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Defending the Informed Consent Case

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Defending the Informed Consent Case

Analyzing the Materiality of the Risk, Causation, and Expert Testimony Requirements

By William G. Cobb

A PATIENT'S physician should provide him or her with relevant and material information regarding the physician's proposed treatment. Disclosing information relating to patient treatment enables the patient to knowingly consent to – or to reject – the treatment that the health care provider is proposing. As Justice Cardozo stated in the often cited case of *Schloendorff v. Society of New York Hospital*, "every 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."[1]

Based upon the disclosure (or nondisclosure) of any risks attendant to such treatment, the issue ultimately becomes whether a reasonably prudent person in the patient's position (or, in certain jurisdictions, whether the patient him or herself) would have consented to the treatment or procedure in light of those risks. The failure to obtain consent for treatment was traditionally considered a battery[2] (or as Justice Cardozo characterized it, an assault). However, most jurisdictions now simply view the failure to address material risks of treatment with the patient as a form of malpractice described as "negligent nondisclosure."[3]

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The material information which should be discussed with the patient is that information which would be considered by the "reasonably prudent patient" as significant when evaluating whether to proceed with the treatment. Information or risks that the reasonably prudent patient knows and commonly appreciates are not material. There is no duty to disclose risks where the procedure is simple, the danger is remote, and it is commonly understood to be remote.[4] Conversely, some jurisdictions have held that where a procedure is inherently associated with a known risk of death or serious injury, the health care provider must disclose those risks and discuss the potential complications with the patient, regardless of how remote the risk may be.[5]

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[1] Schloendorff v. Society of New York Hosp., 105 N.E. 92, 93 (N.Y. 1914).

[2] *See, e.g.*, Bang v. Charles T. Miller Hosp., 88 N.W.2d 186, 190 (Minn. 1958).

[3] *See, e.g.*, Downer v. Veilleux, 322 A.2d 82, 89-90 (Me. 1974); *See* K.A.C. v. Benson, 527 N.W. 2d 553, 561 (Minn. 1995).

[4] "Disclosure is not required where the risk is either known to the patient or so obvious as to justify presumption of such knowledge. . ." Sard v. Hardy, 379 A.2d 1014, 1022 (Ma. 1977); *See also*, Cobbs v. Grant, 502 P.2d 1, 12 (Ca. 1972) ("if the procedure is simple and the danger remote and commonly appreciated to be remote.").

[5] Cobbs, 502 P.2d at 11.

Therefore, the first step in defending an informed consent case is ascertaining whether the non-disclosed risk was material. Expert testimony may be required to determine whether the risk was material, depending upon the jurisdiction where the case is filed. Almost every jurisdiction has embraced the concept that the patient should be informed of *material* risks. Jurisdictions part company on the issue of whether informed consent trials require expert testimony with respect to whether a health care provider under similar circumstances would have discussed those *material* risks with the patient.

Most of the cases interpreting the informed consent issue have arisen in the context of medical malpractice lawsuits. However, it appears that those jurisdictions which have considered the issue have applied the medical malpractice dogma to other health care professionals, such as chiropractors.[6] Defense practitioners should also be aware that the forum where the cause of action arose may have enacted specific state statutes governing the disclosure of information to a patient.[7]

There are two schools of thought for determining whether a material risk should have been discussed with the patient. One approach allows jurors without the assistance (or necessity) of expert testimony to place themselves "in the position of a patient and decide whether, under the circumstances, the patient should have been told of the risk."[8] This approach is referred to as the "material risk" or "patient oriented" standard, and it is based upon the concept that a patient should be adequately informed about risks prior to choosing to undergo a medical procedure.[9]

The other viewpoint on informed consent has been labeled the "professional standard" or the "physician oriented" standard. This approach requires expert testimony from a qualified health care provider who, based upon the standard in the appropriate scientific community, decides whether the information is material and should be disclosed to the patient.[10]

Defense practitioners must ascertain whether the forum jurisdiction embraces the "material risk" standard or the "professional physician oriented" standard, the latter of which requires expert testimony with respect to whether the health care provider should have disclosed any risks to the patient. In either category of jurisdictions, however, except in a few rare instances (such as where a surgeon neglected to remove a surgical instrument and failed to disclose this action with the patient[11]), expert testimony will be required to discuss the materiality, if any, of the risk. Risks which are "immaterial" as a matter of law

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[6] Bronneke v. Rutherford, 89 P.3d 40, 46 (Nev. 2004); Jones v. Malloy, 412 N.W.2d 837, 842 (Neb. 1987); Roberson v. Counselman, 686 P.2d 149 (Kan. 1984) [modified on other grounds by Delaney v. Cade, 873 P.2d 175, 185-86 (Kan. 1994)]; Hartfiel v. Owen, 618 S.W.2d 902 (Tex. Ct. App. 1981); Bakewell v. Kahle, 232 P.2d. 127 (Mont. 1951); Tschirhart v. Pethtel, 233 N.W.2d 93, 95 (Mich. App. 1975); Hannemann v. Bryson, 681 N.W.2d 561 (Wis. App. 2004) (Petition for Review Granted, 689 N.W.2d 55) (Wis. 2004).

[7] *See, e.g.,* NEV. REV. STAT. § 41A.110 and NEV. REV. STAT. § 449.710 (Patient Bill of Rights); *See,* ORE. REV. STAT. § 677.097 (statutory informed consent requirements applicable to physicians, surgeons, and podiatric physicians). WIS. STAT. § 448.30 (physicians required to inform patient of benefits and risks of treatment).

[8] Smith v. Shannon, 666 P.2d 351, 355 (Wash. 1993) (quoting from Miller v. Kennedy, 522 P.2d 852, 864 (Wash. App. 1974), aff'd, 530 P.2d 334, (Wash. 1975)).

[9] Bronneke, 89 P.3d at 42-43.

