### Chapter 33

# Informed Consent to Medical and Surgical Treatment

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Origins of the Informed Consent Doctrine Exceptions to the Requirement of Informed Consent Who can Give Consent? Refusal of Treatment Obtaining and Documenting Consent Conclusion

The requirement that physicians must obtain consent from their patients before proceeding with treatment has been a part of Anglo-American jurisprudence since eighteenth-century England.<sup>1</sup> However, the notion that the patient's consent must be informed in order to be legally effective dates back less than 50 years. The term "informed consent" was first used in 1957 by a California appeals court, which explained: "A physician violates his duty to his patient and subjects himself to liability if he withholds any facts which are necessary to form the basis of an intelligent consent by the patient to the proposed treatment." Since that pronouncement, informed consent has been a fertile ground for litigation.

Although most jurisdictions have sorted out the major issues arising under the informed consent rubric, significant questions remain. Thus, informed consent continues to be an evolving doctrine due to changes in health care practice, health system organization, and information technology, among other factors. Moreover, even though current physicians have lived their entire lives under a regime requiring informed consent, many are uncertain as to the applicable requirements and how to satisfy them in their daily practice routines. This chapter highlights these requirements, describes their legal and ethical underpinnings, and offers suggestions for satisfying them in ways that are not unduly burdensome or intrusive.

Although informed consent claims are fairly common in malpractice litigation, they are generally appended to an underlying count (or counts) of negligent care. Nonetheless, they can be most troublesome, particularly if the informed consent process has not been adequately documented. Claims of negligent care generally can be addressed, and hopefully disproved, by information routinely kept as part of the patient's medical record. However, a claim that the patient was not adequately informed prior to treatment can be difficult to address unless the provider is well schooled on the applicable informed consent requirements and has developed a policy and procedure that supports doing the right thing and also documenting it.

## ORIGINS OF THE INFORMED CONSENT DOCTRINE

Historically, physical treatment of a patient without his or her consent has been treated as a "battery," an unpermitted touching. This principle is reflected in a famous quote by Judge (later Justice) Cardozo in an oft-cited 1914 New York case: "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." Among other situations, a battery action can be brought when the patient is incapable of giving valid consent, when the physician goes beyond the limits of the consent without adequate justification, or when the one who renders care is other than the one authorized to do so.

Because battery is an intentional tort, an invasion of a person's bodily inviolability, a claim can be asserted even if the medical treatment is well intentioned, nonnegligent, and doesn't cause physical harm. Moreover, punitive damages may be awarded to the victim of a technical battery to vindicate his or her rights and make an example of the wrongdoer. As a practical matter, however, lawsuits are rarely brought to challenge a technical battery if no harm was intended and no significant physical consequence was caused. While lack of "informed" consent may be treated as a battery, and has been on occasion,<sup>4</sup> it generally is treated as a negligent tort and somewhat different principles are applied.

For about the past 35 years, litigation involving consent issues has often dealt with the nature and extent of the information provided to a patient in the course of obtaining authorization for treatment. An inadequate disclosure, unless deemed to be deliberate misrepresentation, is generally treated as negligence rather than battery. Damages are awarded only when there is significant harm caused to the victim, so punitive damages are limited to cases where there is *gross* negligence.

The doctrine of informed consent has evolved largely through case law; but about half of the states have defined the doctrine by statute and many have provided statutorily for the standard to be applied in measuring the adequacy of the information provided to the patient. Therefore, a physician seeking to satisfy informed consent requirements needs to check both the statutory and case law in his or her state. Staying current can be challenging because the health care system is still evolving, changing the context in which consent must be obtained. Physicians increasingly practice in group settings where responsibilities for patient care are shared. Thus, questions may arise as to whose responsibility it is to inform the patient, obtain his or her consent to treatment, document that consent, etc.

#### The Foundation of the Doctrine

In the 1957 case of Salgo v. Leland Stanford, Jr., University Board of Trustees,<sup>5</sup> the California appeals court recognized that a patient's consent to a procedure might not be effective if it were not intelligent or "informed." In Salgo, the patient consented to an aortogram without being advised, allegedly, of the risk posed by use of the contrast medium.<sup>6</sup> While Salgo set a precedent requiring adequate disclosure to the patient, it gave little guidance as to just what must be disclosed or how a court would go about judging the adequacy of disclosure in a given instance. Supplying this additional "detail" has proved to be a major undertaking that still is the subject of legal debate.

#### What Must Be Disclosed?

A long line of cases has distilled a generally accepted list of elements that must be disclosed to the patient—or, more accurately, must be known by the patient—for his or her consent to be deemed adequately informed. Those elements are: the diagnosis; the nature and purpose of the proposed treatment; the risks and consequences of the proposed treatment; reasonably feasible alternatives; and the prognosis if the recommended treatment is not provided. Although there is general agreement that these elements must be disclosed, there is far less agreement on the amount and nature of the detail that must be addressed. Moreover, the list of disclosure elements is not limited to these categories. As discussed below, the basic approach a jurisdiction adopts on informed consent will greatly affect whether additional information may have to be disclosed.

