
Making Health Care Decisions

The Ethical and
Legal Implications of
Informed Consent in the
Patient-Practitioner
Relationship

Volume One: Report



President's Commission for the Study of
Ethical Problems in Medicine and
Biomedical and Behavioral Research

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Informed Consent in the
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Relationship

Volume One: Report

October 1982

President's Commission for the Study of
Ethical Problems in Medicine and
Biomedical and Behavioral Research

President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research

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President's Commission for the Study of Ethical Problems
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Suite 555, 2000 K Street, N.W., Washington, DC 20006 (202) 653-8051

October 21, 1982

The President
The White House
Washington, D.C. 20500

Dear Mr. President:

On behalf of the President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research, I am pleased to transmit our Report on Making Health Care Decisions. This is one of several subjects that Public Law 95-622 directs the Commission to study and regarding which we are to report to the President, the Congress, and relevant departments of government.

In mandating a study of "the ethical and legal implications of the requirements for informed consent," the Congress assigned us a subject that is at the heart of current concerns about the relationship between patients and health care professionals. Although our studies have shown that the public and the educators of health professionals are greatly interested in this topic, it is not one that has been primarily a matter of Federal concern.

The Commission does not recommend the adoption of specific regulations on this subject by Federal departments and agencies. Indeed, while recognizing the important role that the law has played in this area, the Commission does not look to the law as the primary means of bringing about needed changes in attitudes and practices. Rather, the Commission sees "informed consent" as an ethical obligation that involves a process of shared decisionmaking based upon the mutual respect and participation of patients and health professionals. Only through improved communication can we establish a firm footing for the trust that patients place in those who provide their health care.

There are, nonetheless, several areas in which the Federal government can play a leading role. For example, it can ensure that the hospitals it operates and the professionals it employs take the steps recommended for all health care providers in this Report. Moreover, it can lend support--especially through the Department of Health and Human Services--to initiatives to develop, evaluate, and disseminate methods of improving the interpersonal side of health care, in line with the efforts that have advanced its scientific side.

The Commission believes that this Report should be of interest to members of the public and of the health care professions, as well as to officials of the Federal government. We are pleased to have had an opportunity to assist in improving understanding of this important topic.

Respectfully,

Morris B. Abram
Chairman



President's Commission for the Study of Ethical Problems
in Medicine and Biomedical and Behavioral Research

Suite 555, 2000 K Street, N.W., Washington, DC 20006 (202) 653-8051

October 21, 1982

The Honorable George Bush
President
United States Senate
Washington, D.C. 20510

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in Medicine and Biomedical and Behavioral Research

Suite 555, 2000 K Street, N.W., Washington, DC 20006 (202) 653-8051

October 21, 1982

The Honorable Thomas P. O'Neill, Jr.
Speaker
U.S. House of Representatives
Washington, D.C. 20515

Dear Mr. Speaker:

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Morris B. Abram
Chairman

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Introduction

What is informed consent to health care, and why has it assumed such an important place in legal and ethical discussions? Is it merely a rhetorical construct, imposed halfheartedly upon medicine by the law? Or is it perhaps a token of larger changes in the relationship between patients and health care professionals, especially physicians? And why does the concept have such importance in the United States today—because of a particular cultural attachment to independence and autonomy? The growing importance of biomedicine in people's lives? Skepticism over "expertise" in many spheres? Or perhaps some combination of these and other factors?

These were among the basic issues before the President's Commission during its Congressionally mandated study of "the ethical and legal implications of the requirements for informed consent to...undergo medical procedures."¹ Rather than embroider the doctrine of informed consent within the confines of the case and statutory law that was its source, the Commission decided early in its study to examine the subject within the broader context of relations and communications between patients and health care professionals. It wished to see whether means could be found to promote a fuller understanding by patients and professionals of their common enterprise, so that patients can participate, on an informed basis and to

¹ 42 U.S.C. § 300v-1(a)(1)(A) (1981) also instructs the Commission to study the implications of "informed consent to participation in research projects." The Commission treats issues of human research generally in its biennial reports, *PROTECTING HUMAN SUBJECTS*. Furthermore, although they developed initially along independent lines, see note 19, Chapter One *infra*, the legal rules for informed consent to treatment and to participation in research spring from common legal and philosophical ground, have had parallel courses of development, and are now basically congruent, so that a separate discussion is not required in this Report.

the extent they care to do so, in making decisions about their health care.

Summary of Conclusions and Recommendations

Before the Commission could consider means of improvement, it had to address the underlying theoretical issues. The ethical foundation of informed consent can be traced to the promotion of two values: personal well-being and self-determination. To ensure that these values are respected and enhanced, the Commission finds that patients who have the capacity to make decisions about their care must be permitted to do so voluntarily and must have all relevant information regarding their condition and alternative treatments, including possible benefits, risks, costs, other consequences, and significant uncertainties surrounding any of this information. This conclusion has several specific implications:

(1) Although the informed consent doctrine has substantial foundations in law, it is essentially an ethical imperative.