[10] *Id.*

[11] *See, e.g.,* Nixdorf v. Hicken, 612 P.2d 348, 352 (Utah 1980) (doctor lost needle inside a patient's body and failed to disclose it; medical expert testimony was unnecessary "because it is common knowledge that reasonable medical practitioners do not leave surgical instruments inside their patients' bodies and then keep it a secret.") Chadwick v. Nielsen, 763 P.2d 819, 821-22 (Utah Ap. 1988); Aiken v. Clary, 396 S.W.2d 668, 675 n.5 (Mo. 1965); *See also*, Malpractice Liability of Physicians, Surgeons, Anesthetists, or Dentists for Injury Resulting From Foreign Object Left In Patient, 10 ALR 3d 9 (1966).

will not need to be addressed with the patient.

The last step of the analysis pertains to causation. Defense practitioners must determine whether the jurisdiction applies a subjective or objective test with respect to whether the patient would not have consented to the procedure if he or she had have been informed of the risk. The second component of the causation test requires proof that the non-consensual procedure actually caused plaintiff's injuries.

I. The Two Approaches of Informed Consent

A. The Material Risk (Patient-Oriented) Standard

The patient-based standard of informed consent stresses the patient's right to self-determination and the fiduciary relationship between a doctor and a patient. This standard balances the patient's need for material information with a physician's discretion. It requires a physician to disclose material information to the patient even if the patient does not ask questions.[12]

The material risk standard was discussed in greater detail in *Woolley v. Henderson*, a 1980 Maine Supreme Court decision.[13] The Court analyzed the rationale behind the material risk standard in the following way:

> [A]n increasing number of courts hold that because a physician's obligation to disclose therapeutic risks and alternatives arises from the patient's right of physical self-determination, the disclosure duty should be measured by the patient's need for information rather than by the standards of the medical profession. These courts reason that physicians have a legal obligation adequately to disclose risk and option information that is material to the patient's decision to undergo treatment and that expert testimony as to medical standards is not required to establish this duty. Under this "material-risk" standard, although expert medical testimony may be necessary to establish the undisclosed risk as a known danger of the procedure, the jury can decide without the necessity of a medical expert whether a reasonable person in the patient's position would have considered the risk significant in making his decision.[14]

Under this approach, the nature of the risk associated with the treatment is brought to the jury's attention, usually through expert testimony. Even those jurisdictions which have adopted the material risk standard also embrace the concept that if a risk itself is not material, it need not be addressed with the patient.[15] Although expert testimony will not be received in these jurisdictions as to whether the risks should have been discussed with the patient, expert testimony will nevertheless be required to evaluate the materiality (or severity or significance) of the risk.

However, assuming the risk is material, or even assuming there is a dispute among experts as to the materiality of the risk, the jury without expert testimony will be allowed to determine whether the patient consented to the procedure with adequate knowledge. Without relying on what the standard may or may not be in the health care community, the jury is permitted in its own discretion to determine whether the health care provider should have disclosed such risks with the patient.

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[12] Canterbury v. Spence, 464 F.2d 772, 781-82 (D.C. Cir. 1972).

[13] 418 A.2d 1123 (Me. 1980).

[14] *Id.* at 1129 (citing, *inter alia*, Canterbury, 464 F.2d at 786-787 and Cobbs, 502 P.2d at 10-11 (Ca. 1972)). The Maine Supreme Court rejected the material risk standard and embraced the professional or physician oriented standard. Wooley, 418 A.2d at 1131.

[15] *See, e.g.,* Cobbs, 502 P.2d at 11.

The plaintiff then has the burden of going forward with evidence of nondisclosure. Once the plaintiff has established that the physician failed to address known material risks, then the physician typically bears the burden of submitting evidence to justify nondislosure or to show that a legally sufficient disclosure was made.[16]

Assuming the jury finds the risk was material and the physician failed to adequately address the risk of treatment, the next step in the material risk jurisdiction (as well as in a "professional standard" jurisdiction) is to determine whether the reasonably prudent patient (or in some jurisdictions, the plaintiff) would or would not have consented to that treatment.

B. The Professional Disclosure (Physician-Oriented) Standard

A small majority of jurisdictions has adopted the "professional disclosure" or "physician oriented" standard. Under this approach, as the Court of Appeals for South Carolina explained in *Hook v. Rothstein*, the physician "is required to disclose those risks which a reasonable medical practitioner of like training would disclose under the same or similar circumstances."[17] The *Hook* court went on to note that, "[i]n most cases, the questions of whether and to what extent a physician has a duty to disclose a particular risk are to be determined by expert testimony which establishes the physician's departure from that standard."[18]

The rationale for this approach is that an informed consent case is no different from any other malpractice action wherein a departure from the accepted standard of care must be established by expert testimony. As the Supreme Court of Missouri stated in *Aiken v. Clary*:

> The basic philosophy in malpractice cases is that the doctor is negligent by reason of the fact that he has failed to adhere to a standard of reasonable medical care, and that consequently the service rendered was substandard and negligent. In our judgment, this is true whether the alleged malpractice consists of improper care and treatment (the usual malpractice case) or whether it is based, as here, on an alleged failure to inform the patient sufficiently to enable him to make a judgment and give an informed consent if he concludes to accept the recommended treatment.[19]

The Missouri Supreme Court in *Aiken* explained both the rationale for the adoption of the professional standard and the manner and quantum of proof required to establish an informed consent case in a jurisdiction which employs the professional standard:

> We have . . . concluded that the question of what disclosure of risks incident to proposed treatment should be made in a particular situation involves medical judgment and that expert testimony thereon should be required in malpractice cases involving that issue. The question to be determined by the jury is whether defendant doctor in that particular situation failed to adhere to a standard of reasonable care. These are not matters of common knowledge or within the experience of laymen. Expert medical evidence thereon is just as necessary as is such testimony on the correctness of the handling in cases involving surgery or treatment.[20]

Citing from an earlier decision, *Aiken* noted that:

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[16] Cobbs, 502 P.2d at 12.

[17] 316 S.E.2d 690, 695 (Ct. App. S.C. 1984) (citing Woolley, 418 A.2d at 1123; Thomas v. Berrios, 348 So. 2d 905 (Fla. App. 1977)).

[18] Hook, 316 S.E.2d at 695 (citing Folger v. Corbett, 394 A.2d 63, 64 (N.H. 1978) and Bly v. Rhoads, 222 S.E.2d 783, 787 (Va. 1976)).

