CHAPTER 5

Informed Consent

Most who have thought carefully about the issue believe that there is more to the ethics of provider–patient relationships than just a regard for truthfulness and confidentiality. A larger, more complex notion often guides such interactions: **informed consent**. At the simplest level, the term refers to the action of an autonomous, informed person agreeing to submit to medical treatment or experimentation. The idea arises from the intuition that patients, as autonomous persons, should have the ultimate say in what is done to their bodies, that they ought not to be treated without their voluntary, informed agreement. Informed consent, then, is thought to be an ethical ideal in which physicians are obligated to tell patients about possible medical interventions and to respect their choices regarding them. It is also a legal requirement, compelling health care providers to disclose information about interventions to patients and obtain their permission before proceeding. (Requirements of informed consent also apply to researchers and research subjects, as discussed in Chapter 6.) The ethical ideal has often proved difficult to define precisely, to apply in real-life cases, and to embody effectively in laws and policies. But among most health care professionals and many of the patients they serve, there is little doubt about its importance and influence.

AUTONOMY AND CONSENT

Philosophers and other thinkers have justified informed consent through appeals to the principles of autonomy and beneficence. The principle of autonomy tells us that we should respect people's capacity for self-determination. To accept this standard is to reject strong medical paternalism, in which physicians or nurses decide unilaterally what is best for patients. Honoring the principle means letting patients voluntarily choose—even when their choices conflict with medical advice. The principle of beneficence urges physicians and nurses to promote patient welfare, and this goal is thought to be consistent with respecting patient autonomy. Thus, bioethicists argue that informed consent promotes the good for patients because knowledgeable, autonomous patients who choose for themselves will advance their own best interests as they themselves conceive them. They will likely avoid unacceptable risks, protect themselves from abuses, and comply with the demands of their chosen treatment.

The ethical underpinnings of informed consent may be old and revered, but the concept as we know it today is young. Throughout most of medical history, devoted physicians practiced the healing arts while paying little attention to notions of patient self-determination and full disclosure. Beginning in the early twentieth century, judicial rulings began to challenge that approach bit by bit. The 1914 case *Schloendorff v. Society of New York Hospital* made it clear that "every human being of adult years and sound mind has a right to determine what shall be done with his own body," but there was no suggestion that any consent had to be informed.[1] Simple consent was sufficient. Not until 1957 in the California court case *Salgo v. Leland Stanford Junior University Board of Trustees* was the physician's disclosure of information firmly tied to the patient's consent. In a ruling that concocted the term "informed consent," the court

held that "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."[2] In the 1960s other cases went further by identifying the basic features of informed consent: the patient's voluntary consent informed by physicians who have a duty to disclose information about the patient's illness, the proposed treatment, its risks and benefits, and treatment alternatives (including no treatment at all).

These rulings still left many unanswered questions about the legal doctrine, most conspicuous among them being how to judge the adequacy of the physician's disclosure. The prevailing view in the early rulings was that disclosure is adequate if it meets the customary standards of medical practice. Information given to patients is sufficient if the medical profession considers it sufficient. But in the 1970s, courts began to insist that the adequacy of disclosure should be judged by what patients themselves find relevant to their situation. The most influential ruling of this kind came in 1972 in the U.S. Court of Appeals case *Canterbury v. Spence*. "The scope of the physician's communication to the patient, then," says Judge Robinson, "must be measured by the patient's need, and that need is the information material to the decision."[3]

Despite such judicial clarifications (and the enactment of countless statutes and institutional policies), much about informed consent remains unsettled—and unsettling. For one thing, many critics see huge discrepancies between the ethical ideal of informed consent and the laws or rules meant to implement it. They know, for example, that too often a patient can sign a form disclosing treatment risks and thereby, according to local law and institutional policy, grant her informed consent. But she may be neither informed nor autonomous and may not intend to consent to anything. Laws and policies may require physicians merely to warn patients of the risks of treatment, a thin imitation of bona fide informed consent. Some observers also decry the gap between theory and everyday medical practice, contending that physicians view informed consent as a bureaucratic or legalistic burden instead of a way to promote patient self-determination and well-being. As one critic put it, "The idea of physicians making decisions *for*, rather than *with*, patients, is still deeply embedded in the ideology of medical professionalism."[4]