#### **Two Standards for Disclosure**

The informed consent doctrine has evolved in such a way that there are basically two approaches, or standards for application of the doctrine. In the first decade of the doctrine's development, courts generally followed the approach of the Kansas Supreme Court in *Natanson v. Kline*, and fixed the required content of a physician's disclosure by reference to what physicians commonly disclose when handling a similar case. Under this "professional community" standard, if a physician discloses what the

relevant physician group does, then he or she has satisfied the "duty to disclose." A key consequence of using this approach is that a patient-plaintiff cannot make out an informed consent claim without introducing expert testimony as to what other physicians normally tell their patients in similar cases. This poses two obvious problems for prospective plaintiffs. First is the difficulty of finding physicians willing to testify as expert witnesses against their colleagues on a matter of questionable substance. Second, the *Natanson* approach left the entire question of what should be disclosed up to the discretion of the physician community, which might exercise that discretion with little regard for what patients want or need to know.

The *Natanson* physician-based approach was rejected in a string of cases starting with the landmark *Canterbury v. Spence*<sup>8</sup> ruling by the U.S. Court of Appeals for the D.C. Circuit in 1972 and followed soon afterward by an equally celebrated California case, *Cobbs v. Grant.*<sup>9</sup> In both cases, the courts ruled that what was needed for an adequate disclosure should be measured by what a reasonable patient would want to know about the proposed treatment, its risks and consequences, and any treatment alternatives before deciding what course to follow. In other words, the courts ruled that the physician must disclose all that he or she should reasonably expect to be "material" to the patient's decision-making process.<sup>10</sup>

This latter, patient-based approach to informed consent avoided the two problems inherent in the Natanson approach. First, the required content of the physician's disclosure was measured by the patient's informational needs rather than by what physicians might, or might not, choose to tell their patients. By focusing on the patient, the Canterbury approach was more faithful to the ideals of patient autonomy and self-determination that were increasingly emphasized in society's values and in related areas of medical jurisprudence, such as the Supreme Court's upholding of a woman's right to have an abortion in its landmark Roe v. Wade<sup>11</sup> decision in 1973. Second, using a patient-based standard meant that patient-plaintiffs no longer had to establish by expert testimony what the "standard disclosure" was for a particular condition or treatment. They could simply assert that the undisclosed information was something that an "average, reasonable patient" would consider material.

Not having to produce an expert witness on the "standard disclosure" point greatly changed the dynamics of lawsuits claiming a lack of informed consent. Because plaintiffs could get their cases before a jury without having to clear a sometimes steep evidentiary hurdle, it was much easier for them to prosecute their claims, thus affecting settlement negotiations and, in turn, affecting the propensity of plaintiffs to include informed consent claims in their malpractice suits. The incidence of informed consent claims increased rapidly in the 1970s and 1980s, much more so in states following *Canterbury* than in those holding fast to the older *Natanson* approach.

Throughout the 1970s and 1980s, states addressed the question of whether informed consent claims should be adjudicated using one or the other of the above standards.

Much of the play was in the courts; but many states also passed statutes that set the standards for measuring physician disclosures. By the end of the 1980s, most states had fallen into one camp or the other. Looking past the small handful of states whose approaches are hybrids or defy classification using the two schemes, a bare majority of the remaining states follow a physician-based standard, while the others follow some variant of the patient-based, or "materiality," standard. (Appendix 33-1 summarizes the various states' positions on this issue.)

# EXCEPTIONS TO THE REQUIREMENT OF INFORMED CONSENT

Full, formal consent from the patient is not always feasible to obtain and is not always required. The law recognizes situations in which something less is acceptable.

#### **Emergency Consent**

In a medical emergency a patient may be unconscious, disoriented, sedated, or otherwise incapable of giving an effective consent. When that is so, and no one is available who would be authorized to act on the patient's behalf, the law generally allows the physician to presume that the patient would want to be treated as necessary to preserve his or her life and/or function.

When a patient cannot give consent and care is urgently needed, the physician should attempt to identify and contact the patient's next of kin or other person legally capable of acting on the patient's behalf. Other people present should assist so that the physician can stay focused on providing needed care. If possible, another physician or health care provider with appropriate expertise should participate in the assessment, to help establish that there was an emergency, that care was needed immediately, that attempts were made to contact next of kin, and that the care rendered did not go beyond that necessary to preserve the patient until full consent might be obtained. An emergency does not give the physician license to do whatever he or she deems advisable for the patient; it supports only limited measures to preserve the status quo.