[19] Aiken v. Clary, 396 S.W.2d at 673-674 (Mo. 1965).

[20] *Id.* at 674.

> Without the aid of expert medical testimony in this case a jury could not, without resorting to conjecture and surmise or by setting up an arbitrary standard of their own, determine that defendants failed to exercise their skill and use the care exercised by the ordinarily skillful, careful and prudent physician acting under the same or similar circumstances.[21]

The *Aiken* decision recognized there are often many factors to consider, beyond mere statistics, when deciding whether to discuss with a patient those risks that are recognized to be associated with the treatment:

> The question is not what, regarding the risks involved, the juror would relate to the patient under the same or similar circumstances, or even what a reasonable *man* would relate, but what a reasonable *medical practitioner* would do. Such practitioner would consider the state of the patient's health, the condition of his heart and nervous system, his mental state, and would take into account, among other things, whether the risks involved were mere remote possibilities or something which occurred with some sort of frequency or regularity. This determination involves medical judgment as to whether disclosure of possible risks may have such an adverse effect on the patient as to jeopardize success of the proposed therapy, no matter how expertly performed. . .After a consideration of these and other proper factors, a reasonable medical practitioner, under some circumstances, would make full disclosure of all risks which had any reasonable likelihood of occurring, but in others the facts and circumstances would dictate a guarded or limited disclosure. In some cases the judgment would be less difficult than in others, but, in any event, it would be a medical judgment.[22]

The *Aiken* Court concluded that the plaintiff was required to "offer expert testimony to show what disclosures a reasonable medical practitioner, under the same or similar circumstances, would have made. . ."[23] In other words, the Court concluded that the "disclosures as made by the defendant do not meet the standard of what a reasonable medical practitioner would have disclosed under the same or similar circumstances."[24]

The Supreme Court of Maine also reviewed the rationale supporting the "professional standard" in its subsequent decision, *Woolley v. Henderson,* noting first that "whether the physician has acted unreasonably is often a question of professional judgment."[25] As the *Aiken* court discussed, *Woolley* similarly predicated its analysis on the fact that more than mere statistical risks of complications may drive the physician's decision.

The *Woolley* and *Aiken* decisions were predicated on the rationale that requiring a plaintiff to prove an informed consent claim with expert testimony imposes no greater burden on a plaintiff than it does in any other medical malpractice case where the plaintiff is required to establish a deviation from the accepted standard of care:

> Moreover, a rule that allows a plaintiff to establish the existence and extent of the defendant-physician's disclosure obligation without regard to medical standards hardly diminishes the importance of expert medical testimony or absolves the

[21] *Id.* (citing Fisher v. Wilkinson, 382 S.W.2d 627, 632 (Mo. 1964)).

[22] *Id.* at 674, 675 (emphasis in the original).

[23] *Id.* at 675.

[24] *Id.*

[25] Woolley, 418 A.2d at 1130-1132 (citations omitted).

> plaintiff from producing such evidence on other issues in the case. The courts that have adopted this rule recognize the necessity, in the usual case, of medical evidence to identify the known risks of treatment, the nature of available alternatives and the cause of any injury or disability suffered by the plaintiff and would allow the defendant to show by expert testimony that his conduct comported with medical standards. Furthermore, when the patient also claims negligent diagnosis or treatment, he will have secured medical experts to testify to the applicable standard of care. It certainly adds little to the burden of the plaintiff on his informed consent claim to require him to produce medical evidence that the physician's nondisclosure departed from prevailing standards of practice.[26]

The *Woolley* decision also contained an excellent discussion of the countervailing considerations that affect a physician's decision making process and that militate against the adopting the material risk standard. The Court noted that "rather than relying on his professional judgment, a physician practicing in a material-risk jurisdiction may well feel compelled at his peril to disclose every imaginable risk and alternative to treatment."[27]

Woolley continued its discussion by recognizing the practical implications of dispensing with expert medical testimony to establish the requisite disclosure duty in a case by noting that "[i]nherent in such a rule is the potential danger that a jury, composed of laymen and gifted with the benefit of hindsight, will divine the breach of a disclosure obligation largely on the basis of the unfortunate result."[28] The Court noted that the matters involved in these types of cases are often quite complicated and technical, and the risk of leaving these decisions to lay witnesses "would pose dangers and disadvantages which far outweigh the benefits and advantages a 'modern trend' rule would bestow on patient-plaintiffs. In effect, the relaxed "modern trend" rule permits lay witnesses to express, when all is said and done, what amounts to a medical opinion."[29] The Court concluded by pointing out that a patient's doctor, as well as his or her patient, would be jeopardized by a rule that would require discussions of every possible risk available to the patient.

Finally, we believe that legal principles designed to provide compensation to persons injured by bad professional practice should not unduly intrude upon the intimate physician-patient relationship. Although the "material-risk" theory may make it easier for some plaintiffs to recover, it does so by placing good medical practice in jeopardy. The physician's attention must be focused on the best interests of his patient and not on what a lay jury, unschooled in medicine, may, after the fact, conclude he should have disclosed. As a North Carolina court noted, (t)o adopt the ("material-risk" standard) would result in requiring every doctor to spend a great deal of unnecessary time in going over with every patient every possible effect of any proposed treatment. The doctor should not have to practice his profession with the knowledge that every consultation with every patient with respect to future treatment contains a potential lawsuit. This approach would necessarily result in the doctor's inability to give the best interest of his patient primary importance.[30]

Summarizing its holding, the Supreme Court of Maine stated "[w]e hold, therefore, that the scope of a physician's duty to disclose is measured by those communications a reasonable medical practitioner in that branch of medicine

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[26] *Id.* at 1130-31 (citations omitted).
[27] *Id.* at 1131 n.8 (citations omitted).
[28] *Id.* at 1131.
[29] *Id.*
[30] *Id.* (citing Butler v. Berkeley, 213 S.E.2d 571, 581 (N.C. App. 1975)).

would make under the same or similar circumstances and that the plaintiff must ordinarily establish this standard by expert medical evidence."[31]

Thus, there are two diametrically opposed approaches to informed consent cases. At the outset of the defense of an informed consent malpractice case, it is defense counsel's responsibility to ascertain whether the trial court will be governed by the material risk standard or the professional judgment standard. Following this article is an Appendix that identifies those jurisdictions that have ruled on informed consent cases and identifies which of the two standards the jurisdiction has adopted. The Appendix also reports whether the jurisdiction utilizes the objective or subjective approach on causation, which is discussed in greater detail in Section III.

