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INFORMED CONSENT: ITS HISTORY AND MEANING

The practice of obtaining informed consent has its history in medicine and biomedical research, where the disclosure of information and the withholding of information are aspects of the daily encounters between patient and physician, as well as subject and investigator. Although discussions of disclosure and justified nondisclosure have played a role in the history of medical ethics, the term *informed consent* emerged only in the 1950s, and discussions of the concept as it is used today began only around 1972. Concomitantly, a revolution was occurring in standards of appropriate patient–physician interaction. Medical ethics moved from a narrow focus on the physician's or researcher's obligation to disclose information to the quality of a patient's or subject's understanding of information and right to authorize or refuse a biomedical intervention.

HISTORICAL BACKGROUND

Many writers have proposed that managing medical information in encounters with patients is a basic moral responsibility of physicians. Pioneering ventures are found in classic documents in the history of medicine, such as the Hippocratic writings (fifth to fourth century, BC), Percival's *Medical Ethics* (1803), and the first *Code of Ethics* (1846–1847) of the American Medical Association, as well as in the historically significant didactic writings on medical

ethics in the eighteenth and nineteenth centuries, sometimes referred to as the "learned" tradition, comprising discursive study of medical ethics through treatises and books.

These codes and writings present a disappointing history from the perspective of the right to give informed consent. The Hippocratic writings did not hint at obligations of veracity or disclosure, and throughout the ancient, medieval, and early modern periods, medical ethics developed predominantly within the profession of medicine. With few exceptions, no serious consideration was given to issues of either consent or self-determination by patients and research subjects. The central concern was how to make disclosures without harming patients by revealing their condition too abruptly and starkly. The emphasis on the principle "first, do no harm" promoted the idea that a health care professional is obligated not to make disclosures because to do so would be to risk a harmful outcome.

The Eighteenth Century

Benjamin Rush and John Gregory have sometimes been acknowledged for their enlightenment-inspired views about disclosure and public education in the eighteenth century. However, neither was advocating informed consent. They wanted patients to be sufficiently educated so that they could understand their physician's recommendations and therefore be motivated to comply. They were not optimistic that patients would form their own opinions and make appropriate medical choices. For example, Rush advised physicians to "yield to them [patients] in matters of little consequence, but maintain an inflexible Authority over them in matters that are essential to life" (Rush, 1786, 323). Gregory underscored that the physician must be keenly aware of the harm that untimely revelations might cause. There is no assertion of the importance of respecting rights of self-determination for patients or of obtaining consent for any purpose other than a medically good outcome (Gregory, 1772). Gregory and Rush appreciated the value of information and dialogue from the patient's point of view, but the idea of informed consent was not foreshadowed in their writings.

The Nineteenth Century

Thomas *Percival's* historic *Medical Ethics* (1803) stands in this same tradition. It makes no more mention of consent solicitation and respect for decision making by patients than had previous codes and treatises. Percival did struggle with the

issue of truth telling, but he held that the patient's right to the truth must yield in the face of an obligation to benefit the patient in cases of conflict—a benevolent deception. Percival maintained that

> to a patient . . . who makes inquiries which, if faithfully answered, might prove fatal to him, it would be a gross and unfeeling wrong to reveal the truth. His right to it is suspended, and even annihilated; because, its beneficial nature being reversed, it would be deeply injurious to himself, to his family, and to the public. And he has the strongest claim, from the trust reposed in his physician, as well as from the common principles of humanity, to be guarded against whatever would be detrimental to him. . . . The only point at issue is, whether the practitioner shall sacrifice that delicate sense of veracity, which is so ornamental to, and indeed forms a characteristic excellence of the virtuous man, to this claim of professional justice and social duty (Percival, 1803, 165–166).

Percival was struggling against the arguments of his friend, the Rev. Thomas Gisborne, who opposed practices of giving false assertions intended to raise patients' hopes and lying for the patient's benefit: "The physician . . . is invariably bound never to represent the uncertainty or danger as less than he actually believes it to be" (Gisborne, 1794, 401). From Percival's perspective, the physician does not lie or act improperly in beneficent acts of deception and falsehood as long as the objective is to give hope to the dejected or sick patient.

The American Medical Association (AMA) accepted virtually without modification the Percival paradigm in its 1847 Code (American Medical Association, 1847, 94). Many passages in Percival appear almost verbatim in this Code (AMA, 1847, "Code of Medical Ethics," see esp. Ch. I, Art. I, sect. 4). This Code, as well as most codes of medical ethics before and after, does not include rules of veracity. For more than a century thereafter, American and British medical ethics remained fundamentally under Percival's vision.

There was, however, a notable nineteenth-century exception to the consensus that surrounded Percival's recommendations. Connecticut physician Worthington Hooker was the first champion of the rights of patients to information, in opposition to the model of benevolent deception that had reigned from Hippocrates to the AMA. He and Harvard Professor of Medicine Richard Clarke Cabot may have been the only physician champions of this model prior to the second half of the twentieth century. Moreover, there may never have been a figure who swam, in regard to truth telling, so against the stream of indigenous medical tradition as Hooker.

Hooker's arguments are novel and ingenious, but do not amount to a recommendation of informed consent. Hooker was concerned with "the

general effect of deception" on society and on medical institutions. He thought the effect disastrous. But no more in Hooker than in the AMA Code is there a recommendation to obtain the permission of patients or to respect autonomy for the sake of autonomy. Hooker's concerns were with expediency in disclosure and truth telling rather than with the promotion of autonomous decision making or informed consent. The idea that patients should be enabled to understand their situation so that they are able to participate with physicians in decisions about medical treatment was an idea whose time had yet to come (Hooker, 1859).

Although the nineteenth century saw no hint of a rule or practice of informed consent in clinical medicine, consent procedures were not entirely absent. Evidence exists in surgery records that consent seeking and rudimentary rules for obtaining consent existed since at least the middle of the nineteenth century (Pernick, 1982). However, the consents obtained do not appear to have been meaningful by standards of informed consent, as they had little to do with the patient's right to decide after being informed. Practices of obtaining consent in surgery prior to the 1950s were pragmatic responses to a combination of concerns about medical reputation, malpractice suits, and practicality in medical institutions. It is physically difficult and interpersonally awkward to perform surgery on a patient without obtaining the patient's permission. Such practices of obtaining permission, however, did not constitute practices of obtaining informed consent, although they did provide a modest nineteenth-century grounding for this twentieth-century concept.

The situation is similar in research involving human subjects. Little evidence exists that, until recently, requirements of informed consent had a significant hold on the practice of investigators. In the nineteenth century, for example, it was common for research to be conducted on slaves and servants without consent on the part of the subject. By contrast, at the turn of the century, American Army surgeon Walter Reed's yellow fever experiments involved formal procedures for obtaining the consent of potential subjects. Although deficient by contemporary standards of disclosure and consent, these procedures recognized the right of the individual to refuse or authorize participation in the research. The extent to which this principle became ingrained in the ethics of research by the mid-twentieth century remains a matter of historical controversy.