#### The "Extension Doctrine"

The so-called "extension doctrine" allows the physician to go beyond the care the patient authorized if an unexpected complication arises that makes it medically advisable to do so. An excellent example of the application of the extension doctrine is the 1956 case of *Kennedy v. Parrott*, <sup>12</sup> in which a physician who was performing an appendectomy on a patient determined that she had an ovarian cyst that should be excised. Because the patient was under general anesthetic and no person authorized to speak on her behalf was available, the physician decided it was medically appropriate to remove the cyst as part of the same operation. Had he not done so, a second surgery—with its attendant

inconvenience, risks, and cost—would have been necessary at a later time. The North Carolina Supreme Court upheld the physician's decision to proceed, reasoning that he had not only the right to do so but also the duty to do what sound medicine dictated.<sup>13</sup>

The extension doctrine does not apply to elective, or nonessential, procedures, <sup>14</sup> nor does it apply when the possible need for extension of the authorized procedure should have been anticipated by the physician prior to beginning it. In such a case, the physician must inform the patient before the fact of the possible need for extension and obtain the patient's express consent. Moreover, current thinking provides very limited support for the "extension doctrine" in the absence of a situation that presents an imminently life-threatening risk to the patient.

#### Waiver

Just as patients are entitled to have information about their health care, they are also entitled *not* to have such information when they would be unduly distressed by it or would simply prefer to let the physician make the necessary treatment decisions. Patients can waive their right to information; but a waiver of information must be knowing and voluntary to be effective. Therefore, the physician must provide enough information so that the patient knows the general nature of the information he or she is forgoing. For example, the physician could tell the patient that there are risks inherent in the procedure being recommended. If the patient then chooses not to have more complete information about the risks, then the requirement of informed consent would be deemed satisfied.

Obviously, any such waiver should be documented. One way to implement this is to have a two-part consent form. In the first part, the recommended treatment is named and general information is given about it, noting, as may be appropriate, that there are risks, consequences, or alternatives. The form then recites that the patient is entitled to full information and the physician stands ready to provide it. The patient initials either a box that indicates the information is desired or one saying that the patient chooses not to have a more complete explanation.<sup>15</sup> A process and associated form like this allows the patient to choose how much information he or she desires and documents the patient's choice. As with other aspects of "managing" informed consent, doing the right thing is only part of the game; the other, crucial part is being able to prove, if challenged, that the right thing was done.

#### Therapeutic Privilege

Many jurisdictions recognize a physician's right to withhold information from a patient if disclosure would be harmful to the patient. Perhaps the best-known statement of this principle, commonly known as "therapeutic privilege," is in the landmark *Canterbury* case:

[An] exception obtains when risk-disclosure poses such a threat of detriment to the patient as to become unfeasible or contraindicated from a medical point of view. It is recognized

that patients occasionally become so ill or emotionally distraught on disclosure as to foreclose a rational decision, or complicate or hinder the treatment, or perhaps even pose psychological damage to the patient. Where that is so, the cases have generally held that the physician is armed with a privilege to keep the information from the patient, and we think it clear that portents of that type may justify the physician in action he deems medically warranted. The critical inquiry is whether the physician responded to a sound medical judgment that communication of the risk information would present a threat to the patient's well-being. 16

This quote nicely summarizes the commonly articulated rationale for therapeutic privilege. In actuality, however, therapeutic privilege has seldom been applied in the case law; thus it is largely "dictum." One should be wary of relying too heavily on this exception and should do so only in exceptional circumstances. In the *Canterbury* case, the defendant neurosurgeon testified that he generally did not tell patients of the paralysis risk inherent in a laminectomy because he thought they might decline surgery he thought they truly needed. Rejecting the therapeutic privilege defense upon these facts, the court explained:

The physician's privilege to withhold information for therapeutic reasons must be carefully circumscribed, however, for otherwise it might devour the disclosure rule itself. The privilege does not accept the paternalistic notion that the physician may remain silent simply because divulgence might prompt the patient to forego therapy the physician feels the patient really needs. That attitude presumes instability or perversity for even the normal patient, and runs counter to the foundation principle that the patient should and ordinarily can make the choice for himself. Nor does the privilege contemplate operation save where the patient's reaction to risk information, as reasonabl[y] foreseen by the physician, is menacing.<sup>18</sup>

A physician seeking to justify nondisclosure on this ground has the significant burden to particularize its application to the individual patient and not contend that patients in general are unable to handle this kind of information.

#### **Causation Issues**

While not exactly an "exception" to the requirement of informed consent, a failure to disclose information to the patient is excused if a court believes the patient was not harmed by the failure. The lack of a causal connection between nondisclosure and the harm suffered by the patient defeats informed consent liability. A patient-plaintiff who brings an informed consent claim is essentially contending that if he or she had known the undisclosed information, he or she would not have opted for the treatment in question. Thus, to recover upon an informed consent claim, the patient-plaintiff must prove that the physician knew, or should have known, the information in question, and did not disclose it; that the treatment caused harm to the patient (medical causation); and that he or she would not

have chosen the treatment if the information had been revealed ("informed consent" causation). On the last point, "informed consent" causation, the patient is arguing that he or she would have acted differently if properly informed.