CONDITIONS OF INFORMED CONSENT

Theorists break down informed consent into components believed to be necessary to the concept. Typically, they maintain that an informed consent exists if and only if (1) the patient is *competent* to decide, (2) she gets an adequate *disclosure* of information, (3) she *understands* the information, (4) she decides about the treatment *voluntarily*, and (5) she *consents* to the treatment.[5] This analysis seems straightforward enough, but complications (and controversy) ensue when we try to specify precisely what these conditions entail and to apply them to real-life cases.

As it pertains to informed consent, **competence** is very roughly the ability to render decisions about medical interventions. Individuals who are incompetent in this sense cannot give their informed consent, in which case the burden of decision-making falls to a surrogate (often a court-appointed guardian or a proxy selected through the patient's advance directive). Most of the time, however, people are presumed to be competent unless there are good reasons to think otherwise. Patients are often judged incompetent in cases of intellectual disability, dementia, psychosis, alcoholism, and minority (being underage). But they may also be thought incompetent in less clear-cut situations—when they are overwhelmed by fear or pain, for instance. In addition, they are sometimes considered incompetent because they lack only one or two particular mental capacities—for example, the ability to communicate a decision, to

understand the implications of a choice, to provide reasons, to explain decision-making, or to understand disclosed information. Still, incompetence is not necessarily total, or global; it may be specific to particular aspects of life. A woman who has been legally declared incompetent to handle her personal finances may be fully competent to give her informed consent. A man who has been involuntarily institutionalized for mental illness may still be able to make decisions regarding his medical treatment.

Sometimes a court will formally determine someone to be incompetent. But in most cases, the judicial system never gets involved, and the task of making informal determinations of incompetence goes to physicians (often in consultation with the patient's family).

To give their informed consent, competent patients must receive an adequate disclosure of information from physicians—but what is an adequate disclosure? What kind and amount of information are sufficient? The ethical doctrine of informed consent says that disclosure is adequate if it allows patients to weigh intelligently the risks and benefits of available choices. But how to achieve this ideal in practice is not obvious. Early court decisions suggested that physicians should be the arbiters of adequate disclosure (the physician-based standard); later rulings insisted that adequate disclosure is whatever satisfies the information needs of a hypothetically reasonable person (the patient-based standard); and others called for a subjective standard in which disclosure is supposed to be based on the information needs of a particular patient. But a purely physician-based standard for disclosure would ignore the patient's needs for information relevant to her own personal decisions. The kind of disclosure suitable for a hypothetically reasonable person would probably be very difficult to determine—and might, like the physician-based standard, impose disclosure criteria that have little to do with the information requirements of a particular patient. And an entirely subjective standard naively assumes that patients can always decide for themselves what facts they do and do not need to evaluate treatment options. Some courts have combined these standards, but no configuration of requirements has been entirely true to the spirit of informed consent.

Despite these difficulties, courts and legislatures have generally mandated the disclosure of several pieces of important information:

1. The nature of the procedure (for example, whether it is a test or treatment, whether it is invasive, and how long it will take to perform)
2. The risks of the procedure (what kind of risks are involved, their seriousness, their probability of occurring, and when they might happen)
3. The alternatives to the proposed procedure—including the option of no treatment (includes information on the options' nature, risks, and benefits)
4. The expected benefits of the proposed treatment—including their extent and their likelihood of being achieved