Although it has often been reported that the obtaining of informed and voluntary consent was essential to the ethics of research and was commonplace in biomedical investigation, it is unclear that consent seeking on the part of investigators was standard practice. Anecdotal evidence suggests that biomedical research often proceeded without adequate consent at least into the 1960s (Faden & Beauchamp, 1986).

Early Twentieth-Century Legal History

The legal history of disclosure obligations and rights of self-determination for patients evolved gradually. In the doctrine of legal precedent, each decision, relying on earlier court opinions, joins a chain of authority that incorporates the relevant language and reasoning from the cited cases. In this way, a few early consent cases built on each other to produce a legal doctrine. The best known and ultimately the most influential of these early cases is *Schloendorff v. Society of New York Hospitals* (1914). *Schloendorff* used rights of "self-determination" to justify imposing an obligation to obtain a patient's consent. Subsequent cases that followed and relied upon *Schloendorff* implicitly adopted its reasoning. In this way, "self-determination" came to be the primary justification for legal requirements that consent be obtained from patients.

In the early twentieth century, the behavior of physicians was often egregious in the neglect of consent, and courts did not shrink from using ringing language and sweeping principles to denounce it. The same language was then applied as precedent in later cases in which physicians' behavior was less outrageous. As the informed consent doctrine developed and problems grew more subtle, the law could have turned away from the language of self-determination, but instead increasingly relied on this rationale as its fundamental premise. The language in the early cases suggests that rights of freedom from bodily invasion contain rights of medical decision making by patients.

The 1950s and 1960s

During the 1950s and 1960s, the traditional duty to obtain consent evolved into a new, explicit duty to disclose certain forms of information and then to obtain consent. This development needed a new term, and so "informed" was tacked onto "consent," creating the expression "informed consent," in the landmark decision in *Salgo* v. *Leland Stanford, Jr. University Board of Trustees* (1957). The *Salgo* court suggested, without accompanying analysis, that the duty to disclose the *risks and alternatives* of treatment was not a new duty, but a logical extension of the already established duty to disclose the treatment's *nature and consequences*. Nonetheless, *Salgo* clearly introduced new elements into the law. The *Salgo* court was not interested merely in whether a recognizable consent had been given to the proposed procedures. The *Salgo* court latched tenaciously onto the problem of whether the consent had been adequately informed. The court thus created the language and the substance of informed consent by invoking the same right of self-determination that had heretofore applied to a less robust consent requirement.

Shortly thereafter, two opinions by the Kansas Supreme Court in the case of *Natanson* v. *Kline* (1960) pioneered the use of negligence in informed consent cases, rather than using battery. The court established the duty of disclosure as the obligation "to disclose and explain to the patient in language as simple as necessary the nature of the ailment, the nature of the proposed treatment, the probability of success or of alternatives, and perhaps the risks of unfortunate results and unforeseen conditions within the body." Thus, the *Natanson* court required essentially the same extensive disclosure—of the nature, consequences, risks, and alternatives of a proposed procedure—as had *Salgo*.

Not surprisingly, the number of articles in the medical literature on issues of consent increased substantially following this and other precedent legal cases. Typically written by lawyers, these articles functioned to alert physicians both to "informed consent" as a new legal development and to potential malpractice risk. How physicians reacted to these legal developments in the 1950s and 1960s is not well documented, but some empirical studies of informed consent in clinical medicine provide insights. A study done in the early to mid-1960s, conducted by the lawyer–surgeon team of Nathan Hershey and Stanley H. Bushkoff, indicates that a preoperative *consent form* was not yet a ubiquitous feature of the practice of surgery. As part of their study, Hershey and Bushkoff required that cooperating surgeons complete a "fill-in-the-blank" consent form for each of their patients. However, surgeons at several hospitals objected to the study because they were not currently using *any* kind of consent form for surgery. In the end, only 10 surgeons, representing but 3 hospitals, participated in the study. Together, these surgeons provided data on "informed consent" in 256 surgical cases. From this limited sample, Hershey and Bushkoff inferred that a consistent standard of disclosure existed among the surgeons studied and that this standard included a description of the operative procedure and its attendant risks and consequences (Hershey & Bushkoff, 1969).

Indifference to consent procedures seems to have begun to change by the late 1960s, when most physicians appear to have recognized some moral and legal duty to obtain consent for certain procedures and to provide some kind of disclosure. There is also evidence, however, that physicians' views about proper consent practices even in the late 1960s differed markedly from the consensus of opinion and convention that would begin to be fixed only 10 years later. For example, in one study, half of the physicians surveyed thought it medically proper, and 30% ethically proper, for a physician to perform a mastectomy with no authorization from the patient other than her signature on the blanket consent form required for hospital admission. Also, more than half of the physicians thought that it was ethically appropriate for a physician not to tell a cancer patient that she had been enrolled in a double-blind clinical trial of an experimental anticancer drug (Hagman, 1970).

An explosion of commentary on informed consent emerged in the medical literature of the early 1970s, but much of this commentary was negative: Physicians saw the demands of informed consent as impossible to fulfill and, at least in some cases, inconsistent with good patient care. Nonetheless, empirical studies conducted at the time suggest that there was at least enough documentable consent seeking in such areas as surgery, organ donation, and angiography to warrant empirical investigation. During this period, the procedure-specific consent form was gaining acceptance, although it was not yet universally in use. Whether in the 1960s physicians generally regarded informed consent as a legal nuisance or as an important moral problem is unclear (Faden & Beauchamp, 1986).

The histories of informed consent in research and in clinical medicine were at this time developing largely as separate pieces in a larger mosaic of biomedical ethics. These pieces have never been well integrated even when they developed simultaneously. Research ethics prior to World War II was no more influential on research practices than the parallel history of clinical medicine was on clinical practices. But events that unquestionably influenced thought about informed consent occurred at the Nuremberg trials. The Nuremberg Military Tribunals unambiguously condemned the sinister political motivation of Nazi experiments. A list of 10 principles constituted the Nuremberg Code. Principle One of the code states, without qualification, that the primary consideration in research is the subject's voluntary consent, which is "absolutely essential" (*United States* v. *Karl Brandt*, 1947).

The Nuremberg Code served as a model for some professional and governmental Codes formulated in the 1950s and 1960s. During this period, several additional incidents involving consent violations moved the discussion of Post-Nuremberg problems into the public arena. Thus began a rich and complex interplay of influences on research ethics: scholarly publications, journalism, public outrage, legislation, and case law. In the United States, one of the first incidents to achieve notoriety in research ethics involved a study conducted at the Jewish Chronic Disease Hospital (JCDH) in Brooklyn, New York. In July 1963, Dr. Chester Southam of the Sloan-Kettering Institute for Cancer Research persuaded the hospital's medical director, Emmanuel E. Mandel, to permit research involving injection of a suspension of foreign, live cancer cells into 22 patients at the JCDH. The objective was to discover whether a decline in the body's capacity to reject cancer transplants was caused by their cancer or by debilitation. Patients without cancer were needed to supply the answer. Southam had convinced Mandel that although the research was nontherapeutic, such research was routinely done without consent. Some patients were informed orally that they were involved in an experiment, but it was not disclosed that they were being given injections of *cancer* cells. No written consent was attempted, and some subjects were incompetent to give informed consent. In 1966, the Board of Regents of the State University of New York censured Drs. Southam and Mandel for their role in the research. They were found guilty of fraud, deceit, and unprofessional conduct (*Hyman v. Jewish Chronic Disease Hospital*, 1965).