(2) Ethically valid consent is a process of shared decision-making based upon mutual respect and participation, not a ritual to be equated with reciting the contents of a form that details the risks of particular treatments.

(3) Much of the scholarly literature and legal commentary about informed consent portrays it as a highly rational means of decisionmaking about health care matters, thereby suggesting that it may only be suitable for and applicable to well-educated, articulate, self-aware individuals. Whether this is what the legal doctrine was intended to be or what it has inadvertently become, it is a view the Commission unequivocally rejects. Although subcultures within American society differ in their views about autonomy and individual choice and about the etiology of illness and the roles of healers and patients,² a survey conducted for the Commission found a universal desire for information, choice, and respectful communication about decisions.³ Informed consent must remain flexible, yet the process, as the Commission envisions it throughout this Report, is ethically required of health care practitioners in their relationships with all patients, not a luxury for a few.

(4) Informed consent is rooted in the fundamental recognition—reflected in the legal presumption of competency—that adults are entitled to accept or reject health care interventions on the basis of their own personal values and in furtherance of

² Robert A. Hahn, *Culture and Informed Consent: An Anthropological Perspective* (1982), Appendix F, in Volume Three of this Report.

³ The Commission's survey of the public broke down these responses on the basis of variables such as age, gender, race, education, and income.

their own personal goals. Nonetheless, patient choice is not absolute.

- Patients are not entitled to insist that health care practitioners furnish them services when to do so would violate either the bounds of acceptable practice or a professional's own deeply held moral beliefs or would draw on a limited resource on which the patient has no binding claim.
- The fundamental values that informed consent is intended to promote—self-determination and patient well-being—both demand that alternative arrangements for health care decisionmaking be made for individuals who lack substantial capacity to make their own decisions. Respect for self-determination requires, however, that in the first instance individuals be deemed to have decisional capacity, which should not be treated as a hurdle to be surmounted in the vast majority of cases, and that incapacity be treated as a disqualifying factor in the small minority of cases.
- Decisionmaking capacity is specific to each particular decision. Although some people lack this capacity for all decisions, many are incapacitated in more limited ways and are capable of making some decisions but not others. The concept of capacity is best understood and applied in a functional manner. That is, the presence or absence of capacity does not depend on a person's status or on the decision reached, but on that individual's actual functioning in situations in which a decision about health care is to be made.
- Decisionmaking incapacity should be found to exist only when people lack the ability to make decisions that promote their well-being in conformity with their own previously expressed values and preferences.
- To the extent feasible people with no decisionmaking capacity should still be consulted about their own preferences out of respect for them as individuals.

(5) Health care providers should not ordinarily withhold unpleasant information simply because it is unpleasant. The ethical foundations of informed consent allow the withholding of information from patients only when they request that it be withheld or when its disclosure per se would cause substantial detriment to their well-being. Furthermore, the Commission found that most members of the public do not wish to have "bad news" withheld from them.

(6) Achieving the Commission's vision of shared decision-making based on mutual respect is ultimately the responsibility of individual health care professionals. However, health care institutions such as hospitals and professional schools have

important roles to play in assisting health care professionals in this obligation. The manner in which health care is provided in institutional settings often results in a fragmentation of responsibility that may neglect the human side of health care. To assist in guarding against this, institutional health care providers should ensure that ultimately there is one readily identifiable practitioner responsible for providing information to a particular patient. Although pieces of information may be provided by various people, there should be one individual officially charged with responsibility for ensuring that all the necessary information is communicated and that the patient's wishes are known to the treatment team.

(7) Patients should have access to the information they need to help them understand their conditions and make treatment decisions. To this end the Commission recommends that health care professionals and institutions not only provide information but also assist patients who request additional information to obtain it from relevant sources, including hospital and public libraries.

(8) As cases arise and new legislation is contemplated, courts and legislatures should reflect this view of ethically valid consent. Nevertheless, the Commission does not look to legal reforms as the primary means of bringing about changes in the relationship between health care professionals and patients.

(9) The Commission finds that a number of relatively simple changes in practice could facilitate patient participation in health care decisionmaking. Several specific techniques—such as having patients express, orally or in writing, their understanding of the treatment consented to—deserve further study. Furthermore, additional societal resources need to be committed to improving the human side of health care, which has apparently deteriorated at the same time there have been substantial gains in health care technology. The Department of Health and Human Services, and especially the National Institutes of Health, is an appropriate agency for the development of initiatives and the evaluation of their efficacy in this area.

