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Casenotes: Torts — Medical Malpractice — Court of Appeals of Maryland Adopts Doctrine of Informed Consent. Sard v. Hardy, 281 Md. 432, 379 A.2d 1014 (1977)

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CASENOTES

TORTS — MEDICAL MALPRACTICE — COURT OF APPEALS OF MARYLAND ADOPTS DOCTRINE OF INFORMED CONSENT. *SARD v. HARDY*, 281 Md. 432, 379 A.2d 1014 (1977).

Maryland has long recognized that a physician treating a mentally competent patient in a non-emergency situation must obtain the patient's consent prior to undertaking any treatment.[1] In *Sard v. Hardy*,[2] the Court of Appeals of Maryland expressly adopted[3] the doctrine of informed consent as a theory of recovery for medical malpractice, even in the absence of negligent performance.[4]

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1. *See* McLees v. Cohen, 158 Md. 60, 62-63, 148 A. 124, 126 (1930); Powell, *Consent to Operative Procedures*, 21 MD. L. REV. 189 (1961).
2. 281 Md. 432, 379 A.2d 1014 (1977).
3. The informed consent principle was tacitly recognized by the court of appeals in Kruszewski v. Holtz, 265 Md. 434, 290 A.2d 535 (1972). That case was decided on purely procedural grounds, and the court was not called upon to determine the very existence of the informed consent doctrine in Maryland. The plaintiff alleged that the defendant-physician had failed to inform her adequately of the inherent risks in, and the alternatives to, a hysterectomy. The court of appeals limited its holding to finding that the form of hypothetical questions addressed to the defendant's expert witness, which sought to establish the applicable standard of care for the defendant's medical community, were proper since they were based upon either uncontradicted facts or assumptions of certain facts as true. *Id.* at 444-45, 290 A.2d at 540.
4. 281 Md. at 439, 379 A.2d at 1019. The informed consent doctrine is rooted in the principle of law aptly stated by Justice Cardozo, that

   > [e]very human being of adult years and sound mind has a right to determine what shall be done with his own body; and a surgeon who performs an operation without his patient's consent, commits an assault, for which he is liable in damages. This is true except in cases of emergency where the patient is unconscious and where it is necessary to operate before consent can be obtained.

   Schloendorff v. Society of New York Hospital, 211 N.Y. 125, 129-30, 105 N.E. 92, 93 (1914).

   Shortly after the *Schloendorff* decision, courts began to rule that a patient's consent to a proposed course of treatment was valid only to the extent the patient was informed by the physician as to what was to be done, the risk involved, and the alternatives to the proposed treatment. *Cf.* Hunter v. Burroughs, 123 Va. 113, 96 S.E. 360 (1918). In *Hunter*, the Virginia court found sufficient evidence of negligent treatment to support a jury verdict in favor of the plaintiff, but discussed, in dicta, the physician's failure to disclose the risks inherent in x-ray therapy for eczema. *Id.* at 133-34, 96 S.E. at 366-67. The informed consent principle remained relatively dormant for a number of years.

   The last two decades, however, have yielded a flood of decisions and commentary on the informed consent issue. See cases collected in Annot., 79 A.L.R.2d 1028 (1961) and representative commentaries in McCoid, *The Care Required of Medical Practitioners*, 12 VAND. L. REV. 549 (1959); Myers, *Informed Consent in Medical Malpractice*, 55 CALIF. L. REV. 1396 (1967); Plante, *An Analysis of Informed Consent*, 36 FORDHAM L. REV. 639 (1968); Waltz and Schueneman, *Informed Consent to Therapy*, 64 NW. U.L. REV. 628 (1970); Note, *Informed Consent Liability*, 26 DRAKE L. REV. 696 (1976); Note, *Failure to Inform as Medical Malpractice*, 23 VAND. L. REV. 754 (1970). *See generally* A. HOLDER, MEDICAL MALPRACTICE LAW at 225-65 (2d ed. 1978).

   The court of appeals adopted the generally accepted informed consent rule:

   > [T]he doctrine of informed consent imposes on a physician, before he subjects his patient to medical treatment, the duty to explain the procedures to the patient and to warn him of any material risks or dangers inherent in or collateral to the therapy, so as to enable the

The court in *Sard* imposed upon physicians a duty to explain all contemplated procedures to the patient and to warn him of any material risks inherent in the proposed treatment prior to obtaining the patient's consent.[5]

This Casenote discusses the *Sard* decision, with particular emphasis on the practical application of the opinion to informed consent cases from both the patient's and physician's perspective. The court of appeals's delineation of the doctrine will be compared with the position adopted by other jurisdictions embracing the informed consent concept by analyzing three major areas of dispute: first, the scope of the physician's duty to warn his patient and the appropriate test for its measure; second, the role of expert testimony in the presentation of the plaintiff's and defendant's case; and finally, the appropriate test for determining causation between the physician's failure to disclose a particular risk and the injury claimed by his patient.

I. *SARD v. HARDY* — THE FACTUAL BACKGROUND

While pregnant with her second child, Katie Sard consulted Dr. Erving Hardy, a specialist in obstetrics and gynecology. Mrs. Sard's first pregnancy had been a difficult one, terminating in the premature Caesarean delivery of a stillborn child.[6] Her second pregnancy resulted in the Caesarean delivery of a healthy baby. When Mrs. Sard became pregnant for the third time, Dr. Hardy again supervised her prenatal care. In light of Mrs. Sard's prior medical difficulties during pregnancy and her assertion that she did not want any more children, the possibility of preventing future conception was discussed.[7] Dr. Hardy offered three options: steriliza-

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patient to make an intelligent and informed choice about whether or not to undergo such treatment.