Physicians are not obligated to provide disclosure in all situations; the duty of physicians to obtain informed consent has exceptions. Disclosure is often dispensed with in emergencies when stopping to obtain consent could seriously harm the patient. As suggested earlier, informed consent is not required when a patient is incompetent. Neither is it obligatory in cases of **waiver**, the patient's voluntary and deliberate giving up of the right to informed consent. It is an exercise in autonomous choice—the choice not to choose or decide. Authority to decide medical issues is turned over to the physician or surrogates. A much more controversial exception is **therapeutic privilege**, the withholding of relevant information from a patient when the physician believes disclosure would likely do harm. The idea behind it is that some patients are so distraught, depressed, or weak that disclosure could make their condition worse. Laws regarding therapeutic privilege vary on when invoking it is justified, with some allowing it only when

IN DEPTH
DECISION-MAKING CAPACITY

How can you tell if a patient is competent to make important decisions about her health? This question is not as easy to answer as you might think, and it is often controversial among medical providers. Here is one example of some carefully crafted guidelines.

Assessing for "decision-making capacity" involves determining whether or not a patient or subject is psychologically or legally capable of adequate decision-making. Illness or medications may impair the ability of patients to make decisions about their health—they may be unable to make decisions at all or may make choices that are not in their best interests and may result in serious harm. It is important to remember that this capacity relates to the specific medical decision at hand and does not imply a global ability to make any or all decisions about health care or other matters. Only a court can deem a patient incapable of making global health care decisions. If that is the case, the patient is deemed to lack "competence" and a surrogate is appointed for the patient. Rarely do we need to involve the court or deem someone to lack competence. Instead, we more commonly refer to decision-making capacity as it relates to individual medical decisions.

HOW IS DECISION-MAKING CAPACITY RELEVANT TO MEDICINE?

In order for a patient to make autonomous decisions or to give informed consent to medical treatments or research participation, an individual must have decision-making capacity. The principle of autonomy requires that a physician respect the authority of a patient to make decisions, even when the decisions appear to be unwise. However, beneficence requires that a physician act in the patient's best interest. . . . [S]ometimes tension exists between the principles of autonomy and beneficence, and it can be difficult to determine the best course of action. However, it is important to recognize that autonomy is only possible when the patient possesses the ability to make relevant health decisions. If individuals lack decision-making capability, they may make decisions that are contrary to their best interests and thus need to be protected from harm. If decision-making capacity is intact, the physician generally should respect the patient's choices. If it is impaired, other arrangements can be made for making health decisions on behalf of the patient.

WHAT ARE THE STANDARDS FOR ASSESSING DECISION-MAKING CAPACITY?

The standards for assessing decision-making capacity are somewhat subjective. However, the patient can generally be considered to possess decision-making capacity if:

- The patient makes and communicates a choice regarding medical treatment/course of action.
- The patient appreciates the following information regarding medical care:
  - medical diagnosis and prognosis
  - nature of the recommended care
  - alternative courses of care
  - risks, benefits, and consequences of each alternative.
- The patient makes decisions that are consistent with his/her values and goals.
- The decision is not the result of delusions.
- The patient uses logical reasoning to make a decision.

WHO DECIDES WHETHER A PATIENT HAS DECISION-MAKING CAPACITY?

In medicine, the attending physician is often the one who determines whether a patient is able to make decisions regarding his/her medical care. Sometimes the courts may be involved, but usually this is too time-consuming and unnecessary. Psychiatrists may be consulted, as they have extensive training in dealing with mentally impaired patients and in talking with patients; however, the attending physician is ultimately responsible for determining whether the patient has decision-making capacity.

(*continued*)

HOW DO YOU DETERMINE WHETHER A PATIENT HAS DECISION-MAKING CAPACITY?