Another major controversy about the ethics of research in the United States developed at Willowbrook State School, an institution for "mentally defective" children on Staten Island, New York. Beginning in 1956, Saul Krugman and his associates began a series of experiments to develop an effective prophylactic agent for infectious hepatitis. They deliberately infected newly admitted patients with isolated strains of the virus based on parental consents obtained under controversial circumstances that may have been manipulative. The issues in the Willowbrook case are more complex than those in the Jewish Chronic Disease Hospital case, and still today there are those who defend, at least in part, the ethics of these experiments. Krugman's research unit was eventually closed, but closure on the debate about the ethics of the studies conducted in the unit was never achieved (*Proceedings of the Symposium on Ethical Issues in Human Experimentation*, 1972).

The most notorious case of prolonged and knowing violation of subjects' rights in the United States was a Public Health Service (PHS) study initiated in the early 1930s. Originally designed as one of the first syphilis control demonstrations in the United States, the stated purpose of the Tuskegee Study, as it is now called, was to compare the health and longevity of an untreated syphilitic population with a nonsyphilitic but otherwise similar population. These subjects, all African American males, knew neither the name nor the nature of their disease. Their participation in a nontherapeutic experiment also went undisclosed. They were informed only that they were receiving free treatment for "bad blood," a term local African Americans associated with a host of unrelated ailments, but which the white physicians allegedly assumed was a local euphemism for syphilis (Jones, 1993).

It was remarkable that, although this study was reviewed several times between 1932 and 1970 by PHS officials and medical societies, and reported in 13 articles in prestigious medical and public health journals, it continued uninterrupted and without serious challenge. It was not until 1972 that the Department of Health, Education, and Welfare (DHEW) appointed an ad hoc advisory panel to review the study and the department's policies and procedures for the protection of human subjects. The panel found that neither the DHEW nor any other government agency had a uniform or adequate policy for reviewing experimental procedures or securing subjects' consents.

The 1970s and 1980s

These events do not, of course, explain why informed consent became the focus of so much attention in both case law and biomedical ethics. Many hypotheses can be invoked to explain these developments. The most likely explanation is that law,

ethics, and medicine were all affected by issues and concerns in the wider society regarding individual liberties and social equality. These issues were made dramatic by an increasingly technological, powerful, and impersonal medical care. The issues raised by civil rights, women's rights, the consumer movement, and the rights of prisoners and the mentally ill often included health care components and helped reinforce public acceptance of rights applied to health care. Informed consent was swept along with this body of social concerns, which propelled the new bioethics throughout the 1970s.

Three 1972 court decisions stand as informed consent landmarks: *Canterbury v. Spence, Cobbs v. Grant, and Wilkinson v. Vesey*. *Canterbury* had a particularly massive influence in demanding a more patient-oriented standard of disclosure. In *Canterbury*, surgery on the patient's back and a subsequent accident in the hospital led to further injuries and unexpected paralysis, the possibility of which had not yet been disclosed. Judge Spottswood Robinson's opinion focuses on the needs of the reasonable person and the right to self-determination. As for sufficiency of information, the court holds: "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."

Among the most important publications in the medical literature to appear during this period was a statement by the Judicial Council of the American Medical Association in 1981. For the first time, the AMA recognized informed consent as "a basic social policy" necessary to enable patients to make their own choices, even if their physician disagrees. The AMA's statement is a testament to the impact of the law of informed consent on medical ethics. The AMA's position roughly followed the language of *Canterbury v. Spence*.

The President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research provides further evidence about the status informed consent had achieved in the 1970s and early 1980s. The President's Commission was first convened in January 1980, with informed consent as a main item on its agenda. In 1982, it produced one three-volume report that dealt directly with informed consent: *Making Health Care Decisions: The Ethical and Legal Implications of Informed Consent in the Patient-Practitioner Relationship*. The President's Commission argued that although informed consent had emerged primarily from a history in law, its requirements are essentially moral and policy oriented. It held that informed consent is based on the principle that competent persons are entitled to make their own decisions from their own values and goals, but that the context of informed consent and any claim of "valid consent" must derive from active, shared decision making. The principle of self-determination was described as the "bedrock" of the President's Commission's viewpoint.

The 1980s saw the publication of several books devoted to the subject of informed consent, as well as hundreds of journal articles and the passage of

procedure-specific, informed consent laws and regulations. These events give testimony to the importance of informed consent in moral and legal thinking about medicine in the United States. By themselves, however, they tell us little about physicians' or researchers' actual consent practices or opinions, or about how informed consent was viewed or experienced by patients and subjects.

As might be expected, the empirical evidence on this subject during the 1980s is mixed, although it is clear that procedures of informed consent had taken a firm hold in some parts of medical practice. For example, routine practice encouraged the obtaining of signatures on consent forms and the disclosing of information about alternative treatments, risks, and benefits. The best data on this subject are the findings of a national survey conducted for the President's Commission by Louis Harris and Associates in 1982. Almost all of the physicians surveyed indicated that they obtained written consent from their patients before inpatient surgery or the administration of general anesthesia. At least 85% said they usually obtained some kind of consent—written or oral—for minor office surgery, setting of fractures, local anesthesia, invasive diagnostic procedures, and radiation therapy. Only blood tests and prescriptions appear to have proceeded frequently without patient consent, although about half of the physicians reported obtaining oral consent.

The overall impression conveyed by this survey is that the explosion of interest in informed consent in the 1970s had a powerful impact on medical practice. However, evidence from the Harris survey and other sources raises questions about the quality and meaningfulness of this consent-related activity. The overwhelming impression from the empirical literature and from reported clinical experience is that the actual process of soliciting informed consent often fell short of a serious show of respect for the decisional authority of patients. As the authors of one empirical study of physician–patient interactions put it, "despite the doctrine of informed consent, it is the physician, and not the patient, who, in effect, makes the treatment decision" (Siminoff & Fetting, 1991, 817).

The history of informed consent, then, indicates that medicine has undergone widespread changes under the influence of legal and moral requirements of informed consent, but it also reminds us that informed consent is an evolving process, not a set of events whose history has passed.

