of the intermediate court [that the jury's refusal to find for Jacobs on the causation issue was against the great weight and preponderance of the evidence.]" *Id.*

146. *Id.*

147. *Id.* Apparently, the Fifth Circuit in *Reyes* was incorrect in reading the *Jacobs* opinion as "affirming the trial verdict [for the defendant]." 498 F.2d at 1281. Moreover, what the Fifth Circuit in *Reyes* had characterized as crucial dicta in *Jacobs* was, in fact, the holding of the Texas Supreme Court. *Jacobs* rebuttable presumption that the user would have read an adequate warning had one been given was subsequently applied in Blackwell Burner Co. v. Cerda, 644 S.W.2d 512, 516 (Tex. Ct. App. 1982), and Webb v. Rodgers Machinery Mfg. Co., 750 F.2d 368, 373 (5th Cir. 1985) (diversity case to which Texas law applied). The *Jacobs* presumption was adopted in Nissen Trampoline Co. v. Terre Haute First Nat'l Bank, 332 N.E.2d 820, 826 (Ind. Ct. App. 1975), rev'd on other grounds, 265 Ind. 457, 358 N.E.2d 974 (1976).

148. 498 F.2d at 1281.

should not destroy the plaintiff's case. As long as plaintiff presents other evidence from which a reasonable jury could conclude that the victim would not have consented, his case should be deemed legally sufficient.

If the lack of informed consent arises out of a doctor-patient relationship, it may be appropriate to afford the plaintiff even greater assistance where he is unable to testify at trial. Quite a few years ago, I suggested that where "patient dies during or shortly after and as a result of the therapeutic procedure utilized, the burden of presenting evidence of an informed consent should be on the physician and that burden should not be deemed satisfied by the uncorroborated testimony of the physician." It seems to me that such a rule would encourage physicians to create and record evidence of patients' informed consent and would, in the process, also sensitize physicians to the importance of "assuring adequate disclosures which are properly comprehended by their patients." Given the personal contact between physician and patient, the physician certainly has the opportunity to do just that.

My suggestion was limited to "shifting the burden of adducing evidence . . . [by] retain[ing] the usual burden of persuasion imposed on the plaintiff, once defendant physician has presented appropriate evidence of patient's informed consent." Such a rule might be extended to apply in any case where patient is unable to testify at trial. The doctor-patient relationship affords physicians a meaningful opportunity to secure patients' informed consent in an appropriate manner, and I believe they should be encouraged to utilize that opportunity. Where a patient is unavailable as a witness at trial, the need for shifting the burden of presentation is apparent.

In Reyes, the defendant did have the opportunity to secure an informed consent from plaintiff's mother. Inasmuch as the State of Texas had Mrs. Reyes sign a release form before administering the

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150. The standard in those jurisdictions applying an objective test is a reasonable person in like circumstances. Evidence of lack of consent might consist of the statistical likelihood of the undisclosed risk, the gravity of the risk when it does eventuate, available alternatives, and the degree of necessity of the proposed treatment or product use. In effect, this was the kind of evidence that led the district court in Hartke to find evidence "from which the jury could find that plaintiff would have declined the procedure had she been informed of the risks." 526 F. Supp. 97, 103 (D.D.C. 1981), aff'd, 707 F.2d 1544 (D.C. Cir.), cert. denied, 464 U.S. 983 (1983).

151. Seidelson, supra note 7, at 345.

152. Id.

153. Id. at 347.
LACK OF INFORMED CONSENT

Sabin vaccine to plaintiff, 154 Wyeth Laboratories could also have included a comprehensible form setting forth the known risks involved in the ingestion of the vaccine. 155 Given Wyeth's knowledge, actual or constructive, that its vaccine was to be administered to minors outside a private doctor-patient relationship, an informed consent form to be signed by the children's parents would have been desirable. A copy of such a form bearing Mrs. Reyes' signature would have provided Wyeth with subsisting evidence of an informed consent.

Given defendant's failure to provide such a form, should the initial burden of presenting evidence of informed consent be shifted to the defendant? In Reyes, plaintiff's mother was alive and able to testify at trial that she would have withheld consent if informed of the risk. Under such circumstances, there seems to be no urgent policy reason for shifting the burden of presentation from the plaintiff to the defendant.

In Jacobs, where plaintiff was injured by an exploding can of freon, there was no justification for shifting the burden of production because the injury-producing product was never intended for use in a doctor-patient relationship, the manufacturer had no meaningful opportunity to secure an informed consent from the user, and plaintiff was alive and able to testify at trial. Therefore, both the Texas Supreme Court in Jacobs and the Fifth Circuit in Reyes gave plaintiffs the benefit of an unnecessary and seemingly inappropriate rebuttable presumption.