II. Materiality of Risk

Courts agree that only those risks which are viewed as "material" must be disclosed, regardless of whether the forum embraces the patient/material risk or the professional/physician standard. However, what is or is not deemed "material" is not subject to a clear definition, as one of the leading informed consent cases, *Canterbury v. Spence*, noted:

> There is no bright line separating the significant from the insignificant; the answer in any case must abide by a rule of reason. Some dangers – infection, for example – are inherent in any operation; there is no obligation to communicate those of which persons of average sophistication are aware. Even more clearly, the physician bears no responsibility for discussion of hazards the patient has already discovered, or those having no apparent materiality to patients' decision on therapy. The disclosure doctrine, like others marking lines between permissible and impermissible behavior in medical practice, is in essence a requirement of conduct prudent under the circumstances. Whenever nondisclosure of particular risk information is open to debate by reasonable-minded men, the issue is for the finder of the facts.[32]

As the *Canterbury* language suggests, there is no clear cut definition of "materiality." Case law suggests that a risk which is not material as a matter of law, or is commonly understood to be obvious, or already known to the patient need not be addressed with the patient.[33] Risk has been found material where there is a 3% chance of death, paralysis, or other serious injury or where 1% chance of hearing loss was foreseeable.[34] On the other hand, a risk was not determined to be significant where there was only a 1.5% chance of the loss of an eye or a 0.001% chance of death.[35]

A risk is considered to be material when a reasonable person in the patient's position would likely attach significance to the potential risk in deciding whether or not to forego the treatment.[36] The first step in determining materiality requires expert testimony to define the existence and nature of the risk and the likelihood of its occurrence.[37] The second step is left to the trier of fact to ascertain whether or not the risk is the type of harm that a reasonable person in the patient's position would have considered in deciding whether to proceed with treatment.[38]

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[31] *Id.*

[32] Canterbury, 464 F.2d at 778.

[33] Hondroulis v. Schuhmacher, 553 So. 2d 398, 413 (La. 1988).

[34] Bowers v. Talmage, 159 So. 2d 888 (Fla. App. 1963); Scott v. Wilson, 396 S.W.2d 532 (Tex. Ct. App. 1965).

[35] Yeates v. Harms, 393 P.2d 982 (Kan. 1964); Pauscher v. Iowa Methodist Med. Ctr., 408 N.W.2d 355 (Iowa 1987).

[36] Canterbury, 464 F.2d at 787.

[37] Hondroulis, 553 So. 2d at 412.

[38] *Id.* at 403.

Some courts have held that all risks that could potentially effect the patient's decision must be disclosed.[39] However, materiality is a function of the severity of the risk and the probability of the risk. Thus, if the probability of the risk is extremely low, then the risk cannot be considered a material factor in a rational patient's decision.[40] "A patient has a right to know those hazards which a reasonably prudent person, in the patient's position, would probably attach significance to when deciding whether to undergo the treatment. If the risk meets this criterion, it is material and must be disclosed."[41]

In *Smith v. Shannon*, the Washington Supreme Court ruled that a physician's liability could not per se be predicated on the physician's failure to inform the patient of all risks involved with the patient's procedure, but rather, depended upon whether undisclosed risks were material. Witnesses described the risks that the Court held were not material and did not have to be discussed with the patient as remote, very rare, occasional, and not material.[42]

In *Pauscher v. Iowa Methodist Medical Center,* the Iowa Supreme Court similarly held that risks must be material in order to warrant disclosure. In *Pauscher,* the undisclosed risk was that the treatment carried a risk of death in one in 100,000 cases. The Court held that this risk was not deemed "materially significant," stating that "no prudent juror could reasonably have considered the [1 in 100,000] risk of permanent paresthesia material to a decision on whether to consent to the procedure."[43]

One of the leading "patient oriented" standard cases, *Cobbs v. Grant*, also embraced the concept that only material risks must be disclosed, stating that the "test for determining whether a potential peril must be divulged is its materiality to the patient's decision."[44] The court went on to state that "[s]uch a disclosure need not be made if the procedure is simple and the danger remote and commonly appreciated to be remote."[45]

The *Cobbs* decision was predicated in part on a civil jury instruction, which provides jurors with the following definitions regarding physicians' duties to disclose risks:

> [A] physician has a duty to disclose to the patient all material information to enable the patient to make an informed decision regarding the proposed operation or treatment.
>
> Material information is information which the physician knows or should know would be regarded as significant by a reasonable person in the patient's position when deciding to accept or reject a recommended medical procedure. To be material a fact must also be one which is not commonly appreciated.
>
> The physician does not have a duty to make disclosure of risks when the patient requests that [the patient] not be so informed or where the procedure is simple and the danger remote and commonly understood to be remote.
>
> Likewise, there is no duty to discuss minor risks inherent in common procedures, when those procedures very seldom result in serious ill effects.

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[39] Blazoski v. Cook, 787 A.2d 910, 917 (N.J. App. 2002), citing Largey v Rothman, 540 A.2d 504 (N.J. 1988).

[40] Feeley v. Baer, 679 N.E.2d 180, 181 (Mass. 1997).

[41] Villanueva v. Harrington, 906 P.2d 374, 376 (Wash. App. 1995).

[42] 666 P.2d 351 at 357 (Wash. 1983) (citations omitted).

[43] 408 N.W.2d 355, 361 (Iowa 1987) citing Henderson v Milobsky, 595 F.2d 654, 659 (D.C. Cir. 1978).

[44] Cobbs, 502 P.2d at 12.