281 Md. at 439, 379 A.2d at 1020.

5. 281 Md. at 433-34, 379 A.2d at 1022. The court also adopted the prevailing view that the physician's violation of this duty is properly cast as a tort action for negligence, as opposed to battery or assault. 281 Md. at 440 n.4, 379 A.2d at 1020 n.4 (citing Cobbs v. Grant, 8 Cal. 3d 229, 502 P.2d 1, 104 Cal. Rptr. 505 (1972)). *But see* Shetter v. Rochelle, 2 Ariz. App. 358, 409 P.2d 74 (1965), *modified on other grounds*, 2 Ariz. App. 607, 411 P.2d 45 (1966) (surgery performed without a patient's informed consent is a battery). For a discussion of the varying requirements under the two theories, see Plante, *An Analysis of Informed Consent*, 36 FORDHAM L. REV. 639 (1968).
6. 281 Md. at 435, 379 A.2d at 1017-18. Mrs. Sard suffered from a dangerous condition known as eclampsia, which is the occurrence of one or more convulsions in a patient with preeclampsia. Preeclampsia is the development of hypertension due to pregnancy. As a consequence, Mrs. Sard experienced a series of convulsions, which necessitated the premature Caesarean delivery of her child. *Id.*
7. 281 Md. at 436, 379 A.2d at 1018. Though Dr. Hardy denied at trial having warned Mrs. Sard that a future pregnancy might imperil her health, he did sign a consultant's report that stated in part, "[t]he patient has been personally examined by me and I feel that future pregnancies would endanger her life. Sterilization is recommended for the following [*sic*] reason." *Id.*

tion, oral contraception, or the use of an intrauterine device.[8] Mrs. Sard chose sterilization by means of a tubal ligation, to be done at the time of Caesarean section.[9]

Dr. Hardy failed to inform Mrs. Sard of the various methods of performing a tubal ligation and their respective failure rates.[10] The failure rates for the various tubal ligation procedures[11] ranged from two percent to less than .1 percent.[12] Dr. Hardy neglected to inform Mrs. Sard that the technique used had a two percent failure rate when performed at the time of Caesarean delivery and that its risks diminished significantly when performed at some time other than Caesarean birth.[13] Denied this information, Mrs. Sard signed a standard hospital consent form indicating her consent to the sterilization.[14]

Despite the performance of a tubal ligation in conjunction with the Caesarean delivery of her third child, Mrs. Sard became pregnant for a fourth time and delivered a healthy baby. Subsequently, Mrs. Sard brought suit alleging, *inter alia*,[15] that Dr. Hardy

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8. 281 Md. at 436, 379 A.2d at 1018. "Mrs. Sard's husband testified that [Dr. Hardy] never mentioned the possibility of vasectomy. Although unable to recall whether he had mentioned this alternative . . ., Dr. Hardy testified that generally it was his practice to do so." *Id.*
9. 281 Md. at 436, 379 A.2d at 1018.
10. "[Dr. Hardy] further testified that it was good medical practice for a physician merely to inform the patient of the fact that a tubal ligation was to be done without discussing the details of the surgical procedures necessary to accomplish sterilization." 281 Md. at 436-37, 379 A.2d at 1018. Dr. Hardy testified that the final choice as to which of the various techniques should be employed was generally made by the surgeon after incision and examination of the uterus. *Id.* at 437, 379 A.2d at 1018.
11. The evidence at trial indicated that there were essentially six methods employed in the United states to effectuate sterilization by tubal ligation: the Madlener and Pomeroy techniques, and the Irving, Uchida, Aldridge, and Erlich methods. 281 Md. at 437, 379 A.2d at 1018. The method used by Dr. Hardy on Mrs. Sard was the Madlener technique. *Id.*
12. *Id.* at 437, 379 A.2d at 1018.
13. *Id.* In fact, the failure rates for all of the tubal ligation procedures diminished dramatically when performed at some time other than Caesarean birth. *Id.*
14. *Id.* at 437-38, 379 A.2d at 1019. The consent form provided, in part: "I/We understand what is meant by sterilization and I/We understand that if this operation is successful, the above named patient will be unable in the future to produce children, but I/We understand that an operation intended to effect sterilization is not effective in all cases."

    The trial court, in directing a verdict in favor of Dr. Hardy, held that the informed consent issue was conclusively settled against Mrs. Sard, since, by signing the consent form, she had acknowledged her understanding that the sterilization procedure was not effective in all cases. The court of appeals, however, gave little effect to the consent form. Instead, the court relegated the issue to a footnote, and stated that the consent form issue must be governed by the same principles used in evaluating Mrs. Sard's informed consent claim generally. *Id.* at 438 n.3, 379 A.2d at 1019 n.3. Thus, the court continued, unless the patient was adequately apprised of the material risks and therapeutic alternatives, the written consent is just as ineffectual as an oral one.
15. The plaintiff's amended declaration set forth a total of eight causes of action based upon informed consent, negligence in the actual performance of the

had failed to adequately inform her about the alternative methods of performing a tubal ligation and the failure rates attendant in each. Mrs. Sard claimed that her consent to the operation was not informed and therefore ineffectual.[16] The trial court granted a directed verdict in favor of the defendant, Dr. Hardy, from which Mrs. Sard appealed.[17]

The court of special appeals adopted the doctrine of informed consent, stating that a physician is under a duty to make an adequate disclosure to his patient of substantial facts that would be material to the patient's decision whether to consent to a proposed operation.[18] In affirming the directed verdict, the court held, as a matter of law, that the two percent risk of failure inherent in the

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sterilization operation, and breach of express warranty. The negligence counts were not pursued by Sard on appeal.

Mrs. Sard's warranty claim relied upon assurances allegedly made by Dr. Hardy both before and after the operation. Sard testified that Dr. Hardy had affirmatively assured her before the operation that she would not be having any more children, 281 Md. at 437, 379 A.2d at 1018-19, and reassured her after the operation that she could engage in sexual intercourse without fear of future pregnancies. *Id.* at 452 n.6, 379 A.2d at 1026 n.6. The court of special appeals, in upholding the directed verdict on Mrs. Sard's warranty claim, held that "an alleged express warranty cannot be enforced unless, (1) it was made before the operation was performed, and was relied upon by the patient in contracting for the service, or (2) it was supported by a separate consideration." Sard v. Hardy, 34 Md. App. 217, 239, 367 A.2d 525, 537 (1976).