In Hartke, where there had been a private doctor-patient relationship and plaintiff was available to testify at trial, the court effected a change in prior law by concluding that it is unnecessary for a jury to determine whether the actual patient, adequately informed by the physician, would have consented. In none of these cases did the plaintiffs need either a rebuttable presumption negating consent or a legal conclusion making their responses to adequate disclosure superfluous. In each case, plaintiff (or, in Reyes, plaintiff's mother) was available at trial to offer direct testimony as to how he or she

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154. 498 F.2d at 1270.
155. "Mrs. Reyes ha[d] a seventh grade education, but her primary language [was] Spanish." Id. Given the facts surrounding the sale of the vaccine from Wyeth to the Texas State Department of Health, Wyeth could have contemplated the need for a warning form that was readily comprehensible to both English- and Spanish-speaking lay users. The argument that a product warning should be presented in symbols in order to be comprehensible by illiterate foreseeable users was made in Campos v. Firestone Tire & Rubber Co., 98 N.J. 198, 208-09, 485 A.2d 305, 310 (1984).
would have reacted to an adequate disclosure.

It could be argued that favoring the plaintiff at trial with a rebuttable presumption is consistent with the theory of placing the economic loss on the party with the deeper pocket. But if trial procedure must be manipulated to accomplish that purpose, why bother with any element of plaintiff’s case other than the fact that plaintiff was injured after utilizing defendant’s product or service and, therefore, defendant should pay? So doing would effectively shift the economic burden to the party with the deeper pocket, making such parties into insurers of their own goods and services. Since neither product liability law nor the law of informed consent was intended to make the defendant an insurer, however, it seems inappropriate to strive toward that result by reallocating the burden of production at trial.

Alternatively, one could argue that so favoring the plaintiff at trial would encourage both manufacturers and physicians to provide product users and patients with adequate disclosures. Certainly this is a goal of both product liability law and the law of informed consent, but is the plaintiff-favoring allocation of proof at trial an appropriate way of achieving that result? The only type of case in which the product user or patient needs relief from the minimal burden of testifying that he would have acted differently if adequately informed, is that where he is unavailable as a witness at trial.

There are at least two ways of resolving this problem. One would be to leave the burden of production on the plaintiff, but allow it to be satisfied by any relevant evidence sufficient to justify a jury finding that, adequately informed, the victim would have acted differently. The other solution would be to shift the burden of production to the defendant. Which is preferable? The former provides adequate amelioration of the plaintiff’s problem without unduly imposing on the defendant, while the latter appears to be an undue imposition on the defendant in those cases where defendant had no

156. Even the Reyes court noted that “Texas courts may hold manufacturers of products which harm consumers liable for the injuries, but, of course, manufacturers are not insurers.” 498 F.2d at 1271. Under Restatement (Second) of Torts § 402A, although negligence is not a condition precedent to liability, the seller’s product must be “defective and unreasonably dangerous” and the plaintiff’s injury must have been occasioned by that product defect. Restatement (Second) of Torts § 402A (1965). In a lack of informed consent case against a physician, a negligent disclosure by the defendant and a cause-and-effect relationship between such negligence and patient’s injury are conditions precedent to liability. “A physician is not a guarantor of either a correct diagnosis or a successful course of treatment.” Young v. Park, 417 A.2d 889, 893 (R.I. 1980), cert. denied, 449 U.S. 1119 (1981).
157. See supra note 150.
opportunity to secure the victim's informed consent.

Consequently, I believe the former solution is more appropriate in situations where defendant had no opportunity to secure subsisting evidence of an informed consent. Where such an opportunity existed, and victim is unavailable at trial, shifting the burden of production to the defendant does not seem to be an undue imposition. Since no potential defendant can ever predict with certainty whether or not his potential victim will be available at trial, all such potential defendants will be encouraged to provide adequate disclosure and to secure a memorialized consent wherever the opportunity to do so exists. The goal of encouraging the defendant to provide an adequate disclosure would therefore be accomplished without shifting the burden of production onto the defendant in those cases where the victim is available at trial.

III. CONCLUSION

In those medical malpractice and product liability cases in which the theory of liability is lack of informed consent, the victim should be required to testify that, adequately informed, he would not have acquiesced in the proposed therapy or contemplated use of the product. Without such testimony, plaintiff's case must fail as a matter of law. In those cases where the victim is unavailable at trial, and the defendant had no opportunity to secure an informed consent from him, plaintiff should retain the burden of producing evidence that, adequately informed, victim would have acted differently, but the burden should be satisfied by any relevant evidence that could lead a reasonable jury to such a conclusion. In cases where the victim is unavailable at trial and defendant did have the opportunity to secure a memorialized informed consent, the burden of producing evidence negating consent should be lifted from the plaintiff, and the burden of producing evidence of an informed consent should be shifted to the defendant. In each case, the burden of ultimate persuasion should remain on the plaintiff.

These conclusions are, I believe, consistent with the policy considerations underlying the substantive law, and both fair and even-handed with regard to the litigants.