- *Does the patient understand disclosed information?*
  - "Tell me what you believe is wrong with your health now."
  - "What will the angiography do for you?"
- *Does the patient appreciate the consequences of his/her choices?*
  - "What do you believe will happen if you do not have the angiography?"
  - "I've described the probable benefits and risks. How do you think your daily activities would be affected if these benefits and risks were to occur?"
- *Does the patient use reasoning to make a choice?*
  - "Tell me how you reached your decision."
  - "Help me understand how you decided to refuse the angiogram."
  - "Tell me what makes angiography seem worse than the alternatives."
- *Talk to the patient's family and friends.*
  - This will help to determine whether the patient's choices are consistent with the patient's values and beliefs. These individuals can also help clarify whether the patient's mental status has changed over time.
- *Mental status examinations.*
  - These tests may be used to evaluate whether the patient is oriented to person, place, and time, attention span, memory function, ability to perform simple calculations, and language skills. However, it is important to remember that these tests do not specifically assess the patient's understanding of the proposed interventions. Individuals with abnormal mental status may be competent to make decisions regarding their health care.
- *Enhance the ability of the patient to make decisions.*
  - Treating underlying medical or psychiatric illnesses may improve the patient's decision-making capacity. Presenting information slowly, in simple language, more than once, and in digestible bits may help patients comprehend the details of their medical conditions and proposed interventions. Having family members present during presentation of information may reduce patient anxiety, help to focus on important points, and correct misunderstandings.

SPECIAL SITUATIONS

- *Mental illness*: Some psychiatric disorders, particularly schizophrenia and depression, can affect a patient's ability to appreciate the relevance of information to his/her situation or to have a rational perspective on treatments. Patients may be involuntarily committed if they pose a danger to self or others. . . . However, involuntary commitment does not give physicians the right to administer treatments without the patient's consent.
- *Religious beliefs*: Patients may make medical decisions on the basis of religious beliefs; this is commonly accepted as a valid reason for refusal of medical treatment. However, it is important to establish that the patient held the same religious beliefs before the treatment and that he/she is not experiencing delusions. In addition, physicians may seek court orders to override parents' refusal of treatment for their children on religious grounds.

HOW ARE DECISIONS MADE FOR PATIENTS WHO LACK DECISION-MAKING CAPACITY?

Once a physician determines that a patient lacks decision-making capacity, the medical community looks to *advance directives* and *surrogate decision-making* to help make medical decisions for the patient.

From Steven Pantilat, "Decision-Making Capacity," *Missing Link*, http://missinglink.ucsf.edu/lm/ethics/index.htm, the Regents, University of California, 2008.

IN DEPTH
TWO VIEWS OF INFORMED CONSENT

While agreeing on the value of informed consent, theorists have differed on its core meaning. For example, some define informed consent as "autonomous authorization," and others seem to equate it with "shared decision-making." Consider these contrasting views:

> [The President's] Commission . . . believes that "shared decisionmaking" is the appropriate ideal for patient-professional relationships that a sound doctrine of informed consent should support. . . . [The doctor–patient interaction] should, at a minimum, provide the patient with a basis for effective participation in sound decisionmaking. . . . It will usually consist of discussions between professional and patient that bring the knowledge, concerns, and perspective of each to the process of seeking agreement on a course of treatment. Simply put, this means that the physician or other health professional invites the patient to participate in a dialogue in which the professional seeks to help the patient understand the medical situation and available courses of action, and the patient conveys his or her concerns and wishes. This does not involve a mechanical recitation of abstruse medical information, but should include disclosures that give the patient an understanding of his or her condition and an appreciation of its consequences.[6]
>
> The idea of informed consent suggests that a patient or subject does more than express agreement with, acquiesce in, yield to, or comply with an arrangement or a proposal. He or she actively *authorizes* the proposal in the act of consent. John may *assent* to a treatment plan without authorizing it. The assent may be a mere submission to the doctor's authoritative order, in which case John does not call on his *own* authority in order to give permission, and thus does not authorize the plan. Instead, he acts like a child who submits, yields, or assents to the school principal's spanking and in no way gives permission for or authorizes the spanking. . . . There is of course an historical relationship in clinical medicine between medical decisionmaking and informed consent. The emergence of the legal doctrine of informed consent was instrumental in drawing attention to issues of decisionmaking as well as authority in the doctor-patient relationship. Nevertheless, it is a confusion to treat informed consent and shared decisionmaking as anything like *synonymous*.[7]

disclosure would be extremely dangerous for the patient or when it would seriously diminish the patient's autonomy. Others permit physicians far more leeway in deciding when to claim the privilege.