The court of appeals, in affirming the rule as formulated by the court of special appeals, agreed that proof of separate consideration is required only when the alleged warranty is made post-operatively. 281 Md. at 452, 379 A.2d at 1026. Since there was no evidence that Dr. Hardy received a separate consideration to support liability for the alleged post-operative warranty, the trial court properly directed a verdict in favor of the physician on that issue. 281 Md. at 452 n.6, 379 A.2d at 1026 n.6. When the warranty is made prior to the surgery or treatment, however, proof of separate consideration is not required, and the patient may recover in contract by proving breach of an express warranty. 281 Md. at 452, 379 A.2d at 1026-27 (citing Sullivan v. O'Connor, 363 Mass. 579, 296 N.E.2d 183 (1973); Guilmet v. Campbell, 385 Mich. 57, 67 n.1, 188 N.W.2d 601, 605 n.1 (1971)). *But see* Rogala v. Silva, 16 Ill. App. 3d 63, 65, 305 N.E.2d 571, 574 (1973) (any liability against a physician founded on breach of express warranty requires proof of separate consideration).

Though separate consideration was not required, Mrs. Sard could recover for breach of an express pre-operative warranty only upon clear and convincing evidence that Dr. Hardy did, in fact, make the alleged warranty. 281 Md. at 453, 379 A.2d at 1027. The court stressed that a physician is not an insurer of the success of his treatment and distinguished between a good faith prediction of a particular outcome and a guarantee that he will effect a given result. *Id.* at 451-52, 379 A.2d at 1026. In the instant case, the court held that the bald statement attributed to Dr. Hardy that Mrs. Sard would not have any more children after the operation did not rise to the level of a guarantee. *Id.* at 453-54, 379 A.2d at 1027. Instead, it was at best a mere hopeful expression of opinion or prediction of an expected result, and the trial court acted properly in directing a verdict for Dr. Hardy on the express warranty claims. *Id.* at 454, 379 A.2d at 1027.

16. 281 Md. at 435, 379 A.2d at 1017.
17. *See* text accompanying note 15 *supra*.
18. Sard v. Hardy, 34 Md. App. 217, 231, 367 A.2d 525, 533 (1976).

Madlener technique would not be material to a reasonable person in deciding whether to consent to sterilization.[19]

The court of appeals reversed, holding that sufficient evidence was presented to require a jury determination of whether the information withheld by Dr. Hardy was material to Mrs. Sard's consent.[20] The court defined a material risk as "one which a physician knows or ought to know would be significant to a reasonable person in the patient's position in deciding whether or not to submit to a particular medical treatment or procedure."[21] The court noted that evidence was presented indicating that Mrs. Sard was concerned about the possibility of serious damage to her health and the financial burden involved in raising another child.[22] In addition, Mrs. Sard testified that Dr. Hardy had affirmatively represented before the operation that she would not become pregnant after the sterilization. Given these facts, the court reasoned that a jury could have found that the projected failure rates for the various procedures would be significant to a reasonable person in Mrs. Sard's position in deciding whether to consent to a particular sterilization procedure.[23] Remanding the case for a new trial, the court of appeals provided specific guidelines for the conduct of future

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19. *Id.* at 234-35, 367 A.2d at 535. Judge Davidson, in her dissenting opinion, found that Mrs. Sard's primary concern was not having any more children. Viewing this evidence in the light most favorable to the plaintiff, Judge Davidson believed that this testimony supported the inference that had Mrs. Sard been told of the possibility of failure she would have rejected the operation. *Id.* at 253, 367 A.2d at 545 (Davidson, J., dissenting).
20. 281 Md. at 446, 379 A.2d at 1023.
21. *Id.* at 444, 379 A.2d at 1022. One potential source of confusion in the court's definition of materiality is the question of whether a physician is under a duty to disclose risks which he believes would be significant to the individual patient but which a reasonable patient would not consider significant. Such a situation may arise when the doctor and patient have enjoyed a long-term, professional relationship whereby the physician knows many of the individual, though unreasonable, concerns of his patient. The patient may, for example, be concerned about minor cosmetic damage in major surgery, which a reasonable patient in the position requiring such surgery would not consider important, in deciding whether to submit to the proposed treatment. It is not clear from the court of appeals's opinion whether "significant to a reasonable person in the patient's position" refers solely to those risks which all reasonable persons requiring a particular treatment would consider significant or instead, includes risks which would be significant only to a reasonable patient with a known individual concern.

    The better interpretation is that the physician is not under a duty to disclose those risks that are significant only to the individual patient. The *Sard* court implied as much by stating, "[o]nce the physician has ascertained the risks and alternatives, and has communicated this information to the patient, it is the patient's exclusive right to weigh these risks together with his individual subjective fears and hopes and to determine whether or not to place his body in the hands of the surgeon or physician." 281 Md. at 443, 379 A.2d at 1021. Purely individual predilictions, it would seem, are to be balanced against the risks by the patient, and not by the physician in deciding the materiality of a particular risk.
22. 281 Md. at 446, 379 A.2d at 1023.
23. *Id.*

medical practitioner of the same specialty would adhere to in the same or similar circumstances.[25]

II. THE PHYSICIAN'S DUTY TO DISCLOSE INFORMATION TO HIS PATIENT

In malpractice actions involving the negligent administration of treatment or negligent performance of a procedure, the physician's duty of care is based on a professional standard.[24] The doctor's duty is to conform to the standard of care that a reasonably competent medical practitioner of the same specialty would adhere to in the same or similar circumstances.[25]

Most of the early informed consent cases utilized the professional standard and held that the plaintiff must prove that the doctor departed from the accepted medical standards of disclosure.[26] Thus, the measure of liability in all medical malpractice cases was the same.