[45] *Id.*

> However, when a procedure inherently involves a known risk of death or serious bodily harm, the physician has a duty to disclose to the patient the possibility of such an outcome and to explain, in lay terms, the complications that might possibly occur.[46]

Regrettably, the Book of Approved Jury Instruction ("BAJI") may create more confusion than it attempts to resolve. For example, the instruction above defines "material information" from the standpoint of what the "physician knows or should know" is "significant." This definition was taken, seemingly, from the D.C. Circuit's decision in *Canterbury* wherein the Court held:

> From these considerations we derive the breadth of the disclosure of risks legally to be required. The scope of the standard is not subjective as to either the physician or the patient; it remains objective with due regard for the patient's informational needs and with suitable leeway for the physician's situation. In broad outline, we agree that "[a] risk is thus 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]

Nevertheless, BAJI 6.11 suggests that California would be one of the jurisdictions which adheres to the "professional" standard and would require expert testimony to demonstrate what the physician should or should not know. However, California is a material risk jurisdiction where experts are not involved in the trial process other than in ascertaining whether the risk is material.[48]

Furthermore, the instruction commands that if the risk involves a chance of death or serious bodily harm, the physician must address it with the patient, apparently regardless of how remote that risk may be. If one interprets BAJI 6.11 in this fashion, then it carries particular implications to physicians practicing in California.

In the recent Nevada Supreme Court decision of *Bronneke v. Rutherford*, the Court addressed an informed consent claim arising from a chiropractic malpractice lawsuit. The Court discussed evidence submitted at trial regarding the risk of stroke being caused by a chiropractic adjustment. Plaintiff's expert in the *Bronneke* case testified that the correlation between a stroke and an adjustment is that the former occurs anywhere between one in every 400,000 adjustments to one in six million. The defendant chiropractor's expert stated the consensus in the chiropractic community was that a stroke would occur once in one million adjustments. This expert also testified that new studies showed the risk to be one in 5,850,000. Of these remote risks, the Nevada Supreme Court stated that "given the evidence in the record that risk of stroke is extremely remote following [an adjustment], a reasonable chiropractor would not have deemed the risk material enough to require disclosure."[49]

While there appears to be no dispute among the jurisdictions that a material risk must be disclosed to and addressed with the patient, defining whether a risk is or is not material is more problematic. If defense practitioners can establish that the risk was not material as a matter of law, then summary judgment may be available to the health care provider.

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[46] Book of Approved Jury Instructions ("BAJI") 6.11 (Vol. I, 9th Ed.).

[47] Canterbury, 464 F.2d at 787 (quoting, Waltz & Scheuneman, *Informed Consent to Therapy*, 64 N.W. U. L. REV. 628, 639-40 (1970).

[48] Cobbs, 502 P.2d at 11.

[49] Bronneke, 89 P.3d at 46.

III. Causation

The last step in the informed consent analysis is to determine whether the forum jurisdiction employs an objective or subjective test of causation. The objective test is generally described as whether a reasonably prudent person in the patient's position would have consented to the treatment had the risk been disclosed. The subjective test is one which determines whether the patient (i.e., the plaintiff) would have consented to the procedure after being informed of the risk.

The *Woolley* decision provides the rationale for Maine's adoption of the "objective test":

> The question we. . .address is whether this second causation requirement is to be judged by a subjective test - whether the particular plaintiff would have undergone the treatment had he been adequately informed – or by an objective test – whether a reasonable person in the plaintiff's position would have submitted to the procedure had there been adequate disclosure. (citations omitted). In the instant case, the presiding Justice instructed the jury, without objection, that it was to apply the objective causation standard.
>
> We believe that the subjective test is an unsatisfactory gauge for determining causality in informed consent actions and, therefore, in accord with those courts that have squarely addressed this issue, we hold that causation should be judged by an objective standard.[50]

The Maryland Supreme Court's decision in *Sard v. Hardy* persuasively summarized the rationale in support of the objective standard:

> [I]f a subjective standard were applied, the testimony of the plaintiff as to what he would have hypothetically done would be the controlling consideration. Thus, proof of causation under a subjective standard would ultimately turn on the credibility of the hindsight of a person seeking recovery after he had experienced a most undesirable result. (citation omitted) Such a test puts the physician in "jeopardy of the patient's hindsight and bitterness."[51]

Under the objective test, a causal connection exists between the defendant's failure to disclose and the plaintiff's injury only if a reasonable person in the position of the plaintiff would have declined the treatment had he been apprised of the risk that resulted in harm. "[T]he patient's hindsight testimony as to what he would have hypothetically done, though relevant, is not determinative of the issue."[52]

Despite the seemingly persuasive logic attendant to the adoption of the "objective" standard, nevertheless, there are several jurisdictions which hold that the "causation" issue must be resolved by plaintiff's testimony that had *he or she* been informed of the risks, *he or she* would not have consented to the procedure. The Rhode Island Supreme Court's decision in *Wilkinson v. Vessey* is an example of the subjective approach:

> In order to prevail in an action, where recovery is based upon the doctrine of informed consent, the plaintiff must prove that if he had been informed of the material risk, he would not have consented to the procedure and that he had been injured as a result of submitting to the procedure.[53]

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[50] Woolley, 418 A.2d at 1132 (citations omitted).

[51] Sard, 379 A.2d at 1025. (citations omitted).

[52] *Id.*

[53] Wilkinson v. Vessey, 295 A.2d 676, 690 (R.I. 1972), citing Shetter v. Rochelle, 409 P.2d 74 (Ariz. App. 1965).

Most recently in Nevada, after discussing the remote correlation between strokes and cervical manipulations, the Nevada Supreme Court, in *Bronneke v. Rutherford,* rejected plaintiff's informed consent claim because the plaintiff "did not make an offer of proof at the pretrial hearing or by affidavit that, had he been informed of the risk of stroke, he would have refused treatment."[54] This holding suggests Nevada would embrace the subjective approach. However, in an earlier Nevada medical malpractice case, *Smith v. Cotter*, the Court held that not only must the evidence show the patient "would have refused the surgery. . .the patient's assertion the patient would have refused the treatment must be reasonable under the circumstances."[55]

Thus, several jurisdictions, including Nevada and Massachusetts,[56] actually employ a hybrid approach to evaluating causation, i.e., a combined subjective-objective analysis. This approach requires proof that not only would the plaintiff have declined treatment had he or she been advised of the risks of treatment but that objectively it would have been reasonable for him or her to have done so.