Courts have been understandably reluctant to accept such after-the-fact causative assertions in situations where they believe a *reasonable and prudent patient* would have followed the physician's recommendation and accepted the treatment in question, even if fully informed of the risks. <sup>19</sup> Thus, most courts facing the issue have opted to use an *objective* standard, asking what an "average, reasonable patient" would have done if he or she actually had been informed about risks that were not disclosed, rather than what *the particular patient* would have done, a *subjective* standard. <sup>20</sup> Using a subjective standard is problematic because there is often no way to know what a given patient would have chosen if things had been different. Once again, the *Canterbury* opinion is instructive:

It has been assumed that the issue [of "informed consent" causation] is to be resolved according to whether the factfinder believes the patient's testimony that he would not have agreed to the treatment if he had known of the danger which later ripened into injury. We think a technique which ties the factual conclusion on causation simply to the assessment of the patient's credibility is unsatisfactory. To be sure, the objective of risk-disclosure is preservation of the patient's interest in intelligent selfchoice on proposed treatment, a matter the patient is free to decide for any reason that appeals to him. When, prior to commencement of therapy, the patient is sufficiently informed on risks and he exercises his choice, it may truly be said that he did exactly what he wanted to do. But when causality is explored at a postinjury trial with a professedly uninformed patient, the question whether he actually would have turned the treatment down if he had known the risks is purely hypothetical: "Viewed from the point at which he had to decide, would the patient have decided differently had he known something he did not know?" And the answer which the patient supplies hardly represents more than a guess, perhaps tinged by the circumstance that the uncommunicated hazard has in fact materialized.<sup>21</sup>

Notwithstanding these practical considerations, some courts have reasoned that because the core objective of informed consent doctrine is to support patient autonomy, their decision should turn on what they believe the particular patient would have chosen, not what some hypothetical patient would have done. Thus, a few states apply a *subjective* standard of causation.<sup>22</sup>

#### WHO CAN GIVE CONSENT?

Although the discussion thus far has largely assumed that it is the patient himself or herself who either gives or withholds consent, there are occasions in which others may be involved, e.g., an emergency situation where a patient who would otherwise have the capacity to consent is under some disability. It is often said that in such situations the

patient's next of kin has authority to grant consent. However, the fact that someone is the next of kin to a patient who temporarily lacks capacity is not enough to bestow decision-making capacity on the relative. Ideally, there should be a court order designating who can decide on the patient's behalf or a document such as a durable power of attorney signed by the patient while he or she was competent.

Without such a designation by a court or the patient, the next of kin can give valid consent only when time is too short to obtain court designation of a surrogate. When the need for care is too urgent to allow court designation, the provider may assume, absent contrary evidence, that the next of kin has the patient's interest at heart and can make the best projection of what the patient would choose. Moreover, any care beyond what is immediately necessary to stabilize and preserve the patient is not properly authorized. Jurisdictions differ on how much latitude the treating physician has to decide what is immediately necessary; but restraint is advised. As much as the physician may feel motivated to push forward and render all the care he or she thinks the patient ultimately needs, going beyond the point of necessity without court endorsement is risky.

#### **Minors**

All jurisdictions have statutes outlining what kinds of medical and related care a minor can consent to, and, in some cases, identifying areas of exception to the general rules. Most states have provisions for "emancipated" minors those living on their own and not dependent on their families for support—to make their own health care decisions. Also, in many states, a "mature" minor—that is, one of sufficient age and discretion to be able to understand his or her situation, the proposed treatment(s), and the consequences likely to flow from the treatment or its alternative(s)—is authorized to make treatment decisions in a situation when care is urgently needed and the minor's parent(s) or guardian are not available. Generally, such exceptions are recognized in the case law rather than statutory law. It is common for statutes to provide that a minor is treated as an adult for the purpose of health care decision-making if the minor is married or pregnant. Many states also allow minors to consent to birth control counseling and assistance and to diagnosis and treatment for sexually transmitted disease and substance abuse without parental consent or notification.

Physicians should find out what the law in their state provides with regard to treatment of and consent by minors. A physician should offer to the minor all information that would otherwise have been given to the minor's parents or guardian(s), adapted as necessary to the minor's age and ability to comprehend it. In addition to documenting that appropriate information was given, the physician should document why it was necessary or advisable to proceed without the parent's (or guardian's) participation. If there is any reason to doubt that the minor was mature enough to give meaningful consent, then the physician

should seek authorization from a court, unless the situation is an emergency.

#### **REFUSAL OF TREATMENT**

Patients have the right to withhold their consent and not be treated, even when this runs counter to the physician's convictions as to what is best for the patient. Issues involving what is necessary for that right to be effectively exercised arise in many different contexts. The following discussion addresses two such issues that arise in more routine treatment situations. Issues involving end-of-life care, refusal of life support, assisted suicide, etc., are beyond the scope of this chapter.

#### "Informed Refusal"

Just as a patient needs adequate information to be able to accept proposed treatment, he or she needs information to be able to decline or refuse it. However, because the informed consent doctrine grew out of the tort of battery, it has not always been clear that a physician has an obligation to provide information in a situation where the patient is *forgoing* treatment.