The justification generally offered for defining the physician's disclosure duty in terms of the professional standard was expressed by the Supreme Court of Missouri in *Aiken v. Clary*.[27] The *Aiken* court reasoned that the question of what risks should be disclosed by a physician necessarily demands consideration of the patient's overall health and mental state.[28] Since these factors involve the exercise of professional medical judgment, a failure to disclose risks becomes potentially compensable[29] only if a reasonable medical practitioner under the same or similar circumstances would have made the disclosure.[30] The plaintiff in *Aiken,* having failed to offer any evidence as to what a reasonably prudent physician would have

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24. "[While] the conduct of the average layman charged with negligence is evaluated in terms of the hypothetical conduct of a reasonably prudent person acting under the same or similar circumstances, the standard applied in medical malpractice cases must also take into account the specialized knowledge or skill of the defendant." Shilkret v. Annapolis Emergency Hospital Ass'n, 276 Md. 187, 190-91, 349 A.2d 245, 247 (1975). *See* W. PROSSER, *Torts* § 32 (4th ed. 1971); McCoid, *The Care Required of Medical Practitioners,* 12 VAND. L. REV. 549, 558 (1959).
25. Shilkret v. Annapolis Emergency Hospital Ass'n, 276 Md. 187, 191-92, 349 A.2d 245, 251 (1975); Blair v. Eblen, 461 S.W.2d 370, 372-73 (Ky. 1970). *See generally* RESTATEMENT (SECOND) OF TORTS § 299A (1965).
26. *See, e.g.,* Shetter v. Rochelle, 2 Ariz. App. 358, 409 P.2d 74 (1965), *modified on other grounds,* 2 Ariz. App. 607, 411 P.2d 45 (1966); Natanson v. Kline, 186 Kan. 393, 350 P.2d 1093, *reh. denied,* 187 Kan. 186, 354 P.2d 670 (1960); Roberts v. Young, 369 Mich. 133, 119 N.W.2d 627 (1963); Starnes v. Taylor, 272 N.C. 386, 158 S.E.2d 339 (1968).
27. 396 S.W.2d 668 (Mo. 1965) (physician failed to adequately disclose the risks inherent in the administration of insulin shock therapy).
28. *Id.* at 674.
29. The physician's breach of his disclosure duty results in liability only if the patient can establish that such a breach was the proximate cause of the injury suffered. *See* text accompanying notes 77-87 *infra.*
30. Aiken v. Clary, 396 S.W.2d 668, 674 (Mo. 1965).

disclosed to a patient about to undergo insulin shock therapy,[31] was foreclosed from recovery.

Similarly, in *Natanson v. Kline*,[32] the Supreme Court of Kansas adopted the professional standard of care, reasoning that such a standard adequately protects the patient's interests because of the medical profession's recognition of its obligation to maintain a high standard of professional care.[33] The court apparently assumed that the medical community as a whole would voluntarily disclose pertinent information to the patient, recognizing the patient's right of self-determination. Such total deference, as in *Natanson*, to the internal standards of the medical profession is subject to question.[34]

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31. *Id.*
32. 186 Kan. 393, 350 P.2d 1093, *reh. denied*, 187 Kan. 186, 354 P.2d 670 (1960).
33. *Id.* at 411, 350 P.2d at 1107.
34. The record before the *Natanson* court indicated that the defendant Kline made no disclosures to his patient whatsoever prior to the administration of radiation therapy. Natanson v. Kline, 186 Kan. at 410, 350 P.2d at 1106. The rule of law formulated by the court appears uniquely hybrid in nature:

> [The informed consent] rule in effect compels disclosure by the physician in order to assure that an informed consent of the patient is obtained. The duty of the physician to disclose, however, is limited to those disclosures which a reasonable medical practitioner would make under the same or similar circumstances. How the physician may best discharge his obligation to the patient . . . involves primarily a question of medical judgment. So long as the disclosure is sufficient to assure an informed consent, the physician's choice of plausible courses should not be called into question if it appears . . . that the physician was motivated only by the patient's best therapeutic interests and he proceeded as competent medical men would have done in a similar situation.

Id. at 409–10, 350 P.2d at 1106. Once a minimum level of disclosure is attained, the professional standard controls. This is difficult to reconcile with the court's assertion that the medical profession's internal standards adequately protect the patient, *Id.* at 411, 350 P.2d at 1107, since the medical standards may fail to meet the minimum level of disclosure. The court remanded for a new trial due to erroneous instructions and suggested a modified instruction that informs the jury that a physician has such discretion, as above indicated, "consistent with the full disclosure of facts necessary to assure an informed consent by the patient." *Id.* at 411, 350 P.2d at 1107.

On the defendant's motion for rehearing, the Supreme Court of Kansas rejected the contention that an absolute duty of disclosure had been imposed without regard to the disclosures that a reasonable medical practitioner would make under the same or similar circumstances. Natanson v. Kline, 187 Kan. 186, 354 P.2d 670 (1960). Instead, the court re-emphasized that Dr. Kline made no disclosures whatever in a non-emergency situation, and stated, "[o]n this state of the record Dr. Kline failed in his legal duty to make a reasonable disclosure to the appellant who was his patient *as a matter of law*." *Id.* at 189, 354 P.2d at 673 (emphasis in original). No expert testimony was required to show that Dr. Kline's failure was contrary to accepted medical practice. *Id.* The door was left ajar, however, by the court's concession that no disclosure may be justified where such practice, under given facts and circumstances, is established by expert testimony to be in accordance with that of a reasonable medical practitioner under the same or similar circumstances. *Id.* In sum, the court's position seems to be that no disclosure at all is presumptively negligent, but the presumption may be overcome where expert testimony establishes such a practice to be medically reasonable under the circumstances. The court has come back full circle to the

Other decisions have recognized that the standard of care formulated within a given profession may itself be inadequate and that blind adherence to the customary practice will not be sufficient to relieve a defendant from liability.[35]

Though still the majority rule,[36] the professional standard for determining the scope of the physician's duty to disclose risk information has come under increasing attack.[37] In *Sard,* the court of appeals aligned itself with a growing minority of jurisdictions that define the physician's duty in terms of a general standard of reasonableness measured by the materiality of the information to the patient.[38] Under this standard, whether the disclosure would have been made by a reasonably competent physician under the same or similar circumstances is not dispositive of the issue of

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original problem, that is, the patient's dilemma when the medical practice is to remain totally silent.

Further explanation of the Kansas position was forthcoming in Collins v. Meeker, 198 Kan. 390, 424 P.2d 488 (1967). The plaintiff alleged a failure on the part of two physicians, Dr. Meeker and Dr. Mastio, to inform Collins of the risks inherent in hernia operations performed a year apart. *Id.* at 392-93, 424 P.2d at 492. The court's application of *Natanson* to the two defendants clarified *Natanson's* scope, but left the patient's dilemma unsolved.