As to what constitutes reasonableness with respect to plaintiff's assertion at trial that he or she would have refused treatment, *Smith v. Cotter* offers these guidelines:

> The plaintiff's assertion that he or she would have refused the treatment must be reasonable under the circumstances. In determining reasonableness, the court may consider the testimony of the patient as well as medical evidence regarding the risks of remaining untreated, the possible alternative treatments and the risks and expected benefits of alternative treatments. This evidence may also include testimony from witnesses who observed the patients at the time they elected to undergo the treatment. No single type of evidence is to be conclusive; rather, all the evidence must be considered by the fact-finder in determining whether, had the full extent of the risk been known, the plaintiff would have reasonably refused treatment.[57]

Finally, while this article's intent is not to identify the specific information that a health case professional should communicate to a patient, the physician should ensure that the patient is furnished facts and information sufficient to inform the patient of the following:

1) The nature of the procedure to be undertaken.
2) The material risks inherent in such treatment, particularly if the risk inherently involves a known risk of death or serious bodily harm.
3) The probability that those risks may occur.
4) The availability and nature of alternative treatment options, if any.
5) The risks and dangers attendant to remaining untreated.

The informed consent paradigm should not be solely relegated to a simple form, although written confirmation to the patient to memorialize the process is always advisable. Defense practitioners should encourage physicians to incorporate a process that notifies patients of potential risks, thereby allowing the patients to voluntarily accept the proposed treatment plan after they have been fully advised.

VI. Conclusion

The indispensable first step that defense attorneys must undertake is ascertaining

[54] Bronneke, 89 P.3d at 46.

[55] Smith v. Cotter, 810 P.2d 1204, 1209 (Nev. 1991).

[56] Harnish v. Children's Hosp. Med. Ctr., 439 N.E.2d 240, 243-44 (Mass. 982).

[57] Smith, 810 P.2d at 1209.

which standard (patient-oriented or physician-oriented) the forum jurisdiction employs in informed consent cases. The next step is determining the materiality of the risk, which will likely require expert witness involvement. Materiality of the risk may actually provide a basis for a favorable pretrial resolution of the malpractice claim. The final step involves causation and ascertaining, in light of the failure to address the risk, whether the reasonably prudent patient – or the plaintiff – would or would not have proceeded with the treatment and, if not, whether the treatment was indeed a cause of plaintiff's injuries.

Appendix

Survey of Jurisdictions Applying Patient-Oriented v. Physician-Oriented Standard

Patient-Oriented Standard

Alaska

Applies the subjective test of causation. ALASKA STAT. § 09.55.556 (LEXIS L. Publg. 2003); *Parker v. Tomera*, 89 P.3d 761 (Alaska 2004).

California

Applies the objective test of causation. *Cobbs v. Grant*, 502 P.2d 1, 11-12 (Cal. 1972); *Arato v. Avedon*, 858 P.2d 598 (Cal. 1992).

Connecticut

Applies the objective test of causation. *Janusauskas v. Fichman*, 826 A.2d 1066, 1076 (Conn. 2003); *Logan v. Greenwich Hosp. Assn.*, 465 A.2d 294, 300-01 (Conn. 1983); *Hammer v. Mount Sinai Hosp.*, 596 A.2d 1318, 1325 (Conn. App. 1991).

District of Columbia

Applies the subjective test of causation. *Canterbury v. Spence*, 464 F.2d 772 (D.C. Cir. 1972); *Gordon v. Neviaser*, 478 A.2d 292, 294 (D.C. App. 1984).

Georgia

Applies the objective test of causation. Expert testimony is required to establish that the particular risk was or should have been known. *Ketchup v. Howard*, 543 S.E.2d 371, 378-79 (Ga. App. 2000).

Hawaii

Applies the objective test of causation. Expert testimony is required to establish the materiality of the risk, i.e., nature of risks inherent in a particular treatment, the probabilities of success, frequency of the occurrence of particular risks, nature of available alternatives. *Carr v. Strode*, 904 P.2d 489 (Haw. 1995); *see also, Barcai v. Betwee*, 50 P.3d 946, 959-60 (Haw. 2002).

Iowa

Applies the objective test of causation. Expert testimony is required to establish the nature of the risk and the likelihood of its occurrence. *Pauscher v. Iowa Methodist Med. Ctr.*, 408 N.W.2d 355, 359 (Iowa 1987); *Cox v. Jones*, 470 N.W.2d 23, 26-27 (Iowa 1990); *Bernholtz v. Des Moines Orthopedic Surgeons*, 662 N.W.2d 372 (Iowa. App. 2003).

Louisiana

Applies the objective test of causation. LA. REV. STAT. §40:1299.40 (2004). Expert testimony is required to establish the nature of the existence, nature, and probability of risk. Disclosure must be made only when a risk is medically known and of a magnitude that would be material in a reasonable patient's decision to undergo treatment. *Hondroulis v. Schuhmacher*, 555 So.2d 398, 404 (La. 1998); *Yahn v. Folse*, 639 So.2d 261, 266 (La. App. 1993).

Maryland

Applies the objective test of causation. Expert testimony is required to establish the nature of the risks inherent in a particular treatment, the probabilities of therapeutic success, the frequency of the occurrence of particular risks, the nature of available alternatives to treatment and whether or not disclosure would be detrimental to a patient. *Sard v. Hardy*, 379 A2d 1014, 1022, 1024 (Md. 1977).

Massachusetts

Applies the objective and subjective test of causation. Expert testimony is required to establish the requisite knowledge that a physician should have, which may include the nature of the patient's condition, nature and probability of risks involved, benefits reasonably expected, or inability of the physician to predict results. *Harnish v. Children's Hosp. Med. Ctr.*, 439 N.E.2d 240, 243-44 (Mass. 1982). Does not include the duty to warn of risks associated with mis-diagnosis. *Grapsas v. Frangieh*, 775 N.E.2d 811 (Mass. App. 2002).