Truman v. Thomas, 23 decided by the California Supreme Court in 1980, is often cited for the principle of "informed refusal." Truman held that a physician who recommends a procedure—in that case, a diagnostic Pap smear test—must ensure that a patient who rejects this recommendation understands the consequences of not having the test. Although the decision has not been widely followed, its core rationale—that a physician should provide the information needed to support the patient's decision-making, even when the decision is to refuse the treatment—is sound. It is consistent with the longstanding convention that when someone leaves a hospital emergency room before receiving all the treatment the personnel there believe is needed, efforts are made to get the patient to sign a form indicating that he or she left "against medical advice." To give good protection against an informed refusal claim, this form should contain a clear statement of the risks and consequences of not getting the recommended care.

#### Refusal by Others on the Patient's Behalf

The above discussion of who can consent on the patient's behalf dealt mostly with situations where the next of kin purporting to speak for the patient's interest was willing to authorize the treatment in question. Where that is not the case, the provider obviously faces significant risk. If the provider disregards the next of kin's objections, renders the care, and there is a bad outcome, a lawsuit is to be expected. When time permits, a court order authorizing the treatment should be sought. When there is no time and the provider feels he or she must proceed anyway, great care should be taken to ensure that the objecting party understands why treatment is urgently needed and to document this. Where possible, confirmation by

independent medical personnel is strongly advised. Finally, where the provider heeds the patient's next of kin and does not provide care, it is still important to document that full information was given to the one rejecting the care on the patient's behalf.

## OBTAINING AND DOCUMENTING CONSENT

Successful compliance with informed consent requirements as part of regular practice routines raises numerous issues. The issues in the following sections are the ones most frequently encountered.

## Who Is Responsible to Obtain Informed Consent?

Generally speaking, the physician rendering the care in question is the one who should obtain the patient's informed consent to that care. However, that task may be delegated to another health care provider, e.g., a resident, nurse practitioner, etc. If adequate and accurate information is provided and it can be proven that the correct consent was obtained from the patient, it doesn't matter who performed the tasks necessary to achieve this. If the consent falls short in some way, however, then the physician rendering the care bears the primary responsibility and the potential liability resulting from this failure. Thus, each person "laving on hands" or otherwise treating the patient must take care that the consent obligations are fully satisfied with regard to his or her aspect of the treatment. One can delegate the function of obtaining adequately informed consent; but if the function is not fulfilled, the delegator cannot avoid the underlying legal responsibility.

Complexity can enter the picture when a major, or primary, treatment being rendered to the patient is comprehensive enough in scope to subsume other ancillary procedures. For example, if a surgeon has assistants helping to install a prosthetic device in a patient's leg, then separate consents would not be needed for the assistants' actions, even if those actions were medically and factually discrete. The surgeon in charge might use an intern or resident to close and suture the patient after the main part of the operation is complete. In such a case, the surgical consent should be drawn broadly enough to encompass the others who were integrally involved in the overall surgical procedure, particularly where the surgeon was in charge of the overall procedure and the other participants looked to the surgeon for supervision. The reasonable scope of control of the surgeon should be the determining factor.

### **Duty of Hospitals or Other Health Care Institutions**

When care is delivered in a hospital or other institutional setting, or under the auspices of a managed care organization, one might try to hold the institution liable for any failure to obtain an adequate informed consent. However, courts have been reluctant to find such institutions liable for inadequate disclosure, recognizing the institution's inability to police the details of information transmission and also respecting the close, personal nature of the physician-patient relationship.<sup>24</sup> They have gone so far as to hold the institution obligated to have policies and procedures in place to facilitate and help ensure that adequate consent is obtained, particularly when the institution holds itself out to the public as meeting standards that include assurance of patients' rights.<sup>25</sup> Courts have not gone the additional distance of holding the institution responsible for the content of the physician's disclosure to the patient; but they might do so if it could be shown that the institution knew, or had reason to know, either in a particular instance or in general, that the physician was treating a patient (or patients) without adequate consent. Of course, if the physician is employed by the institution, vicarious liability likely would be imposed under the doctrine of respondeat superior.<sup>26</sup>

#### **Documenting Consent**

From a practical standpoint, documentation of adequate patient consent may be as important as the actual satisfaction of the underlying obligation. Often in litigation the decisive question is not whether the right thing was done but, rather, whether that can be proven. A problem with the implementation of informed consent doctrine is that excessive emphasis is often put on the completion of a consent form, sometimes eclipsing concern for the human interaction and two-way information exchange that is supposed to take place. The challenge is to balance the substantive aspects of the consent process with the procedural challenge of effective documentation while avoiding cumbersome and costly intrusion into day-to-day medical practice and the physician–patient relationship.

Except in a dozen or so states whose statutes put special emphasis on written consent,27 an oral (spoken) consent is as good as a consent in writing, except that written documentation generally makes it easier to prove that a satisfactory consent actually was obtained. The classic format for written consent is a form signed by the patient, identifying and authorizing the treatment to be administered, naming the provider(s) authorized to render the treatment, and acknowledging, in a reasonable degree of detail, that information was provided on the required disclosure elements, such as risks and consequences of, and alternatives to, the proposed treatment. The form commonly will recite that the patient was given an opportunity to ask questions and to receive answers and explanations from the physician(s) involved. The form can be specially prepared for a particular patient and treatment situation, or it can be a standardized form, crafted for repeated use with the same treatment, but perhaps tailored to accommodate any special facts or circumstances of the current case. Both types of forms have their adherents and reasonable arguments pro and con for their use.