The record revealed that Dr. Meeker did not disclose the possible adverse effects that might follow a hernia operation. *Id.* at 397-98, 424 P.2d at 495. Therefore, the court held, the plaintiff was not required to present expert evidence to establish a violation of Meeker's disclosure duty and reversed the summary judgment entered in favor of Meeker. *Id.* at 398, 424 P.2d at 495. Even though the plaintiff was relieved of the burden of showing, by expert evidence, that his doctor's silence deviated from acceptable medical practice, there was nothing in the *Natanson* rule that precluded the doctor from showing that his silence did in fact comply with medical standards under the facts then facing him. *Id.* at 397, 424 P.2d at 494-95.

As to the defendant Mastio, there was uncontradicted evidence that some risk disclosure was made. *Id.* at 398, 424 P.2d at 495. Since the disclosures would have to be ascertained by the trier of fact, *Natanson* required expert medical testimony to establish that the disclosures made did not accord with those which reasonable medical practitioners would divulge under the same or like circumstances. *Id.*

35. *See, e.g.,* Incollingo v. Ewing, 444 Pa. 263, 299, 282 A.2d 206, 217 (1971). In an action for the negligent administration of antibiotic drugs, the court quoted Justice Holmes: "What usually is done may be evidence of what ought to be done, but what ought to be done is fixed by a standard of reasonable prudence, whether it is usually complied with or not." Texas and Pacific Ry. Co. v. Behymer, 189 U.S. 468, 470 (1903).
36. *See* Note, *Informed Consent Liability,* 26 DRAKE L. REV. 696, 702-04 (1976), and accompanying footnotes for a collection of majority and minority view cases.
37. The most universally voiced criticism of the professional standard is that it endows the medical profession with virtually absolute discretion in fixing the standard for adequate disclosure. The Supreme Court of California has found this discretion "irreconcilable with the basic right of the patient to make the ultimate informed decision regarding the course of treatment to which he knowledgeably consents to be subjected." Cobbs v. Grant, 8 Cal. 3d 229, 243, 502 P.2d 1, 10, 104 Cal. Rptr. 505, 514 (1972). *See* Myers, *Informed Consent in Medical Malpractice,* 55 CALIF. L. REV. 1396, 1404 (1967); Note, 75 HARV. L. REV. 1445, 1447 (1962).
38. 281 Md. at 443-44, 379 A.2d at 1022.

liability.[39] Instead, the physician's duty to disclose is based upon what the patient needs to know in order to make an intelligent decision concerning proposed treatment.[40]

The trend toward defining a physician's duty to disclose by considering the patient's "need to know" was hastened by several influential 1972 decisions.[41] In *Canterbury v. Spence*,[42] for example, a physician failed to warn his patient of the one percent risk of paralysis in a laminectomy, a surgical procedure utilized to correct a ruptured disc. The Court of Appeals for the District of Columbia conceded that a physician's departure from professional custom may, like any other departure from prevailing medical practice, give rise to liability, but found that a cause of action under the informed consent doctrine is not dependent upon the existence and nonperformance of a professional custom.[43] While recognizing that the physician's professional expertise may make the appropriate course of action obvious to him, the court stated, "it is the prerogative of the patient, not the physician, to determine for himself the direction in which his interests seem to lie."[44] The court further reasoned that the duty to disclose "arises from phenomena apart from medical custom and practice, [thus a] definition of scope in terms purely of a professional standard is at odds with the patient's prerogative to decide on projected therapy himself."[45] Accordingly, the *Canterbury* court adopted a reasonable man standard, holding that the physician is obligated to disclose those risks which may be material to the patient's decision concerning suggested treatment.[46] A risk was held to be material "when a reasonable person, in what the physician knows or should know to be the patient's position, would be likely to attach significance to the risk or cluster of risks in deciding whether or not to forego the proposed therapy."[47]

The court of special appeals followed the *Canterbury* analysis by defining the required scope of disclosure in terms of the information's materiality to the patient,[48] a position affirmed by the court of appeals.[49] Where the court of appeals disagreed was in the application of that standard to the facts of the *Sard* case. The court of special appeals failed to consider adequately the evidence presented at trial concerning the alternative methods of performing a

39. *Id.*
40. *Id.* at 442, 379 A.2d at 1021.
41. Cobbs v. Grant, 8 Cal. 3d 229, 502 P.2d 1, 104 Cal. Rptr. 505 (1972); Wilkinson v. Vesey, 110 R.I. 606, 295 A.2d 676 (1972); Canterbury v. Spence, 464 F.2d 772 (D.C. Cir.), *cert. denied*, 409 U.S. 1064 (1972).
42. 464 F.2d 772 (D.C. Cir.), *cert. denied*, 409 U.S. 1064 (1972).
43. *Id.* at 783.
44. *Id.* at 781.
45. *Id.* at 786.
46. *Id.* at 787.
47. *Id.*
48. Sard v. Hardy, 34 Md. App. 217, 231, 367 A.2d 525, 533 (1976).
49. Sard v. Hardy, 281 Md. 432, 445, 379 A.2d 1014, 1023 (1977).

tubal ligation that were available to Dr. Hardy and the failure rates for each. Instead, the court relied upon evidence showing that no physical harm came to Mrs. Sard and that the operation had a ninety-eight percent chance of success.[50] The court of special appeals emphasized the probability of success in the Madlener technique rather than the possibility of failure. On that basis, the court held, as a matter of law, that the withheld information was not material because a reasonable person would not have considered the two percent failure rate significant.[51]

The court of appeals, however, placed greater import on the evidence indicating that not only did Dr. Hardy neglect to inform Mrs. Sard of the failure potential in the Madlener technique, but that he also neglected to advise her of the available, alternative sterilization methods and their lower failure rates. If the Madlener technique had been the only means of performing a tubal ligation, the court of special appeals's position would have been more tenable. In such a case, a reasonable person with the objective of avoiding future pregnancy might not have found the one chance in fifty that the operation might fail significant.[52] Where more effective procedures are readily available, however, a reasonable person might have found the chances of success in each significant in deciding which procedure to select. The court of appeals's decision was based upon Dr. Hardy's nondisclosure of available alternatives. Because Dr. Hardy knew that Mrs. Sard's primary objective was to eliminate the possibility of future pregnancy, he should have recognized that a reasonable patient in that position would find the chances of success in various procedures significant to the patient's decision.