THE CONCEPT AND ELEMENTS OF INFORMED CONSENT

Informed consent began to play a central role in clinical and research ethics when problems of the autonomy of subjects gradually grew more insistent in twentieth-century practice and research, and when the idea of respecting autonomy gained equal recognition as a form of justification for protecting against risk. The practice of obtaining consent is a social phenomenon, and no analysis of the

concept of informed consent will succeed if it ignores the contexts in which informed consent arose. Considerable vagueness has attended the term *informed consent* in these contexts, leaving a need to sharpen the concept.

Presumptions About the Concept

The claim that something is an informed consent or that an informed consent has been obtained cannot always be taken at face value. Before we can confidently infer that what appears to have been or was called an "informed consent" is a bona fide instance of informed consent, we need to know what to look for. This inquiry requires criteria of what will qualify for the label "informed consent."

If overdemanding criteria such as "full disclosure and complete understanding" are adopted, an informed consent becomes impossible to obtain. Conversely, if underdemanding criteria such as "the patient signed the form" are used, an informed consent becomes too easy to obtain and the term loses all moral significance. Many interactions between a physician and a patient or an investigator and a subject that have been called informed consents have been so labeled only because they rest on underdemanding criteria; they are inappropriately referred to as informed consents. For example, a physician's truthful disclosure to a patient has often been declared the essence of informed consent, as if a patient's silence following disclosure could add up to an informed consent. The existence of such inadequate understandings of informed consent can be explained in part by empirical information about physicians' beliefs concerning informed consent.

Contemporary Presumptions in Medicine

Some data about the meaning of informed consent are found in the aforementioned survey of physicians conducted by Louis Harris (Harris, in President's Commission, 1982, 302), which asked physicians, "What does the term informed consent mean to you?" In their answers, only 26% of physicians indicated that informed consent had anything to do with a patient giving permission, consenting, or agreeing to treatment; only 9% indicated that it involved the patient making a choice or stating a preference about his or her treatment. Similar results have been found in recent surveys of Japanese physicians' beliefs about informed consent (Hattori, 1991; Kai, 1993; Mizushima, 1990; Takahashi, 1990).

Like lawyers and courts, the overwhelming majority of these doctors appeared to recognize only disclosure as the criterion of "informed consent." That is, they view informed consent as explaining to a patient the nature of his or her medical condition together with a recommended treatment plan. But if physicians regard informed consent as nothing more than an event of conveying information to patients, rather than a process of discussion and obtaining permission from the patient, then claims that they regularly "obtain consents" from their patients before initiating medical procedures are vague and unreliable unless we know in some detail about the procedures used.

Matters may be worse than they appear: Perhaps all these physicians understand by "informed consent" is that the patient's signature has been obtained, or perhaps they mean only that some kind of disclosure has been made. This interpretation fits with the results of several studies of informed consent that have failed to find any sizeable evidence of "informed consent" in clinical medicine and that have found little evidence that the consents being obtained are meaningful exercises of informed choice by patients (Quaid, 1990, 249–259; Scherer & Reppucci, 1988, 123–141; Siminoff & Fetting, 1991, 813–818; Siminoff, Fetting, & Abeloff, 1989, 1192–1200).

The Authority of Oaths, Codes, and Treatises

Similar problems exist regarding what can be reasonably inferred from oaths, prayers, Codes of ethics, published lectures, and general pamphlets and treatises on medical conduct, usually written by individual physicians or medical societies for their colleagues. In the absence of more direct data about actual consent practices, these documents have been relied on heavily in writings on informed consent as sources that provide information about the history of informed consent and related matters of clinical medical ethics. However, it is often difficult to determine whether the statements that appear in these documents are primarily exhortatory, descriptive, or self-protective. Some writings describe, for educational purposes, conduct that was in accordance with prevailing professional standards. Other documents aim at reforming professional conduct by prescribing what should be established practice. Still others seem constructed to protect the physician from suspicions of misconduct or from legal liability.

The Elements of Informed Consent

Legal, philosophical, regulatory, medical, and psychological literatures have often tried to define or analyze informed consent in terms of its "elements." The following elements have been widely mentioned as fundamental to the concept: (1) disclosure, (2) comprehension, (3) voluntariness, (4) competence, and (5) consent (Levine, 1978, 3–9; Meisel & Roth, 1981; National Commission, 1978, 10). The

postulate is that a person gives an informed consent to an intervention if and only if the person is competent to act, receives a thorough disclosure about the procedure, comprehends the disclosed information, acts voluntarily, and consents.

This definition is attractive because of its consistency with standard usage of the term *informed consent* in medicine and law. However, medical convention and malpractice law tend to distort the meaning of informed consent in ways that need correction. Analyses using the aforementioned five elements, as well as conventional usage in law and medicine, are best suited for cataloging the analytical *parts* of informed consent and for delineating moral and legal *requirements* of informed consent, not for conceptually analyzing the *meaning* of "informed consent." Neither requirements nor parts amount to a *definition*.

To take but one instance of the potential bias at work in this form of definition, the U.S. Supreme Court addressed the definition of informed consent in *Planned Parenthood of Central Missouri v. Danforth* as follows: "One might well wonder . . . what 'informed consent' of a patient is. . . . We are content to accept, as the meaning [of informed consent], the giving of information to the patient as to just what would be done and as to its consequences" (1976, 67, *n.* 8). The exclusive element of informed consent here is *disclosure*, which recalls the assumptions made by physicians in the Harris poll. However, nothing about an informed consent requires disclosure as part of its *meaning*. A patient or subject already knowledgeable about a proposed intervention could give a thorough informed consent without having received a disclosure from a second party. Similarly, other conditions in the aforementioned list of conditions are not necessary. For example, persons who are legally incompetent (see element 4) sometimes give informed consents, and in some instances even psychologically incompetent persons (also often the referent of element 4) may be able to consent meaningfully to or refuse a particular intervention. These norms delineate an *obligation to make disclosures* so that a consent can be informed, rather than a *meaning of informed consent*. Even all five of these elements merged as a set do not satisfactorily capture the meaning of "informed consent."

The following seven categories express the analytical components of informed consent more adequately than the aforementioned five categories, but this sevenfold list still does not adequately express the *meaning* of "informed consent" (Beauchamp & Childress, 1994):

I. **Threshold elements (preconditions)**
   1. Competence (to understand and decide)
   2. Voluntariness (in deciding)

II. **Information elements**
   3. Disclosure (of material information)
   4. Recommendation (of a plan)
   5. Understanding (of elements 3 and 4)

III. **Consent elements**
   6. Decision (in favor of a plan)
   7. Authorization (of the chosen plan)

The language of "material information" in element 3 is pivotal for an adequate analysis of the elements of disclosure (element 3) and understanding (element 5). Critics of legal requirements of informed consent have often held that procedures sometimes have so many risks and benefits that they cannot be disclosed and explained, but "material risks" are simply the risks a reasonable patient needs to understand in order to decide among the alternatives. Only these risks and benefits need to be disclosed and understood.

Informed consent *requirements* can be constructed to correspond to each of the aforementioned *elements*. That is, specific disclosure requirements, comprehension requirements, noninfluence requirements, competence requirements, authorization requirements, and the like can be fashioned. These requirements would specify the conditions that must be satisfied for a consent to be *valid*, but they may not provide an adequate analysis of the meaning of "informed consent."