(10) Because health care professionals are responsible for ensuring that patients can participate effectively in decision-making regarding their care, educators have a responsibility to prepare physicians and nurses to carry out this obligation. The Commission therefore concludes that:

- Curricular innovations aimed at preparing health professionals for a process of mutual decisionmaking with patients should be continued and strengthened, with careful attention being paid to the development of methods for evaluating the effectiveness of such innovations.

- Examinations and evaluations at the professional school and national levels should reflect the importance of these issues.
- Serious attention should be paid to preparing health professionals for team practice in order to enhance patient participation and well-being.

(11) Family members are often of great assistance to patients in helping to understand information about their condition and in making decisions about treatment. The Commission recommends that health care institutions and professionals recognize this and judiciously attempt to involve family members in decisionmaking for patients, with due regard for the privacy of patients and for the possibilities for coercion that such a practice may entail.

(12) The Commission recognizes that its vision of health care decisionmaking may involve greater commitments of time on the part of health professionals. Because of the importance of shared decisionmaking based on mutual trust, not only for the promotion of patient well-being and self-determination but also for the therapeutic gains that can be realized, the Commission recommends that all medical and surgical interventions be thought of as including appropriate discussion with patients. Reimbursement to the professional should therefore take account of time spent in discussion rather than regarding it as a separate item for which additional payment is made.

(13) To protect the interests of patients who lack decisionmaking capacity and to ensure their well-being and self-determination, the Commission concludes that:

- Decisions made by others on patients' behalf should, when possible, attempt to replicate the ones patients would make if they were capable of doing so. When this is not feasible, decisions by surrogates on behalf of patients must protect the patients' best interests. Because such decisions are not instances of personal self-choice, limits may be placed on the range of acceptable decisions that surrogates make beyond those that apply when a person makes his or her own decisions.
- Health care institutions should adopt clear and explicit policies regarding how and by whom decisions are to be made for patients who cannot decide.
- Families, health care institutions, and professionals should work together to make health care decisions for patients who lack decisionmaking capacity. Recourse to courts should be reserved for the occasions when concerned parties are unable to resolve their disagreements over matters of substantial import, or when adjudication is clearly required by state law. Courts and legislatures should be cautious about

requiring judicial review of routine health care decisions for patients who lack capacity.

- Health care institutions should explore and evaluate various informal administrative arrangements, such as "ethics committees," for review and consultation in nonroutine matters involving health care decisionmaking for those who cannot decide.
- As a means of preserving some self-determination for patients who no longer possess decisionmaking capacity, state courts and legislatures should consider making provision for advance directives through which people designate others to make health care decisions on their behalf and/or give instructions about their care.

The Commission acknowledges that the conclusions contained in this Report will not be simple to achieve. Even when patients and practitioners alike are sensitive to the goal of shared decisionmaking based on mutual respect, substantial barriers will still exist.⁴ Some of these obstacles, such as long-standing professional attitudes or difficulties in conveying medical information in ordinary language, are formidable but can be overcome if there is a will to do so. Others, such as the dependent condition of very sick patients or the ever-growing complexity and subspecialization of medicine, will have to be accommodated because they probably cannot be eliminated. Nonetheless, the Commission's vision of informed consent still has value as a measuring stick against which actual performance may be judged and as a goal toward which all participants in health care decisionmaking can strive.

The Commission's Process

The Commission's inquiry into the ethical, legal, and practical aspects of informed consent in health care has drawn on the expertise of leading scholars from around the country, on the existing literature, on newly commissioned empirical studies, and on testimony from health care professionals, consumers, and commentators. The Commissioners devoted five hearings to informed consent and deliberated on the subject at three additional meetings.

Over the five days of hearings, testimony was heard on the components and functions of informed consent in health care, the relationships between patients and health care professionals, ways to increase patient participation in decisionmaking, the issue of patient competence and the roles of families in health care decisionmaking, and the education of physicians and nurses about informed consent issues. The witnesses

⁴ Jay Katz, *Informed Consent—A Fairy Tale?: Law's Vision*, 39 U. PITT. L. REV. 137 (1977).

included physicians, nurses, health care administrators, representatives of consumer groups, and professors of sociology, philosophy, history, law, and public health. In addition, the Commission convened a panel of nursing experts from all over the country to discuss these issues.⁵

The Commission also contracted for three empirical studies in order to clarify certain aspects of informed consent in practice.⁶ The results of these studies are used throughout the Report to illustrate key points and to measure the extent of discrepancy between current practice and the goals for communication and decisionmaking articulated by the Commission.