Minnesota

Uses a modified-objective approach to establish a physician's duty to inform a patient. A physician has a duty to make such disclosures that a reasonable physician under similar circumstances would make; however, the physician must also disclose those risks that the patient has attached significance to even though they are generally not disclosed. Applies the objective test of causation. Expert testimony is necessary to identify the risks of treatment and the gravity and likelihood of occurrence of such risks. Patient must also establish that the defendant physician had a duty to know of the risk. *Cornfeldt v. Tongen*, 262 N.W.2d 684, 702 (Minn. 1977); *Kinikin v. Heupel*, 305 N.W.2d 589, 595 (Minn. 1981); *K.A.C. v. Benson*, 527 N.W.2d 553, 561 (Minn. 1995).

Mississippi

Applies the objective test of causation. *Reikes v. Martin*, 471 So.2d 385, 392-93 (Miss. 1985).

New Jersey

Applies the objective test of causation. Expert testimony is necessary to determine medically reasonable alternatives. The physician has a duty to inform patient of all medically reasonable alternatives. *Matthies v. Mastromonaco*, 733 A.2d 456 (N.J. 1999).

New Mexico

Applies the objective test of causation. Expert testimony is generally indispensable to identify and explain the risks of treatment and consequences of not submitting to the treatment. *Gerety v. Demers*, 589 P.2d 180, 195 (N.M. 1978).

North Dakota

Applies the objective test of causation. Expert testimony is generally required unless the risk is within the common knowledge of laymen. *Jaskoviak v. Gruver*, 638 N.W.2d 1, 8, 9 (N.D. 2002).

Ohio

Applies the objective test of causation. Expert testimony is generally required to explain the nature, probable consequences, risks, hazards, and benefits of the treatment. *Nickell v. Gonzalez*, 477 N.E.2d 1145 (Ohio 1985); *Congrove v. Holmes*, 308 N.E.2d 765, 771 (Ohio Misc. 1973).

Oklahoma

Applies the subjective test of causation. *Scott v. Bradford*, 606 P.2d 554, 558 (Okla. 1980).

Pennsylvania

Applies the substantial factor test which requires the patient to establish that the undisclosed information would have been a substantial factor in the patient's decision whether to undergo the treatment. Expert testimony is required to establish the risks of treatment, alternative treatments, and the feasibility of alternative treatments. 40 P.S. § 1303.504 (2004); *Hohns v. Gain*, 806 A.2d 16, 19-21 (Pa. Super. 2002); *Festa v. Greenberg*, 511 A.2d 1371, 1378 (Pa. Super.1986).

Rhode Island

Applies the subjective test of causation. Expert testimony is required to establish the known risks involved in the treatment. *Wilkinson v. Vesey*, 295 A.2d 676 (R.I. 1972).

South Dakota

Applies the objective test of causation. *Wheeldon v. Madison*, 374 N.W.2d 367, 374, 376 (S.D. 1985).

Texas

Applies the objective test of causation. Expert testimony is required to establish that the medical condition complained of is a risk inherent in the medical procedure performed. *Barclay v. Campbell*, 704 S.W.2d 8, 9-10 (Tex. 1986).

Vermont

Applies the objective test of causation. Expert testimony is not necessary. *Small v. Gifford Mem'l Hosp.*, 349 A.2d 703, 706-07 (Vt. 1975).

Washington

Applies the objective test of causation. Expert testimony is necessary to establish the existence of the risks and alternatives. *Miller v. Kennedy*, 522 P.2d 852, 861, 863 (Wash. App. 1974). Applied to chiropractors. *Herman v. Estabrook*, 117 Wash. App. 1007 (Wash. App. 2003).

West Virginia

Applies the objective test of causation. Expert testimony required to establish the possibility of surgery, the risks involved concerning a particular method of treatment, alternative methods of treatment, the risks relating to such alternative methods of treatment and the results likely to occur if the patient remains untreated. *Cross v. Trapp*, 294 S.E.2d. 446, 468, 454 (W. Va. 1982); *Adams v. El-Bash*, 338 S.E.2d 381, 386 (W. Va. 1985).

Wisconsin

Applies the objective test of causation. WIS. STAT. §§ 448.30 (2004); *Martin by Scoptur v. Richards*, 531 N.W.2d 70, 77 (Wis. 1995); *Hannemann v. Craig Boyson, D.C.*, 681 N.W.2d 561 (Wis. App. 2004).

Professional/Physician-Oriented Standard

Alabama

Applies the objective test of causation. Expert testimony required to establish standard of disclosure of same general line of practice in the nation. ALA. CODE 6-5-484 (2003); *Fain v. Smith*, 479 So.2d 1150, 1152 (Ala. 1985); *Wells v. Storey*, 792 So.2d 1034, 1037-38 (Ala. 1999).

Arizona

Applies the subjective test of causation. Expert testimony is required to establish the standard of disclosure of physician. *Potter v. Wisner*, 823 P.2d 1339 (Ariz. App. 1991); *Riedisser v. Nelson*, 534 P.2d 1052, 1054-55 (Ariz. 1975).

Arkansas

Applies the objective test of causation. Expert testimony is required to

establish the standard of disclosure of physicians in the same specialty and same or similar locality. ARK. CODE ANN. §16.114.206(b)(1); *Eady v. Lansford*, 92 S.W.3d 57 (Ark. 2002). *Aronson v. Harriman*, 901 S.W.2d 832, 840 (Ark. 1995); *Fuller v. Starnes,* 597 S.W.2d 88 (Ark. 1980).

Colorado

Applies the objective test of causation. Expert testimony is required to establish the standard of disclosure of physicians in the same specialty and in the same or similar community. *Gorab v. Zook*, 943 P.2d 423, 426-27 (Colo. 1997); *Bloskas v. Murray*, 618 P.2d 719 (Colo. App. 1980)(rev'd on other grounds, *Bloskas v. Murray*, 646 P.2d 907 (Colo. 1982)).

Delaware

Applies the subjective test of causation. DEL. CODE ANN. Tit. 18 §6852 (2004); *Barriocanal v.* Gibbs, 697 A.2d 1169, 1171-72 (Del. Super. 1997); *Robinson v. Mroz*, 433 A.2d 1051 (Del. Super. 1981).