With either type of form, one has to choose between greater or lesser specificity regarding the information the form purports to document. A less specific form that simply says the patient acknowledges having received "full information as to expected benefits, risks and consequences of the proposed treatment, as well as alternatives thereto," leaves it open for the patient to later claim that certain information was not disclosed. The form evidences that some risks were disclosed, but it stops short of proving that a particular risk was mentioned. On the other hand, if the form is very specific and attempts to list all the risks that were disclosed, on occasion an undisclosed risk might be omitted from the list. In such a case, the form could serve as persuasive, albeit misleading, proof that the information in question was not provided. Thus, if a specific form is to be used, it must be exactly right every time.

Other approaches to documenting informed consent are also possible. The physician can simply make a note in the patient's record that he or she discussed the nature of the procedure, material risks, reasonable benefits to be expected, and available alternatives. Such a contemporaneous recording in the medical record is often very persuasive to a jury, particularly when a physician is able to testify that such a notation refreshes his or her recollection about the nature and scope of the discussion ordinarily undertaken with patients in similar situations. Greater documentation is desirable to guard against informed consent challenges, but the degree of effort put toward documentation must be weighed against the projected risks of a challenge.

#### CONCLUSION

Informed consent is more than a legal doctrine and a trap for unwary practitioners. It is a concept central to American beliefs about individual rights and the proper relationship between patients and providers. Physicians should look beyond the specifics of the consent requirements discussed here and be mindful of the larger goal—respect for the dignity and autonomy of individual patients and a commitment to help them participate fully and meaningfully in the decisions that affect their bodies and their lives.

#### **Endnotes**

- 1. Slater v. Baker & Stapleton, 95 Eng. Rep. 860 (K.B. 1767).
- 2. Salgo v. Leland Stanford, Jr., Univ. Bd. of Trustees, 317 P. 2d 170, 181 (Cal. App. Ct. 1957).

- Schloendorff v. Society of New York Hosp., 105 N.E. 92, 93 (N.Y. 1914).
- 4. See, e.g., Perna v. Pirozzi, 457 A. 2d 431 (N.J. 1983).
- 5. Salgo, 317 P. 2d 170.
- 6. Id. at 180-81.
- 7. 350 P. 2d 1093 (Kan. 1960).
- 8. Canterbury v. Spence, 464 F. 2d 772 (D.C. Cir. 1972).
- 9. 502 P. 2d 1 (Cal. 1972).
- 10. Canterbury, 464 F. 2d at 786.
- 11. 410 U.S. 113 (1973).
- 12. 90 S.E. 2d 754 (N.C. 1956).
- 13. Id. at 759.
- 14. See, e.g., Lloyd v. Kull, 329 F. 2d 168 (7th Cir. 1964) (physician liable for cosmetic excision of a mole on an unconscious patient's thigh while correcting a vesicovaginal fistula). See also Smith v. Portera, 2005 Tenn. App. Lexis 313.
- 15. This approach has been suggested by Dr. Ralph Alfidi of the Cleveland Clinic in *Informed Consent: A Study of Patient Reaction*, 216 J.A.M.A. 1325 (1971). It is also the approach required under Oregon's medical consent statute. Ore. Stats. §677.097 (2001).
- 16. Canterbury, 464 F. 2d at 783.
- 17. See, e.g., Margaret A. Somerville, Therapeutic Privilege: Variation on the Theme of Informed Consent, 12 L. Med. & Health Care 4, 11 (1984).
- 18. Canterbury, 464 F. 2d at 789.
- 19. See, e.g., Fischer v. Wilmington Gen. Hosp., 149 A. 2d 749 (Del. Super. Ct. 1959).
- 20. See, e.g., Fain v. Smith, 479 So. 2d 1150, 1152–54 (Ala. 1985) (citing other jurisdictions that have adopted the objective standard). See also Ashe v. Radiation Oncology Assocs., 9 S.W. 3d 119, 121 (Tenn. 1999) and extensive sources cited therein.
- 21. Canterbury, 464 F. 2d at 790.
- 22. See, e.g., Arena v. Gingrich, 748 P. 2d 547 (Or. 1988); Spencer v. Seikel, 742 P. 2d 1126 (Okla. 1987).
- 23. 611 P. 2d 902 (Cal. 1980).
- 24. See, e.g., Smith v. Gaynor, 591 A. 2d 834 (Conn. Super. Ct. 1991).
- 25. See, e.g., Robinson v. Bleicher, 559 N.W. 2d 473, 476 (Neb. 1997) (duty of hospital to have informed consent procedures in place).
- See, e.g., Doctors Mem'l Hosp. v. Evans, 543 So. 2d 809 (Fla. Dist. Ct. App. 1989); Campbell v. Pitt County Mem'l Hosp., 362 S.E. 2d 273 (N.C. 1987).
- 27. See, e.g., Fla. Stat. Ann. §766.103 (West 2002); Ga. Code Ann. §31-9-6.1(b)(2) (2002); Idaho Code §39-4305 (2002); Iowa Code Ann. §147-137 (West 2001); La. Rev. Stat. Ann. §40:1299.40 (West 2002). Maine, Nevada, North Carolina, Ohio, Texas, Utah, and Washington, among others, also have statutory provisions regarding written consent.