Two Meanings of "Informed Consent"

The question "What is an informed consent?" is complicated because at least two common, entrenched, and irreducibly different meanings of "informed consent" have been at work in its history. That is, the term is analyzable in different ways because different conceptions of informed consent have emerged. In one sense, an informed consent is an *autonomous authorization* by individual patients or subjects. In the second sense, informed consent is analyzable in terms of *institutional and policy rules of consent* that collectively form the social practice of informed consent in institutional contexts (Faden & Beauchamp 1986, 276–287).

In the first meaning, an *autonomous authorization* requires more than merely acquiescing in, yielding to, or complying with an arrangement or a proposal made by a physician or investigator. A person gives an informed consent in this first sense if and only if the person, with substantial understanding and in substantial absence of control by others, intentionally authorizes a health professional to do something. A person who intentionally refuses to authorize an intervention, but otherwise satisfies these conditions, gives an *informed refusal*. This first sense

derives from philosophical premises that informed consent is fundamentally a matter of protecting and enabling autonomous or self-determining choice.

In the second meaning, "informed consent" refers only to a legally or institutionally effective approval given by a patient or subject. An approval is therefore "effective" or "valid" if it conforms to the rules that govern specific institutions, whatever the operative rules may be. In this sense, unlike the first, conditions and requirements of informed consent are relative to a social and institutional context and need not be autonomous authorizations. This meaning is driven by demands in the legal and health care systems for a generally applicable and efficient consent mechanism by which responsibilities and violations can be readily and fairly assessed.

Under these two contrasting understandings of "informed consent," a patient or subject can give an informed consent in the first sense, but not in the second sense, and vice versa. For example, if the person consenting is a minor and therefore not of legal age, he or she cannot give an effective or valid consent under the prevailing institutional rules; a consent is invalid even if the minor gives the consent autonomously and responsibly. ("Mature minor" laws do sometimes make an exception and give minors the right to authorize medical treatments in a limited range of circumstances.)

"Informed consent" in the second sense, as institutional consent, has until very recently constituted the mainstream conception in the regulatory rules of federal agencies as well as in health care institutions. The documents governing consent in these contexts derive from a conception of what the rules must be in order to promote effective authorizations in these institutions, but the rules were only rarely premised on a conception of autonomous authorization that had more than a superficial quality. However, literature in bioethics has increasingly suggested that any justifiable analysis of informed consent must be rooted in autonomous choice by patients and subjects.

In principle, although less clearly in practice, the conditions of informed consent as autonomous authorization can function as model standards for fashioning the institutional and policy requirements of informed consent—a model of autonomous choice thus serving as the benchmark against which the moral adequacy of prevailing rules and practices might be evaluated.

Autonomous Choice

It has often been said that the justification of requirements of informed consent (in the first sense at least) is the principle of respect for autonomy. However, the goal of ensuring that persons make "autonomous choices" has proved to be difficult to implement. Historically, little more can be said beyond the fact that a clear societal consensus has developed that there must be adequate protection of patients' and subjects' decision-making rights, especially their autonomy rights. We therefore need to examine the meaning of "autonomy" in addition to the meaning of "informed consent."

In the literature on informed consent, "autonomy" and "respect for autonomy" are terms loosely associated with several ideas, such as privacy, voluntariness, self-mastery, choosing freely, the freedom to choose, choosing one's own moral position, and accepting responsibility for one's choices. Because of this conceptual uncertainty, the concept of autonomy and its connection to informed consent need careful analysis.

In moral philosophy, personal autonomy has come to refer to personal self-governance: personal rule of the self by adequate understanding while remaining free from controlling interferences by others and from personal limitations that prevent choice. Many issues about consent concern failures to respect autonomy, ranging from manipulative underdisclosure of pertinent information to nonrecognition of a refusal of medical interventions. To respect an autonomous agent is to recognize with due appreciation the person's capacities and perspective, including his or her right to hold certain views and to take certain actions based on personal values and beliefs. Accordingly, an informed consent based on an autonomous authorization suggests a well-informed agent with the competence to authorize or refuse authorization of a medical or research intervention.

It has sometimes been claimed that informed consent, so understood, has a mythical quality, because true informed consent is never obtained under such a high ideal. The idea is that most patients and subjects cannot comprehend enough information or appreciate its relevance sufficiently to make decisions about medical care or about participation in research. This objection, however, springs from a misunderstanding of the nature and goals of informed consent, based in part on unwarranted standards of full disclosure and full understanding. The ideal of complete disclosure of all possibly relevant knowledge needs to be replaced by a more acceptable account of how patients and subjects understand relevant information. Merely because our actions fail to be fully informed, voluntary, or autonomous is no indication that they are never adequately informed or autonomous. We would never autonomously sign contracts, have automobiles repaired, file income-tax returns, and the like if this were the case.

This argument does not deny that some individuals have a knowledge base that is so impoverished that autonomous decision making about alien or novel situations is exceedingly difficult, but even under difficult situations there may be no reason to foreclose the possibility of making an adequate decision. Successful communication of novel, alien, and specialized information to laypersons can be accomplished by drawing analogies between the information and more ordinary events with which the patient or subject is familiar. Similarly, professionals can

express probabilities in both numeric and nonnumeric terms while helping the patient or subject to assign meanings to the probabilities through comparison with more familiar risks and prior experiences.

THE LAW AND ITS LIMITS

The law of informed consent has been more influential as an authoritative set of statements and source of reflection than any other body of thought on the subject. "The doctrine of informed consent," as it is sometimes called, *is* the legal doctrine; and "informed consent" has often been treated as synonymous with this legal doctrine, which derives from the common law and includes the entire body of law dealing with the obligation to obtain consent. This legal vision is focused on *disclosure* and on *liability for injury*. There are good reasons, as we shall now see, why the law turns on such a narrow basis and also why it is ill-equipped to serve beyond these boundaries.

Theory of Liability

The primary basis for the legal doctrine is tort law. A "tort" is a civil injury to one's person or property that is inflicted by another and that is measured in terms of, and compensated by, money damages. This law imposes duties on members of society, and one who fails to fulfill a legal duty is liable for compensation for the misdeed (in the civil law). The theory of liability under which a case is tried determines the duty that must be fulfilled. In recent informed consent cases, negligence is the theory of liability almost uniformly applied. However, the informed consent doctrine originally developed and flourished under battery, which is a different theory of liability. Currently, no unified legal theory underlies all informed consent cases.

Under battery theory, the defendant is held liable for any intended (i.e., not careless or accidental) action that results in physical contact for which the plaintiff has given no permission. A defendant need not have an evil intent, nor must injury result; the unpermitted contact is itself considered wrongful. Under negligence theory, by contrast, unintentional, "careless" action or omission is the source of liability. The carelessness occurs in regard to some activity in which the defendant has a duty to take care or to behave reasonably toward others, and an injury measurable in monetary terms is caused by failure to discharge the duty (*Berkey*, 1969; Meisel, 1977; *Schloendorff*, 1914).