The materiality standard adopted in *Sard* is not without limits. "The physician need not deliver a 'lengthy polysyllabic discourse on all possible complications. A mini-course in medical science is not required.' "[53] Only those risks that are material to the informed decision of a reasonably prudent patient need be disclosed.[54] Even with this basic limitation on the physician's duty, the materiality test adopted in *Sard* is preferable to the professional standard of care. Under the materiality standard, due consideration is given to the self-determination interests of the patient[55] while still allowing for the exercise of valid medical judgment in deciding whether disclosure is warranted in a particular case. The court of appeals

50. Sard v. Hardy, 34 Md. App. at 234-35, 367 A.2d at 535.
51. *Id.*
52. This is assuming, of course, that the threshhold decision to submit to a tubal ligation of some type, as opposed to a vasectomy or oral contraceptives, was informed.
53. 281 Md. at 444, 379 A.2d at 1022 (quoting Cobbs v. Grant, 8 Cal. 3d 229, 244, 502 P.2d 1, 11, 104 Cal. Rptr. 505, 515 (1972)).
54. 281 Md. at 444, 379 A.2d at 1022.
55. *But cf.* Natanson v. Kline, 186 Kan. 393, 409, 350 P.2d 1093, 1106, *reh. denied*, 187 Kan. 186, 354 P.2d 670 (1960).

noted that, in certain circumstances, there would be exceptions to full disclosure. A qualified privilege to withhold material facts from the patient exists in a number of situations. Such a privilege exists where disclosure would have a detrimental physical or psychological effect,[56] in instances of the patient's mental disability or infancy,[57] or where the patient himself has suggested that such facts not be disclosed to him. The privilege also exists in cases of emergency[58] or where the material risk is an obvious feature of the proposed treatment.[59] Low incident risks which are inherent in common procedures and are commonly known to exist need not be disclosed by the attending physician. Finally, since the degree of medical knowledge is constantly expanding, the physician is not under a duty to disclose risks that would not have been known to him by the exercise of ordinary care.[60] These medical judgment considerations are matters of affirmative defense to be presented by the physician.[61]

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56. *Id.* There may be cases when full and total disclosure of risks could so alarm the patient that it would constitute bad medical practice. *Id.* at 406, 350 P.2d at 1103.
57. Sard v. Hardy, 281 Md. at 445, 379 A.2d at 1022.

    The procedure to be followed by physicians when a patient lacks the mental or physical capacity to give a legally valid informed consent is unclear. Under Maryland law, a person is presumed competent, even if institutionalized, MD. ANN. CODE art. 59, § 51 (1972) (civil rights of patients); art. 59A, § 35 (Supp. 1977) (civil rights of mentally retarded persons), unless after proper notice and hearing, he is judicially declared to have a mental disorder, MD. ANN. CODE art. 59, §§ 12, 13 (1972 & Supp. 1977) and a guardian is appointed MD. EST. & TRUSTS CODE ANN. § 13-704 (1974). Because of the delays often inherent in the judicial hearing process, physicians may be forced to obtain substitute consent from a patient's family rather than waiting for a judicial determination of competency.

    In an attempt to clarify the role of the physician, patient, patient's family, and substitute decision-maker, the Maryland General Assembly, in 1979, will consider a Health Care Procedures-Consent Bill. This bill, introduced in the 1977 session as Senate Bill 734, was debated and defeated on the Senate floor by a vote of 21 to 20. A key provision of the bill is the establishment of a state-wide system of Substitute Consent Review Boards that would make an initial determination of capacity to give informed consent and, when necessary, appoint an appropriate substitute decision-maker. The hope is that the Review Boards will expedite the appointment of necessary guardians and provide for more informed competency determinations.

    For an analysis of the Health Care Procedures-Consent Bill, see Shuger & Somerville, *The Informed Consent Dilemma: A Legislative Solution,* Summer 1978 MD. B.J. 25.
58. *Id.* These exceptions to the physician's disclosure duty are actually limits on the physician's general duty to obtain the patient's consent prior to treating his patient. If there is no need to obtain any consent, it is obvious that any risk disclosure would be superfluous. For consent exceptions, *see generally* Powell, *Consent to Operative Procedures,* 21 MD. L. REV. 189, 199-203, 207-18 (1961).
59. Sard v. Hardy, 281 Md. at 445, 379 A.2d at 1022. One example would be the risk of infection. *See* Roberts v. Young, 369 Mich. 133, 137-38, 119 N.W.2d 627, 629 (1963).
60. Sard v. Hardy, 281 Md. at 445, 379 A.2d at 1022-23. *See* Trogun v. Fruchtman, 58 Wis. 2d 569, 604, 207 N.W.2d 297, 315 (1973) (overwhelming evidence that reasonably competent physicians were unaware of the risk of hepatitis from the administration of the drug isoniazid hydrazate (INH) for treatment of an inactive TB condition).
61. Myers, *Informed Consent in Medical Malpractice,* 55 CALIF. L. REV. 1396, 1411-14 (1967).

The practical effect of the materiality test is that the plaintiff is not required to prove that prevailing medical practice justified nondisclosure.[62] Requiring the physician to present evidence of those medical considerations that may justify nondisclosure is preferable to requiring the patient to prove an essentially negative fact. Thus, under the *Sard* decision, the plaintiff is not required to prove what prevailing medical practice would have been in his case.

III. THE ROLE OF EXPERT TESTIMONY

The court of appeals's adoption of the materiality test for determining the physician's disclosure duty and the resultant allocation of the burden of production, "virtually dictates"[63] the role of expert testimony in an informed consent case. Unlike those states adhering to the professional standard,[64] the plaintiff in Maryland is not bound to produce expert evidence to prove that the defendant violated prevailing medical practice by failing to inform his patient of certain risks and treatment alternatives.[65] Expert evidence will, however, still play a crucial role in the successful presentation of the plaintiff's case.