#### APPENDIX 33-1: OVERVIEW OF STATES' POSITIONS ON DISCLOSURE STANDARD

Note: This Appendix classifies states between the physician-based or patient-based disclosure standard for informed consent and identifies those few states that do not follow either of these standards or cannot be confidently classified. The classification was based upon statutory and case law research updated in January 2006 and is believed to be accurate and up to date as of publication. Readers are cautioned, however, to confirm any classifications herein before relying upon them in any way.

#### States following a Physician-Based Standard

Alabama Fain v. Smith, 479 So. 2d 1150 (Ala. 1985), applying Ala. Code §6-5-484 (2005).

Arizona Gurr v. Willcutt, 707 P. 2d 979 (Ariz. Ct. App. 1985), applying Ariz. Rev. Stat. §§12-561, 12-563 (2005). Arkansas Aronson v. Harriman, 901 S.W. 2d 832 (Ark. 1995); Brumley v. Naples, 896 S.W. 2d 860 (Ark. 1995); Ark. Code Ann.

Colorado Gorab v. Zook, 943 P. 2d 423 (Colo. 1997); Colo. Rev. Stat. Ann. §13-64-401 (West 2005) (physician-based standard,

but defendent may have some burdenof providing standard was met).

Delaware Rowe v. Kim, 824 A. 2d 19 (Del. Super. Ct. 2003), applying Del. Code Ann. tit. 18, §6852 (2005).

Florida Ritz v. Florida Patient's Compensation Fund, 436 So. 2d 987 (Fla. Dist. Ct. App. 1983); Fla. Stat. Ann. §766.103 (West 2005). Idaho

Anderson v. Hollingsworth, 41 P. 3d 228 (Idaho 2001). See also Shabinaw v. Brown, 963 P. 2d 1184 (Idaho 1998), applying

Idaho Code §39-4304 (repealed 2005).

Illinois Ramos v. Pyati, 534 N.E. 2d 472 (III. App. Ct. 1989).

McGee v. Bonaventura, 605 N.E. 2d 792 (Ind. Ct. App. 1993); See generally Ind. Code Ann. §34-18-12-1 et seq. (West 2005). Indiana

Stovall v. Harms, 522 P. 2d 353 (Kan. 1974). But see Kan. Stat. Ann. §65-6709 (2004) (applying reasonable Kansas

patient/materiality standard as to abortion).

. Ouellette v. Mehalic, 534 A. 2d 1331 (Me. 1988),applying Me. Rev. Stat. Ann. tit. 24, §2905 (West 2005). Maine

Michigan Marchlewicz v. Stanton, 213 N.W. 2d 317 (Mich. Ct. App. 1973).

Mississippi Whittington v. Mason, 905 So. 2d 1261 (Miss. 2005) (overruling Hudson v. Parvin, 582 So. 2d 403 (Miss. 1991)).

Baltzell v. Baptist Med. Ctr., 718 S.W. 2d 140 (Mo. Ct. App. 1986); Wilkerson v. Mid-America Cardiology, Missouri

908 S.W. 2d 691 (Mo. Ct. App. 1995).

Llera v. Wisner, 557 P. 2d 805 (Mont. 1976). Montana

Neb. Rev. Stat. §44-2816 (2005); physician-based standard criticized but followed in Eccleston v. Chait, Nebraska

492 N.W. 2d 860, 868 (Neb. 1992).

Bronneke v. Rutherford, 89 P. 3d 40 (Nev. 2004); Smith v. Cotter, 810 P. 2d 1204 (Nev. 1991), Nevada

applying Nev. Rev. Stat. §§41A.110, 449.710 (2005).

New Hampshire Smith v. Cote, 513 A. 2d 341 (N.H. 1986), applying N.H. Rev. Stat. Ann. §507-E:2 (West 2005).

Henning v. Parsons, 623 P. 2d 574 (N.M. Ct. App. 1980) ("Doctor's duty to disclose risks of treatment, whether New Mexico

alternative treatments are available, and what results should be anticipated if treatment is not rendered, is one of law,

not resting solely in medical expertise, but requiring doctor to disclose what reasonable men who possessed

his medical talent probably would.").

Karlin v. IVF America, Inc., 712 N.E. 2d 662 (N.Y. 1999), applying N.Y. Pub. Health Law §2805-d (McKinney 2005). New York

Zacher v. Petty, 826 P. 2d 619 (Or. 1992), applying Or. Rev. Stat. §677.097 (2005). Oregon

South Carolina Baxley v. Rosenblum, 400 S.E. 2d 502 (S.C. Ct. App. 1991).