The Duty of Disclosure

Two competing disclosure standards have evolved as attempts to resolve problems regarding the nature and amount of the information that must be disclosed: the professional practice standard and the reasonable person standard. A third standard, the subjective standard, has also been discussed in legal commentary. The professional practice standard holds that both the range of the duty to disclose and the criteria of adequate disclosure are properly determined by the customary practices of a professional community. These practices establish the standards of care for disclosure and care alike. The patient, subject, or reasonable person lacking expert knowledge is considered unqualified to decide what should be disclosed.

Although the professional practice standard remains the primary standard in informed consent law, it contains inadequacies and it may be doubted whether a customary standard of disclosure exists for much of medical practice. A basic problem is that negligent care might be perpetuated if relevant professionals throughout the profession offer inferior information, and another doubtful premise is that physicians have sufficient expertise to be able to judge in many cases which items of *information* their patients need. However, the principal objection to this standard is its failure to promote decisional autonomy, the protection of which is generally accepted as the primary function and moral justification of informed consent requirements.

In contrast to the professional practice standard, the reasonable person standard focuses on the information a "reasonable person" needs to know about procedures, risks, alternatives, and consequences. The legal test of an adequate disclosure is the "materiality," or significance, of information to the decision making of the patient. Thus, the right to decide what information is material and due is shifted away from the physician to the reasonable patient. The reasonable person standard requires a physician to divulge any fact that is material to a reasonable person's decision, but no requirement exists to meet the unreasonable demand of a patient.

This reasonable person standard is as vulnerable to criticism as the professional-based standard. It can be doubted whether the reasonable person standard serves the interests of those patients who know little about either their informational needs or the medical system. The interpretation of the standard for clinical practice is also difficult, because it specifies no precise duty for physicians. Both the concept of material information and the central concept of the reasonable person are left at an intuitive level. It can therefore be doubted whether the reasonable person standard more adequately protects the patient's right to choose than does the professional practice standard.

These arguments are not intended to eliminate standards of disclosure. In the absence of a disclosure initiated by a professional, patients or subjects often cannot

formulate their concerns and ask meaningful questions. A patient or subject needs to understand what an informed professional judges to be of value for most patients or subjects as material information, and what it means for consent to be an authorization to proceed. The problem is not whether we need adequate disclosures but whether a legal vehicle can be expected to provide an adequate standard of disclosure for clinical practice and research settings. I shall return to this issue under the discussion of "the quality of consent."

The larger problem with these standards is that they will not be of major assistance in formulating a conception of informed consent for clinical medicine and research. Because courts are captivated by the context of after-the-fact resolution of narrow and concrete questions of duty, responsibility, blame, injury, and damages in specific cases, the law has no systematic way of affecting *contemporary* medical practice other than by a somewhat muted threat of prosecution for legal wrongdoing.

For all of these reasons, the heart of issues about informed consent is not legal but moral. Informed consent has less to do with the liability of professionals and more to do with the understanding and autonomous choices of patients and subjects.

THE QUALITY OF CONSENT

In discussing both autonomous choice and the limits of law, we have noted that problems about the quality and adequacy of consent probably cannot be resolved unless conventional disclosure rules are redirected toward the quality of understanding present in a "consent." This approach focuses on the need for communication, dispensing with liability-oriented discussions about proper legal standards of disclosure. The key to effective communication is to invite participation by patients or subjects in an exchange of information and dialogue. Asking questions, eliciting the concerns and interests of the patient or subject, and establishing a climate that encourages the patient or subject to ask questions seem more important for medical ethics than requirements of disclosure in law.

Without a proper climate in the consent context, a request from a professional that the patient or subject ask for information is as likely to result in silence as to elicit the desired result of a meaningful informational exchange and consent. Patients find it difficult to approach physicians with questions or concerns, and even when they do not understand their physicians, many still do not ask questions. The extent to which this passive attitude characterizes research subjects is less clear. Although still understudied, it is a good guess that relatively little educating of this quality occurs at present in either clinical practice or research in the United States.

VULNERABLE SUBJECTS AND COMPLIANT PATIENTS

Patients and subjects are entitled to expect that physicians and research investigators who request decisions will do so free of coercion and manipulation. Much discussion about the morality of asking subjects and patients to consent centers not on how *informed* the subjects are, but on how *free* they are. For example, this topic dominated the deliberations of the National Commission for the Protection of Human Subjects over the involvement of prisoners in drug research. The National Commission raised the question of "whether prisoners are, in the words of the Nuremberg Code, 'so situated as to be able to exercise free power of choice.'" The National Commission answered that "although prisoners who participate in research affirm that they do so freely, the conditions of social and economic deprivation in which they live compromise their freedom. The Commission believes, therefore, that the appropriate expression of respect consists in protection from exploitation" (National Commission, 1976, 5–7).

The National Commission went on to recommend a ban on drug research with prisoners, on grounds that in coercive institutions free choice would be too often compromised. Six years later this argument continued: Robert Levine, who had served on the staff of the National Commission, argued—as had a minority of commissioners—that prisoners are actually better off, not worse off, by their involvement in research and that exclusion from research was a deeper restriction of free choice than allowing inclusion in the research (Levine, 1982, 6). Many were dubious, however, that such abstract statements take account of the realities of manipulation and coercion in the prison (Dubler, 1982, 10).

A similar controversy occurred in the 1980s when Dr. Mortimer Lipsett at the National Institutes of Health (National Institute of Child Health and Human Development) explored the question of whether phase I clinical trials of cancer chemotherapies involve a special class of subjects deserving special protections. He presented the problem as follows:

> The President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research developed and extended the concept of the vulnerable subject in medical research. Children, prisoners, and the mentally disabled were defined as vulnerable because a variety of constraints and inducements effectively removed their capacity to function autonomously. Similarly, patients with advanced cancer are faced with inducements that may sway their judgment of the risk-benefit ratio. Should such patients be treated as vulnerable research subjects necessitating extraordinary supervision by third parties? (Lipsett, 1982, 941–942)

Lipsett answered that every patient entering such a therapeutic trial is vulnerable by virtue of the disease state and the unique opportunity to receive a promising drug, but he maintained that the problem could be and was being overcome by "painstaking consultation and preparation" involving families, institutional review boards, third-party consultation, and the like. He concluded that, as conducted, phase 1 clinical trials of "cancer chemotherapies are ethical and necessary" (Lipsett, 1982, 941–942).