Critics worry that too many physicians use therapeutic privilege when they should in fact tell patients the facts and that overuse of it can undo informed consent. In any case, informed consent seems to imply that physicians should not use therapeutic privilege merely to avoid giving patients unpleasant news or to prevent them from rejecting a treatment.

It seems obvious that there can be no informed consent unless patients understand the information disclosed to them (although the law is equivocal on this point). But it is less clear what such understanding amounts to. At a minimum, informed consent seems to require that patients be able to take in the relevant information and assess it well enough to appreciate the consequences of their choices. They need not completely fathom all the information given, but they should comprehend what is most relevant to their decision. And their refusal to submit to a recommended treatment

LEGAL BRIEF

Important Informed Consent Cases

- *Schloendorff v. Society of New York Hospital* (1914)—Justice Cardozo underscored the value of patient self-determination and voluntary consent, declaring that "every human being of adult years and sound mind has a right to determine what shall be done with his body."
- *Salgo v. Leland Stanford Jr. University Board of Trustees* (1957)—The California Supreme Court found that physicians "have the duty to disclose any facts which are necessary to form the basis of an intelligent consent by the patient to proposed treatment."
- *Natanson v. Kline* (1960) and *Mitchell v. Robinson* (1960)—These decisions further specified the information to be conveyed to patients, insisting that the risks involved in a medical procedure should be disclosed.
- *Cobb v. Grant* (1972)—The California Supreme Court held that disclosure must consist of "all information relevant to a meaningful decisional process."
- *Canterbury v. Spence* (1972)—The U.S. Court of Appeals ruled that the adequacy of disclosure by a physician should not be judged by what the medical profession thinks is appropriate but by what information the patient finds relevant to his or her decision.
- *Catalano v. Moreland* (2002)—The Supreme Court of New York held that the adequacy of informed consent cannot be ascertained by merely applying a hospital's bylaws. The court declared, "Thus . . . the reasonableness of defendant's conduct will be measured, not against the Hospital bylaws, but rather against what would have been disclosed by a reasonable medical practitioner."
- *Shinal v. Toms* (2017)—The Pennsylvania Supreme Court ruled, in a 4–3 decision, that informed-consent information that surgeons must provide to their patients about surgical procedures must be delivered to patients in person, not through a nurse or other intermediary.

should not be taken as evidence of a lack of understanding.

Of course, impediments to sufficient understanding abound. It can be deficient if physicians overload the patient with information or frame it in misleading ways (by playing up minimal benefits while playing down significant risks, for instance). The patient's ability to process or appreciate information can be shattered by fear, denial, wishful thinking, magical thinking, and false beliefs. But these problems do not show that acquiring an understanding sufficient for informed consent is impossible—only that it can be difficult and that physicians cannot assume that mere disclosure is enough.

The consent of an informed, competent, understanding patient cannot be legitimate unless it is given voluntarily—that is, freely, without undue (autonomy-robbing) pressure from others. Coercion and manipulation are the most obvious examples of such pressure. Some philosophers have plausibly defined coercion as the intentional use of "a credible and severe threat of harm or force to control another."[8] We might therefore judge a patient to be coerced if her doctor threatens to abandon her unless she submits to treatment, or if he plays on her fear of disability to get her to be more cooperative. Manipulation refers to many noncoercive ways of controlling someone's actions—for example, giving false or misleading information or withholding relevant facts. The use of therapeutic privilege to control a patient's decisions is, of course, manipulative—and corrosive to

informed consent. But note that these forms of undue pressure can come not just from health care providers but also from the patient's family and friends.

Everyday life is filled with social influences on our actions, beliefs, and reasoning. But these pressures are typically not so powerful that they overwhelm our autonomy. Likewise, physicians can influence patients through reasoning, emotional appeals, and authority—yet these pressures are not necessarily undue. In any given case, the line may be difficult to draw between pressures that render consent involuntary and those that do not.