Florida

Applies the objective test of causation. Expert testimony is required unless there is a complete lack of disclosure. FLA. STAT. ANN. § 766.103 (West 2004); *Thomas v. Berrios*, 348 So.2d 905,907-08 (Fla. App. 1977); *Ritz v. Fla. Patient's Compensation Fund*, 436 So.2d 987 (Fla. App. 1987).

Idaho

Applies the objective test of causation. IDAHO CODE § 39-4304 (2004). Expert testimony required to establish the standard of disclosure of physician in similar circumstances. *Sherwood v. Carter,* 805 P.2d 452, 461, 465 (Idaho. 1991).

Illinois

Applies the objective test of causation. Expert testimony is required as to reasonableness of the physician's conduct in comparison with the standard of disclosure of physicians in the same or similar community or national or international standard. *Weekly v. Solomon*, 510 N.E.2d 152, 156 (Ill. App. 1987); *Lowney v. Arciom*, 597 N.E.2d 817, 819 (Ill. App. 1992); *Sheahan v. Dexter*, 483 N.E.2d 402, 407 (Ill. App. 1985); *Schiff v. Friberg*, 771 N.E.2d 517, 529-30 (Ill.App. 2002); *Guebard v. Jabaay*, 452 N.E.2d 751, 757-58 (Ill. App. 1983).

Indiana

Applies the objective test of causation. Expert testimony is required to establish the standard of disclosure of a reasonably prudent physician. *Culbertson v. Mernitz*, 602 N.E.2d 98, 100, 104 (Ind. 1992); *Revord v. Russell*, 401 N.E.2d 763, 766-67 (Ind. App. 1980); *Bowman v. Beghin*, 713 N.E.2d 913, 917 (Ind. App. 1999).

Kansas

Applies the objective test of causation. Expert testimony is required. *Funke v. Fieldman*, 512 P.2d 539 (Kan. 1973). Applied to chiropractors. *Roberson v. Counselman*, 686 P.2d 149, 152 (Kan. 1984).

Kentucky

Applies the objective test of causation. KY. REV. STAT. ANN. § 304.40-320. Statute does not apply where there is a complete lack of informed consent and the action is one for battery. *Coulter v. Thomas*, 33 S.W.3d. 522, 525 (Ky. 2000).

Maine

Applies the objective test of causation. Expert testimony required to establish the standard of disclosure. *Woolley v. Henderson*, 418 A.2d 1123, 1129-31 (Me. 1980).

Michigan

Expert testimony is required to establish the standard of care. *Roberts v. Young*, 119 N.W.2d 627, 630 (Mich. 1963). Applied to chiropractors in *Tschirhart v. Pethtel,* 233 N.W.2d 93, 95 (Mich. App. 1975).

Missouri

Applies the objective test of causation. Expert testimony is required to establish the standard of disclosure. *Aiken v. Clary,* 396 S.W.2d 668, 675 (Mo. 1985).

Montana

Expert testimony required. *Llera v. Wisner*, 557 P.2d 805, 810 (Mont. 1976). Applies to chiropractors. *Bakewell v. Kahle*, 232 P.2d 127, 129 (Mont. 1951).

Nebraska

Applies the objective test of causation. Expert testimony is required. *Smith v. Weaver,* 407 N.W.2d 174, 177-78 (Neb. 1987). Informed consent rule for medical malpractice applies equally to chiropractors. *Jones v. Malloy,* 412 N.W.2d 837, 842 (Neb. 1987).

Nevada

Applies a hybrid test of causation. A patient's testimony is relevant but not conclusive on issue of causation. Expert testimony is required to establish the standard of disclosure. *Smith v. Cotter*, 107 Nev. 267, 274-75 (1991). Applied to chiropractors. *Bronneke v. Rutherford*, 89 P.3d 40 (Nev. 2004).

New Hampshire

Applies the subjective test of causation. Expert testimony is required. *Folger v. Corbett*, 394 A.2d 63, 64 (N.H. 1978); *Smith v. Cote*, 513 A.2d 341, 347 (N.H. 1986).

New York

Applies the objective test of causation. Expert testimony is required to establish the standard of care. *King v. Jordan*, 696 N.Y.S.2d 280, 281 (1999); *Eppel v. Fredericks*, 610 N.Y.S. 2d 25 (1994).

North Carolina

Applies the objective test of causation. N.C. Gen. Stat. § 90-21.13 (2004).

Oregon

Applies a hybrid form of the professional standard. A physician has a duty to inform the patient of the proposed treatment, any alternatives to treatment, and any risks associated with the treatment. OR. REV. STAT. ANN. § 677.097(1). The physician then must ask the patient if further disclosure is desired. OR. REV. STAT. ANN. § 677.097(2). If requested, the additional disclosure must conform to the community standard of disclosure. *Id.* Expert testimony is only required to establish the standard of disclosure required in §§ (2). Applies a subjective test of causation. *Tiedememann v. Radiation Therapy Consultants, P.C.*, 701 P.2d 440 (Or. 1985); *Zacher v. Petty*, 826 P.2d 619 (Or. 1991); *Arena v. Gingrich*, 733 P.2d 75, 79 (Or. App. 1987) (rejecting the objective test).

South Carolina

Applies the objective test of causation. Expert testimony is required to establish the standard of disclosure. *Hook v. Rothstein*, 316 S.E.2d 690, 698, 705 (S.C. App. 1984).

Tennessee

Applies the objective test of causation. TENN. CODE ANN. § 29-26-118 (2004); *German v. Nichopoulos,* 577 S.W.2d 197, 202 (Tenn. App. 1978), overruled on other grounds. *Mitchell v. Ensor*, 2002 WL 31730908 (Tenn. App. 2002).

Utah

Applies the objective test of causation. UTAH CODE ANN. § 78-14-5 (2004).

Virginia

Applies the subjective test of causation. Expert testimony is required. *Bly v. Rhoads*, 222 S.E.2d 783, 787-88 (Va. 1976); *Tashman v. Gibbs*, 556 S.E.2d. 772, 779 (Va. 2002).

Wyoming

Applies the objective test of causation. Expert testimony is required to establish the standard of disclosure. *Weber v. McCoy*, 950 P.2d 548, 552 (Wyo. 1997); *Roybal v. Bell*, 778 P.2d 108, 112-13 (Wyo. 1989) (adopting objective test).