Some published responses to Lipsett were less sanguine: Alexander Capron, who had been staff director of the President's Commission, as well as Terrence Ackerman and Carson Strong, argued that the notion of therapeutic intent in the trials is easily subject to misunderstanding by patients, who may be misled by the hope of a favorable effect, especially when the prospect for therapeutic efficacy is as remote as it often is at the dosage level offered. They maintained that patients should be given a realistic picture of how they are contributing to medical knowledge and noted the dangers of "manipulating" subjects and of subjecting them to "affective" factors that impair understanding and judgment. In general, they challenged the view that present safeguards are sufficient to preclude exploitation (Ackerman & Strong, 1983, 883; Capron, 1983, 882–883).

Underlying these discussions is a theoretically difficult and partially unresolved set of problems about free choice, coercion, and manipulation. Certain forms of withholding information, playing on emotion, or presenting constraints can rob an autonomous person of the capacity of free choice through manipulation or coercion. Deceptive and misleading statements limit freedom by restricting the range of choice and by getting a person to do what the person otherwise would not do (cf. Bok, 1992, 1118–1119). The National Commission was worried about *coercion* in the case of prisoners; by contrast, those engaged in the discussion of phase I trials and cancer chemotherapies were interested in *manipulation*.

A continuum of controlling influences is present in our daily lives, running from coercion, which is at the most controlling end of the continuum (compare the National Commission's model of prisoners), to persuasion and education, which are not controlling at all, even though they are influences. For an action to be classified as either voluntary or nonvoluntary, cut-off points on the continuum of control to noncontrol are required. To fix the point of voluntariness, only a *substantial* satisfaction of the condition of noncontrol is needed. The line between the substantial and the insubstantial can be fixed in light of specific objectives of decision making. These lines will be influenced by moral views of when it is appropriate to respect a person's decision as substantially voluntary, but this connection need not be pursued here.

Influence does not necessarily imply constraint, governance, force, or compulsion, although these concepts are essential to certain kinds of influence. Important decisions are usually made in contexts replete with influences in the form of

competing claims and interests, social demands and expectations, and straightforward or devious attempts by others to bring about the outcome they desire. Some of these influences are unavoidable, and some may be desirable. Not all of them interfere with or deprive persons of autonomous belief and action, as when patients are persuaded by sound reasons to do something.

Coercion that involves a threat of harm so severe that a person is unable to resist acting to avoid it is always completely controlling. It entirely negates freedom because it entirely controls action. Persuasion, by contrast, is the intentional and successful attempt to induce a person, through appeals to reason, to freely accept the beliefs, attitudes, values, intentions, or actions advocated by the persuader. Like informing, persuading is entirely compatible with free choice.

The most sweeping and difficult area of influence is manipulation, a broad, general category that runs from highly controlling to altogether noncontrolling influences. The essence of manipulation is getting people to do what the manipulator intends without resort to coercion or to reasoned argument. In a paradigm case of manipulation in contexts of informed consent, information is closely managed to bring about the "choice" by a patient that the physician wants the patient to make, and the patient does not know what the manipulative physician intends. Whether such uses of information necessarily compromise or restrict free choice is an unresolved and untidy issue, but one plausible view is that some manipulations (e.g., the use of rewards such as reduced medical fees for being involved in research) are compatible with free choice, whereas others (e.g., deceptive offers of hope of a cure where there is none) are not compatible with free choice.

In informed consent contexts, the central question is not whether we are entirely free of manipulative influences, but whether we are *sufficiently* free to remain autonomous—free to perform our own actions—as opposed to controlled by the actions of another. The thorniest of all problems about autonomy and manipulation is not that of punishment and threat, but the effect of rewards and offers. This category refers to the intentional use of offers of rewards to bring about a desired response. For example, during the Tuskegee Syphilis experiments, various methods were used to stimulate and sustain the interest of subjects in continued participation. They were offered free burial assistance and insurance, free transportation, and a free stop in town on the return trip. They were also rewarded with free medicines and free hot meals on the days of the examination. The deprived socioeconomic condition of these subjects made them easily manipulable by those means.

This general range of problems is compounded further by what is sometimes called the problem of "coercive situations," but is better formulated as "constraining situations." Most accounts of coercion require that coercion be intentional by the coercer, but constraining situations suggest nonintentional "coercion" where the person is controlled by the situation, not by the design of another person.

Sometimes people unintentionally make other persons feel "threatened," and sometimes situations of illness and economic necessity present "threats" of serious harm that a person feels compelled to prevent at all costs. The earlier example of using prisoners in experimentation is again applicable if we assume that a prisoner is left without any viable alternative to participation in research because of the risks of the alternatives in the circumstance or because of what may appear to be threats presented by prison officials. As Alvin Bronstein, director of the National Prison Project, once put the problem for informed consent, "You cannot create... [a prison] institution in which informed consent without coercion is feasible" (Bronstein, 1975, 130–131).

Beyond the prison, in circumstances of severe physical or health deprivation, a person might accept an offer or sign a contract that the person would refuse under less stringent circumstances. Cancer patients provide good examples: The prospect of death if an objectionable toxic drug is rejected seems to "coerce" a choice of the drug no less than an intentional threat. The psychological effect on the person forced to choose may be identical, and the person can appropriately say in both cases, "There was no real choice; I would have been crazy to refuse." But if, as we usually believe, a contract signed under another person's threat is invalid (and the consent behind the signing an invalid consent), can we not say that a person who agrees to drug experimentation in a constraining situation has made an invalid contract (and given an invalic consent)?

It is a mistake to suppose that persons in such constraining situations cannot act *autonomously*. A loss of alternatives cannot be equated with coercion. It is, then, a confusion to move from a correct claim about a loss of options caused by desperate circumstances to the conclusion that there has been a loss of autonomy because of a constraining situation. Nevertheless, even if knowledgeable intent to threaten is not present, one may feel just as forced to a choice and may just as heartily wish to avoid it. Such perceptions are why the issues are often presented in the language of "vulnerable subjects." Their situation does make them vulnerable, even desperately vulnerable, and may subject them to "control" by their emotions and anxieties to an abnormal degree.

Despite the tense and pressured nature of such circumstances, most patients have the ability to consent freely and will do so if properly managed. What may be doubted is how often a free informed consent does in fact occur.

COMPETENCE TO CONSENT

I observed earlier that competence is commonly considered a necessary condition of informed consent. In legal and policy contexts, reference to competent persons is far more common than reference to autonomous persons. Competence

judgments function as a gatekeeping device for informed consent. That is, competence judgments function to distinguish persons from whom consent should be solicited from those from whom consent need not or should not be solicited. In health care, competence judgments distinguish the class of individuals whose autonomous decisions must be respected from those individuals whose decisions need to be checked and perhaps overridden by a surrogate (Buchanan & Brock, 1989, 26–27; Faden & Beauchamp, 1986, 287–292).

Competence can be either a factual or a categorical determination. Minors, for example, are incompetent in law, whereas adults can generally be declared legally incompetent only on the basis of some factual determination. The issue of legal capacity is more complex for adult patients, for whom an individual determination normally must be made. If a person is incompetent, the physician is usually required, absent an emergency, to secure some form of third-party consent from a guardian or other legally empowered representative. Placement of the label "incompetent" on a patient or subject automatically introduces the possibility of coercive treatment and the presumption that there is no need to obtain consent. "Competence" commonly functions to denote persons whose consents, refusals, and statements of preference will be accepted as binding, while "incompetence" denotes those who are to be placed under the guidance and control of another.