The plaintiff generally must present evidence establishing the materiality of the withheld information to his consent.[66] This burden requires evidence demonstrating the nature of the risk inherent in the particular treatment and the frequency of its occurrence.[67] The materiality of information necessarily involves consideration of both the nature of its risk and its incidence. A minor risk, even though occurring relatively frequently, may not be material in light of a treatment's potential benefit.[68] Conversely, materiality is generally

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62. Requiring the physician to produce evidence justifying non-disclosure allows the plaintiff to avoid the potential of confronting a "conspiracy of silence" within the medical community. Cooper v. Roberts, 220 Pa. Super. Ct. 260, 267, 286 A.2d 647, 650 (1971).
63. 281 Md. at 446, 379 A.2d at 1023. *See generally* Annot., 52 A.L.R.3d 1084 (1973).
64. These states uniformly require expert testimony to establish the applicable standard of care. *See, e.g.,* Casey v. Penn, 45 Ill. App. 3d 573, 360 N.E.2d 93 (1977).
65. Sard v. Hardy, 281 Md. at 447, 379 A.2d at 1024.
66. *See, e.g.,* Beauvais v. Notre Dame Hospital, ___ R.I. ___, ___, 387 A.2d 689, 691-92 (1978). Unlike medical malpractice cases founded upon the negligent administration of treatment, the plaintiff in an informed consent action cannot rely on the common knowledge of jurors in order to establish materiality. Where the risk is so commonly known that expert testimony would not be required to establish materiality, the plaintiff can hardly claim that it was unknown to him. *Cf.* Thomas v. Corso, 265 Md. 84, 97-99, 288 A.2d 379, 387-88 (1972) (medical expert testimony may not be required where negligence is so obvious that common knowledge or experience of jurors is sufficient for them to recognize negligence from the facts).
67. Sard v. Hardy, 281 Md. at 448, 379 A.2d at 1024. *See generally* Mason v. Ellsworth, 3 Wash. App. 298, 310-14, 474 P.2d 909, 918-19 (1970).
68. Shetter v. Rochelle, 2 Ariz. App. 358, 409 P.2d 74 (1965), *modified on other grounds,* 2 Ariz. App. 607, 411 P.2d 45 (1966). The patient suffered hemorrhaging in his eye as a result of an operation for the removal of cataracts, an injury

established where the risk is one of grave and permanent damage, even though it occurs infrequently.[69] If the only risk is that the particular treatment proposed may not succeed, the incidence of that failure and its consequences must be established.[70] Some treatments may also involve risks that are collateral, rather than the mere risk of failure. In those cases, the probability of those risks ultimately materializing must be established by the plaintiff.[71] Finally, the existence of any nondisclosed alternative treatments, together with their collateral dangers and risk of failure, must be demonstrated by expert testimony.[72] This evidence concerning collateral risks, probabilities of failure, and treatment alternatives is within the exclusive domain of medical experts, but whether such expert testimony presents a material fact is to be determined by the "reasonable man" standard.[73]

Expert testimony may also be vital to the successful defense of an informed consent action. Whenever the exercise of appropriate medical judgment is relied upon by the defendant to justify nondisclosure, expert testimony is required to establish that, under the prevailing professional practice, nondisclosure was warranted.[74] Thus, expert evidence is required whenever the defendant seeks to justify his withholding of material information on the grounds of its harmful effect on the patient in order to establish the validity of those medical considerations.[75] Any of the other affirmative defenses available to the defendant, for example, incapacity or emergency, may also require expert evidence to establish the existence of

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occurring in 2-25 percent of such operations. The court stated, "[t]he risks of injury are not so great as to cause most reasonable persons to decline to have such a beneficial operation performed, one that has such a good chance of restoring the sight of a substantially nonfunctional eye to an eye capable of 20/20 vision without aid of a lens." *Id.* at 367, 409 P.2d at 83.

69. Cooper v. Roberts, 220 Pa. Super. Ct. 260, 263, 286 A.2d 647, 648 (1971) (.0004 percent risk of perforating the stomach during course of a gastroscopic examination).
70. Sard v. Hardy, 281 Md. at 448, 379 A.2d at 1024. *See also* Small v. Gifford Memorial Hospital, 133 Vt. 552, 554, 349 A.2d 703, 705 (1975).
71. Sard v. Hardy, 281 Md. at 448, 379 A.2d at 1024.
72. *Id.*
73. The court indicated that, upon remand, Mrs. Sard would be required to produce expert testimony to show the nature of the various methods of sterilization or birth control available in 1967, the nature of the specific operative procedures, if any, employed to effect sterilization by a particular method, the respective failure rates for each of the methods and procedures, both when performed at the time of Caesarean section and at other times, and the risk of harm to mother and child inherent in each available method or procedure. *Id. See also* Small v. Gifford Memorial Hospital, 133 Vt. at 554-55, 349 A.2d at 705.
74. Only medical experts can determine the validity of the physician's concern for the harmful effect disclosure might have on a patient or the incompetency of a patient to evaluate material information. "When medical judgment enters the picture and for that reason the special standard [of care] controls, prevailing medical practice must be given its just due." Canterbury v. Spence, 464 F.2d 772, 785 (D.C. Cir.), *cert. denied,* 409 U.S. 1064 (1972).
75. Sard v. Hardy, 281 Md. at 448, 379 A.2d at 1024.

medical considerations that foreclosed full disclosure. Proof of such compliance will not be conclusive under the *Sard* materiality test, as "it is still for the jury to decide whether adherence to the professional standard deprived the patient of his right of self-determination."[76]

IV. CAUSATION

In an informed consent action, the plaintiff must establish proximate cause between the defendant's nondisclosure of material information and the harm ultimately suffered by proving that "the reasonable man" would not have given his consent to the proposed treatment had a full and adequate disclosure been made at the time consent was originally given.[77] As the *Sard* court noted, there is still the question of whether causation should be judged by a purely subjective test — what the patient himself would have done had full disclosure been made, or an objective test — what a reasonable person in the patient's position would have done had he been fully informed.[78]