In the ethical ideal, consent is more than assent—more than the patient's giving into the physician's wishes or doing what is expected. As several theorists have insisted, it is a kind of authorization to proceed with a course of action. When a patient authorizes her physician to treat her, she does not merely say yes, but autonomously, knowledgeably decides and *assumes responsibility* for the decision.[9] Actual practice, however, usually falls far short of the ideal, with form-signing and acquiescence substituting for free, informed authorization.

APPLYING MAJOR THEORIES

In what light would the major moral theories have us view informed consent? To ask a more precise question, would they require physicians to obtain informed consent before treating patients? Utilitarianism wants us to judge actions involving informed consent by the overall good they would produce, everyone considered. For an act-utilitarian, this standard must be applied to each individual case, and whether a physician should try to obtain informed consent depends on the benefits generated for all concerned (patient, medical providers, family, and others). There is both good and bad to weigh. Providing relevant information to the patient and seeking her authorization for treatment might reduce her anxiety and depression, increase her compliance and cooperation, enhance her satisfaction with treatment, or encourage her to be actively involved in her own care. But the process might also frighten or confuse her, force her to make decisions that she would rather leave to the physician, prompt her to choose a treatment judged by her physician not to be in her best interests, or take up too much of the physician's time. Forgoing the process altogether might also exact a toll in patient confusion, anxiety, and depression, and there would be the possibility of an erosion of trust between doctor and patient and, in the worst scenarios of mistrust, lawsuits.

So by act-utilitarian lights, in some instances a physician may be obliged to obtain informed consent, but in others she may be justified in ignoring it, even invoking therapeutic privilege. On this view, though informed consent may be frequently used, it is not a moral requirement.

A rule-utilitarian might conclude that the best overall consequences would be achieved if physicians consistently followed a rule requiring informed consent (except in a few extraordinary circumstances). In some cases, adhering to the rule might have worse results than ignoring it, but overall it would produce the greatest good for patients, physicians, nurses, and the medical profession.

The requirement of informed consent can be derived directly from Kantian ethics. As autonomous beings, people are entitled to respect, to be treated as ends in themselves, never merely as a means to an end. They therefore cannot be subjected to medical treatment just because physicians believe it is in their best interests. They must voluntarily consent to be treated, and for the choice to be fully autonomous, they must be informed truthfully about what is involved. To lie to them, withhold relevant information from them, coerce them, or manipulate them is to treat them merely as a means.

From a strictly Kantian viewpoint, therapeutic privilege is never permissible, but waiver is allowed because it represents an autonomous choice not to choose. Some theorists make an

exception to these restrictions if the therapeutic privilege or other manipulative tactic is used to help restore or enhance a person's autonomy.

Rawls's contract theory calls for equal liberties for all, a demand that seems to support the doctrine of informed consent. Treating people without their informed authorization would be a violation of such liberties, and manipulation and coercion to obtain consent would be impermissible. This would be the case even if treating a few patients without informed consent would somehow benefit all of society.

CLASSIC CASE FILE

Jerry Canterbury

How much are physicians obligated to disclose to patients, and by what standard should the adequacy of the disclosure be judged? In 1972 some answers came in the turning-point case *Canterbury v. Spence.*

Nineteen-year-old Jerry Canterbury entered the hospital for tests to determine the cause of the excruciating pain he felt between his shoulder blades. He had been in pain for months, and the prescription medications he had been taking weren't helping. Dr. William Spence ordered a myelogram, an x-ray of the spinal column taken after the column is injected with a traceable dye. After seeing the test results, Dr. Spence told Canterbury that the problem was probably a ruptured disk, and he recommended surgery on the spinal column to correct the problem. Canterbury consented to the procedure.

After the operation, he seemed to be recovering normally, but then he fell in the hospital and became paralyzed from the waist down. He learned later that paralysis was a possible risk of the kind of surgery he had undergone, but Dr. Spence had not mentioned it. Eventually he regained some muscle control but, even years later, needed crutches to walk and suffered from paralysis of the bowels and urinary incontinence.