Ashe v. Radiation Oncology Assocs., 9 S.W. 3d 119 (Tenn. 1999), applying Tenn. Code Ann. §29-26-118 (2005). Tennessee

Perkins v. Windsor Hosp. Corp., 455 A. 2d 810 (Vt. 1982), applying Vt. Stat. Ann. tit. 12, §1909 (2005). Vermont

Virginia Tashman v. Gibbs, 556 S.E. 2d 772 (Va. 2002); Va. Code Ann. §8.01-581.20 (2005).

Weber v. McCoy, 950 P. 2d 548 (Wyo. 1997). Wyoming

#### States following a Patient-Based Standard

Alaska Korman v. Mallin, 858 P. 2d 1145 (Alaska 1993), applying Alaska Stat. §09.55.556 (2004). California Arato v. Avedon, 858 P. 2d 598 (Cal. 1993) (discussing Cobbs v. Grant, 502 P. 2d 1 (1972).

Connecticut DeGennaro v. Tandon, 873 A. 2d 191 (Conn. App. Ct. 2005).

Gordon v. Neviaser, 478 A. 2d 292 (D.C. 1984). District of Columbia

Georgia Ketchup v. Howard, 543 S.E. 2d 371 (Ga. Ct. App. 2000), applying Ga. Code Ann. §31-9-6.1 (2005).

(Note: An appendix to this opinion offers a state-by-state analysis of informed consent approaches.)

Hawaii Carr v. Strode, 904 P. 2d 489 (Haw. 1995); Haw. Rev. Stat. §671-3 (2005) (patient-based standard, but with

state medical board responsible to develop specific standards for disclosure).

Iowa Iowa Code Ann. §147.137 (West 2005) makes a written consent containing general information presumptively valid;

Bray v. Hill, 517 N.W. 2d 223 (lowa Ct. App. 1994), and other cases recognize a patient-based standard.

Louisiana La. Rev. Stat. Ann. §40:1299.40 (West 2005) makes a written consent containing general information presumptively valid;

Boudoin v. Crawford & Marshall, Ltd., 709 So. 2d 798 (La. Ct. App. 1998), and other cases recognize

a patient-based standard.

#### Appendix 33-1: Overview of States' Positions on Disclosure Standard 345

Maryland Faya v. Almaraz, 620 A. 2d 327, 334 (Md. 1993).

Masachusetts Feeley v. Baer, 669 N.E. 2d 456 (Mass. App. Ct. 1996); Harnish v. Children's Hosp. Med. Ctro, 439 N.E. 2d 240 (1982).

Minnesota Russell v. Johnson, 608 N.W. 2d 895 (Minn. App. 2000). New Jersey Acuna v. Turkish, 808 A. 2d 149 (N.J. Super Ct. Law Div. 2002).

North Dakota Jaskoviak v. Gruver, 638 N.W. 2d 1 (N.D. 2002).

Ohio Bedel v. University of Cincinnati Hosp., 669 N.E. 2d 9 (Ohio Ct. App. 1995); Ohio Rev. Code Ann.

§2317.54 (Banks-Baldwin 2005).

Oklahoma Spencer v. Seikel, 742 P. 2d 1126, 1129 (Okla. 1987) (language suggests that a "subjective

patient standard" be applied).

Pennsylvania Southard v. Temple Univ. Hosp., 781 A. 2d 101 (Pa. 2001); 40 Pa. Cons. Stat. §1303.504 (2005).

Rhode Island Lauro v. Knowles, 785 A. 2d 1140 (R.I. 2001); R.I. Gen. Laws §9-19-32 (2005).

South Dakota Wheeldon v. Madison, 374 N.W. 2d 367 (S.D. 1985).

Texas Price v. Hurt, 711 S.W. 2d 84 (1986); see also Tex. Civil Practice & Remedies Code Ann. §74.101 (2005).

Utah Nixdorf v. Hicken, 612 P. 2d 348 (Utah 1980); Utah Code Ann. §78-14-5 (2005).

Washington Seybold v. Neu, 19 P. 3d 1068 (Wash. App. Ct. 2001); Backlund v. University of Washington, 975

P. 2d 950 (Wash. 1999); Wash. Rev. Code Ann. §7.70.050 (West 2005).

West Virginia Adams v. El-Bash, 338 S.E. 2d 381 (W. Va. 1985).

Wisconsin Hannemann v. Boyson, 698 N.W. 2d 714 (Wis. 2005); Wis. Stat. Ann. §448.30 (West 2005).

#### States with other Approaches or not Classified

Kentucky Keel v. St. Elizabeth Medical Ctr., 842 S.W. 2d 860 (Ky. 1992), applying Ky. Rev. Stat. Ann. §304.40-320

(Banks-Baldwin 2005) (physician-based standard with a "reasonable individual [patient]" overlay).

North Carolina Osburn v. Danek Medical, Inc., 520 S.E. 2d 88 (N.C. Ct. App. 1999), applying N.C. Gen. Stat. §90-21.13 (2005)

(physician-based standard with a "reasonable person [patient]" overlay).