The subjective test is a distinct minority view.[79] A purely hypothetical test that ultimately turns on the credibility of a patient seeking to recover after suffering a most undesirable result puts the physician in jeopardy of the patient's hindsight and bitterness.[80] Thus, the court of appeals aligned itself with the majority of jurisdictions which view causation objectively.[81] Under the objective test, the crucial inquiry is whether a reasonable person in the patient's position would have withheld consent to the surgery or treatment had all material risks been disclosed.[82] The plaintiff's hindsight testimony as to what he would have done may be relevant, but it is not required nor is it dispositive of the causation issue.[83]

Few states have addressed in any detail the causation problems which may arise when the plaintiff is not reasonable. For example,

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76. *Id.* at 445, 379 A.2d at 1023.
77. *Id.* at 448-49, 379 A.2d at 1024 (citing Wilkinson v. Vesey, 110 R.I. 606, 628-29, 295 A.2d 676, 690 (1972)); Beauvais v. Notre Dame Hospital, ___ R.I. ___, ___, 387 A.2d 689, 692 (1978). This is really little more than an application of the "but for" rule, which comes as close to the essence of proximate cause as any concept. *See generally* RESTATEMENT (SECOND) TORTS § 432 (1965).
78. Sard v. Hardy, 281 Md. at 449, 379 A.2d at 1024-25.
79. Even those courts that deny recovery where the plaintiff fails to testify that he would have refused the treatment had full disclosure been made often make reference to the course of action to be expected of a reasonable person. *See* Shetter v. Rochelle, 2 Ariz. App. at 369, 409 P.2d at 83.
80. *See* Canterbury v. Spence, 464 F.2d at 790-91.
81. The court of special appeals intimated that Mrs. Sard's failure to testify that she would have refused the tubal ligation had all material risks been disclosed might have served as an alternative basis for upholding the directed verdict. Sard v. Hardy, 34 Md. App. at 234-35, 367 A.2d at 535.
82. Sard v. Hardy, 281 Md. at 450, 379 A.2d at 1025.
83. *Id.* For a similar analysis of the limited effect to be given the plaintiff's hindsight testimony, *see* Small v. Gifford Memorial Hospital, 133 Vt. 552, 558, 349 A.2d 703, 707 (1975).

although adopting the objective test for causation, the Supreme Court of Wisconsin recognized that a jury could find that a reasonable man, when apprised of the material risks involved, would have consented to the treatment even though the plaintiff would not have consented.[84] In such a case, the plaintiff is denied recovery under the objective test, notwithstanding the fact that the personal interest of the plaintiff's right to self-determination was infringed. The Wisconsin court held, however, that the objective test is on balance more fair in that while a jury may take the plaintiff's subjective feelings into account, it is not limited solely by that consideration.[85]

A more difficult problem is presented when a reasonable person in the patient's position would have refused the treatment had full disclosure been made, but the particular plaintiff would have consented nonetheless.[86] Presumably, under the objective standard, the causation requirement would be satisfied even though that patient's consent was not affected by his lack of information. The thrust of the objective standard is what the "reasonable man" would consent to in the same or similar circumstances; thus, under any circumstances, the defendant's burden of proof remains the same.[87]

As a practical matter, the plaintiff should testify in all informed consent cases that he would have refused the treatment had there been a complete disclosure of risks. Such testimony will still be relevant to the ultimate resolution of the causation issue under the objective test recognized by the court of appeals.[88] The defendant should be prepared to produce evidence indicating that a reasonable person would have consented to the therapy, given the potential benefits, even had all risks and alternatives been fully explained.

V. CONCLUSION

The court of appeals in *Sard* adopted a modern viewpoint of informed consent that attempts to balance the interests of both patient and physician. By defining the physician's duty to disclose

84. Scaria v. St. Paul Fire and Marine Ins. Co., 68 Wis. 2d 1, 14–15, 227 N.W.2d 647, 654–55 (1975).

85. *Id.*

86. The defendant may be able to demonstrate, for example, that the plaintiff has in the past submitted, after full disclosure, to operations with a greater risk and less potential benefit than the treatment at issue.

87. The plaintiff will not, of course, be able to testify that he personally would have refused the proposed treatment if the risk that ultimately materialized was death. This has been one source of criticism against the subjective causation test, as a plaintiff who dies or becomes severely incapacitated is foreclosed from recovery. Aiken v. Clary, 396 S.W.2d 668–76 (Mo. 1965).

The difficulty can be solved, however, by merely reallocating the burden of proof for the causation issue. The plaintiff, by demonstrating that a reasonable man would have refused the treatment, creates a presumption that he too would have personally withheld his consent.

88. Sard v. Hardy, 281 Md. at 450, 379 A.2d at 1025.

information in terms of its materiality to the patient, the patient's right to self-determination is fully realized. The physician is allowed to exercise some discretion in withholding material information when the medical considerations involved are important enough to override the patient's right to be informed. By adopting the objective test for determining causation, the court also strives to protect the physician from the hindsight credibility of his patient. The *Sard* decision is nonetheless a boon to the patient, and the medical community will certainly take small comfort from the court's limited concession to the exercise of medical expertise.

The express recognition of the informed consent doctrine in Maryland may result in a proliferation of medical malpractice cases, since the cause of action is completely independent from one based on negligence.[89] Conversely, a fully informed patient may well hesitate to undertake purely elective surgery, thereby resulting in a decrease of such treatments and a reduction in the incidence of malpractice claims.[90] In any event, the Court of Appeals of Maryland has given express recognition to Justice Cardozo's oft-quoted statement that "[e]very human being of adult years and sound mind has a right to determine what shall be done with his own body."[91]

John R. Penhallegon

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89. It still remains to be seen whether Maryland's rejection of the "locality rule" in traditional malpractice actions, wherein the plaintiff was required to establish the professional standard of care in the defendant-physician's own community, Shilkret v. Annapolis Emergency Hospital, 276 Md. 187, 349 A.2d 245 (1975), will cause an increase in malpractice litigation.
90. Myers, *Informed Consent in Medical Malpractice,* 55 CALIF. L. REV. 1396, 1418 (1967).
91. Sard v. Hardy, 281 Md. at 439, 379 A.2d at 1019 (quoting Schloendorff v. Society of New York Hospital, 211 N.Y. 125, 129, 105 N.E. 92, 93 (1914)).