Canterbury sued Dr. Spence for failure to tell him before the surgery of the risk of paralysis, and the court found in his favor, marking out some tenets of informed consent along the way. The court strongly affirmed the doctrine and the rationale upon which it rests:

> True consent to what happens to one's self is the informed exercise of a choice, and that entails an opportunity to evaluate knowledgeably the options available and the risks attendant upon each. The average patient has little or no understanding of the medical arts, and ordinarily has only his physician to whom he can look for enlightenment with which to reach an intelligent decision. From these almost axiomatic considerations springs the need, and in turn the requirement, of a reasonable divulgence by physician to patient to make such a decision possible. . . . And it is evident that it is normally impossible to obtain a consent worthy of the name unless the physician first elucidates the options and the perils for the patient's edification.[10]

In a departure from most other rulings on informed consent, the court declared that the standard for judging whether a physician's disclosure is acceptable should not be the customary practices of physicians but the patient's requirements for pertinent information. In many situations, the court said, no relevant customary practice may exist, and—more importantly—to let the professional customs of physicians decide is to undermine the patient's right of self-determination. The rights and needs of patients set the bar:

> In our view, the patient's right of self-decision shapes the boundaries of the duty to reveal. That right can be effectively exercised only if the patient possesses enough information to enable an intelligent choice. The scope of the physician's communications to the patient, then, must be measured by the patient's need, and

> that need is the information material to the decision. Thus the test for determining whether a particular peril must be divulged is its materiality to the patient's decision: all risks potentially affecting the decision must be unmasked.[11]

The court characterized the test as what a reasonable person would likely need to know to make an informed decision about a proposed treatment.

Nevertheless, the judges recognized that the physician's invoking of therapeutic privilege (withholding information) is sometimes reasonable and proper. But they rejected "the paternalistic notion that the physician may remain silent simply because divulgence might prompt the patient to forgo therapy the physician feels the patient really needs."[12] Dr. Spence had cited this very notion in his defense.

Some have accused the court of being unclear on the issues of therapeutic privilege and the customary-practice standard of disclosure. But whether or not that's true, *Canterbury v. Spence* helped delineate essential features of the doctrine of informed consent that are now widely accepted. After *Canterbury*, there seemed no going back to the old ideas about disclosure.

KEY TERMS

competence
informed consent
therapeutic privilege
waiver

SUMMARY

Informed consent refers to the action of an autonomous, informed person agreeing to submit to medical treatment or experimentation. It is a powerful notion that thinkers have justified by appealing to the principles of autonomy and beneficence. Court decisions have helped to establish the doctrine in law and society, most notably the case of *Canterbury v. Spence*, which asserted that the adequacy of disclosure by physicians should be judged by what patients think is relevant to their situations.

Theorists maintain that an informed consent exists if and only if (1) the patient is competent to decide, (2) she gets an adequate disclosure of information, (3) she understands the information, (4) she decides about the treatment voluntarily, and (5) she consents to the treatment. Competence is the ability to render decisions about medical interventions. Incompetent patients cannot give their informed consent and must rely on surrogates. What constitutes an adequate disclosure of information to patients is controversial, but the courts have generally ruled that disclosure must include information about the nature of the procedure, its risks, its alternatives (including no treatment), and its expected benefits.

Informed consent is not obligatory in cases of waiver, the patient's voluntary and deliberate giving up of the right to informed consent. It is an exercise in autonomous choice; authority to decide medical issues is turned over to the physician or surrogates. A controversial exception to informed consent is therapeutic privilege, the withholding of relevant information from a patient when the physician believes disclosure would likely do harm. Laws regarding therapeutic privilege vary on when invoking it is justified, with some allowing it only when disclosure would be extremely dangerous for the patient or when it would seriously diminish the patient's autonomy. Others permit physicians far more leeway in deciding when to claim the privilege.

An act-utilitarian would judge whether a physician should try to obtain informed consent according to the benefits generated for all concerned. A rule-utilitarian might conclude that the best overall consequences would be achieved