JUSTIFICATIONS FOR NOT OBTAINING CONSENT

Several standard exceptions to requirements of informed consent exist in law and ethics. All courts passing judgment on the issue have ruled that a patient's right to self-determination is not absolute. Five exceptions to the informed consent requirement are generally recognized: the public health emergency, the medical emergency, the incompetent patient, the therapeutic privilege, and the patient waiver (Meisel, 1979). All but the therapeutic privilege have been widely accepted in law and ethics. However, the therapeutic privilege has elicited a particularly furious exchange over whether autonomy rights can be validly set aside.

The therapeutic privilege allows a physician to withhold information based on a sound medical judgment that to divulge the information would be potentially harmful to a depressed, emotionally drained, or unstable patient. Several harmful outcomes have been cited, including endangering life, causing irrational decisions, and producing anxiety or stress (*Canterbury v. Spence*, 1972, 785–789; van Oosten, 1991, 31–41). In clinical settings, this privilege has long been used to justify not obtaining consent. If framed broadly, the therapeutic privilege can permit physicians to withhold information if disclosure would cause *any* countertherapeutic deterioration, however slight, in the physical, psychological, or emotional condition of the patient. If framed narrowly, it can permit the physician to withhold

information if and only if the patient's knowledge of the information would have serious health-related consequences—for example, by jeopardizing the success of the treatment or harming the patient psychologically by impairing decision making.

The narrowest formulation is that the therapeutic privilege can be validly invoked only if the physician has good reason to believe that disclosure would render the patient incompetent to consent to or refuse the treatment—that is, would render the decision nonautonomous. To invoke the therapeutic privilege under such circumstances does not conflict with respect for autonomy, because an autonomous decision could not be made. However, broader formulations of the privilege that require only "medical contraindication" do operate at the expense of autonomy. These formulations may unjustifiably endanger autonomous choice, as when use of the privilege is based on the belief that an autonomous patient would refuse an indicated therapy for medically inappropriate reasons.

Unless the therapeutic privilege is tightly and operationally formulated, the medical profession can use it to deprive the unreasonable but competent patient of the right to make decisions, especially if the physician sees his or her commitment to the patient's best interest as the overriding consideration. Loose standards can permit physicians to climb to safety over a straw bridge of speculation about the psychological consequences of information. In short, there is a significant potential for abuse of the privilege because of its inconsistency with the patient's rights to know and to decline treatment (Faden & Beauchamp, 1986, 38).

In 1986, U.S. Supreme Court Justice Byron White vigorously attacked the idea that concerns about increasing a person's anxiety about a procedure provide grounds for an exception to rules of informed consent: "It is the very nature of informed consent provisions that they may produce some anxiety in the patient and influence her in her choice. This is in fact their reason for existence, and . . . it is an entirely salutary reason" (*Thornburgh v. American College of Obstetricians*, 1986, 2199–2200). White is suggesting that the legal status of the doctrine of therapeutic privilege is no longer as secure as it once was.

In addition to the five standard exceptions to informed consent, several circumstances are encountered in contemporary medicine and research that suggest a need to relax requirements of informed consent. For example, in observational studies that examine behavior without the subject's knowledge and in secondary-data analysis, we often need only to avoid invasions of privacy and the presentation of significant risk to subjects without procuring consents. Some vital research in epidemiology could not be conducted if consent were needed to obtain access to records. Use of records without consent is not necessarily an ethical violation. Research may be the first stage of an investigation to determine whether one needs to trace and contact particular individuals and obtain their permission for further participation in a study. In other cases, third-party consent

is sometimes acceptable when access to a subject is impractical or the subject is incompetent. In some cases of low-risk research, subjects of research need not be contacted at all, and occasionally disclosures and warnings may be substituted for obtaining explicit informed consents. Thus, disclosures and warnings may sometimes justifiably be substituted for informed consents.

Finally, it does not follow from the great social importance of the rules and practices of informed consent that institutional policies of informed consent must rank the protection of decision making above all other values. The preservation of autonomous choice is the first, but not the only, institutional commitment. For example, a patient's need for education and counseling must be balanced against the interests of other patients and of society in maintaining a productive and efficient health care system. Accordingly, institutional policies must consider what is fair and reasonable to require of health care professionals and researchers and what the effect would be of alternative consent requirements on efficiency and effectiveness in the delivery of health care and the advancement of science.

CONCLUSION

Jay Katz has argued that the history of the physician–patient relationship from ancient times to the present reveals how inattentive physicians have been to their patients' rights and needs. Katz is equally unrelenting in his criticisms of court decisions and legal scholarship. He regards the declarations of courts as filled with overly optimistic rhetoric. The problem, in his view, is that the law has little to do with fostering real communication in the clinic and tends to line up with the professional judgments of physicians in the crucial test cases (Katz, 1984, 2–4, 28, 49–50, 79; 1987).

Katz is correct in judging that informed consent has always been an alien notion in the history of medicine and medical ethics and that informed consent requirements have still not deeply modified forms of communication between physicians and their patients. At the same time, the scene in medicine throughout the world is undergoing what may prove to be an extensive transformation through the implementation of the idea of informed consent. Patients are giving more "informed consents" and more attention is being paid in institutions to the quality of those consents. It is indisputable that research ethics and policies have been dramatically affected by requirements of informed consent.

Before we condemn the defects in the writings and practices of the past, we should remember that the history of informed consent is still unfolding and that our failures may be no less apparent to future generations than are the failures that we find with the past.

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WHO DESERVES AUTONOMY AND WHOSE AUTONOMY DESERVES RESPECT?

"Autonomy," "respect for autonomy," and "rights of autonomy" are strikingly different notions. "Respect for autonomy" and "rights of autonomy" are moral notions, but "autonomy" and "autonomous person" are not obviously moral notions. Indeed, they seem more metaphysical than moral. However, this distinction between the metaphysical and the moral has fostered precarious claims such as these: (1) analysis of autonomy is a conceptual, metaphysical project, not a moral one; (2) a theory of autonomy should not be built on moral notions, but on a theory of mind, self, or person; and (3) the concept of autonomy is intimately connected to the concept of person, which anchors the concept of moral status.

I will be assessing these claims with the objective of determining who qualifies as autonomous and what sort of autonomy deserves our respect. I will argue that moral notions—in particular, respect for autonomy—should affect how we construct theories of autonomous action and the autonomous person. However, theories of autonomy should only be *constrained* by the principle of respect for autonomy, not wholly *determined* by it.

CONCEPTS AND THEORIES OF AUTONOMY

Autonomy is generally understood as personal self-governance: personal rule of the self free of controlling interferences by others and free of personal limitations that prevent choice. Two basic conditions of autonomy, therefore, are (1) *liberty*