Although health care is clearly a diverse enterprise, the legal doctrine of informed consent seems to operate on the implicit assumption that medical care is only concerned with invasive procedures (typically surgery). To redress the narrowness of this focus, the first commissioned study sought to determine whether and how decisionmaking and communication between patients and health care professionals varied in different health care settings according to the nature of the illness and treatments under consideration, the types of health care providers, and patient characteristics. The study was conducted through interviews and observation under the direction of Professors Charles W. Lidz and Alan Meisel of the University of Pittsburgh and of the Western Psychiatric Institute and Clinic. Two researchers observed a surgical outpatient clinic and cardiology and surgery wards in a university hospital over a period of several weeks, throughout the day and evening. After noting the routines in each setting for several days, information was gathered on almost 200 cases. In 124 of these, the encounters between patients, physicians, and nurses were observed and recorded, and semistructured interviews were conducted with all who were involved in the decision at hand, often including family members.

Much has been written about the potentially negative consequences of providing patients with full information about their conditions and treatment, especially when it leads to refusals of "medically necessary" treatment, yet only scattered anecdotal evidence of such refusals exists. The Commission's

⁵ For a complete list of witnesses and consultants, see the Addendum, pp. 189-91 *infra*.

⁶ Reports from the commission's own studies and a review of the empirical literature may be found in the Appendices, published as Volume Two of this Report. The focus of most of these studies has been on physicians, with very little attention paid to nurses and other health professionals who interact with patients. Where information about the roles of nonphysician professionals is available it has been included.

other observational study sought to determine the frequency, nature, causes, and effects of treatment refusals. It found that treatment refusals were usually triggered by too little information rather than too much. The study was conducted in three stages by Drs. Paul S. Appelbaum and Loren H. Roth of the Western Psychiatric Institute and Clinic in Pittsburgh.

In the first stage, seven wards in four different medical hospitals were studied: a medicine, a surgery, and a neurology ward in a university-affiliated teaching hospital; a gynecology ward in a university-affiliated women's hospital; an ophthalmology ward in a university-affiliated specialty hospital; and a medical and a surgical ward in a large community hospital. Each ward was visited for most of a day four times at one-week intervals, with each visit being held on a different day of the week. Information was provided by the nurse on all treatment refusals in the previous 24 hours; charts were reviewed and interviews conducted with the nurse most familiar with the case, with the staff member who elicited the refusal, and with the patient.⁹

In the second stage, more in-depth study was made of the longitudinal course of refusals on the medical and surgical wards of the university-affiliated teaching hospital. Daily rounds were made for a three-week period of the surgery ward and for an eight-week period on the medicine ward. One observer made rounds with house staff and conducted interviews with physicians and nurses while the other observer interviewed patients. In the third stage, a case study approach was used to follow a number of cases of treatment refusal through the end of the patients' hospitalization. Medical charts were reviewed daily, extensive initial interviews were conducted with patients and they were re-interviewed at least every other day, and in most cases a family member was interviewed as well.

In the third empirical study done for the Commission, Louis Harris and Associates conducted parallel national surveys of physicians and the public regarding their attitudes toward, experience with, and knowledge of informed consent, disclosure of information, and decisional authority in medical care. The questionnaires were designed by Commission staff in conjunction with John M. Boyle and Paul J. Brounstein of the Harris organization. Telephone interviews were conducted with representative national samples of 800 physicians and 1250 adults in the general public. According to the accepted principles for such polls, the sample sizes were sufficiently large to allow general statements to be made about the populations from which they were drawn with 95% confidence that estimates were correct to within 3%, and to permit analysis by subgroups with reasonable confidence. For the

public an "area probability sample" based on random-digit dialing was used,⁷ and for the physician survey a random sample was drawn of doctors who spend the majority of their time in direct care of adult patients.⁸ The response rate to both surveys was approximately 70%, which is well within (or above) the range of statistical acceptability for such surveys.

In analyzing the data from the surveys, many cross-tabulations were performed to see whether there were variations in attitudes or behavior by subgroups of the public or the physicians. For the public survey all questions concerning disclosure of information, decisionmaking, and knowledge of informed consent were examined in relation to the respondents' age, gender, race, family income, education, self-reported health status, and health insurance status, whether or not the person had ever had a life-threatening illness, and the locale where he or she usually received medical care. For the physician sample all data were examined in relation to specialty, year of graduation from medical school, type of medical school attended (public, private, or foreign, and extent of research involvement), normal location of practice (office or hospital), the proportion of patients under the physician's care who were seriously ill, the proportion who were poor, and the proportion who the physician thought could understand most aspects of their condition and treatment.

It is important to note that different empirical methods yield data that can differ in several ways. Surveys are based on self-reports about past or hypothetical situations and therefore may not be entirely accurate reflections of practice. Regarding health care, surveys are known to overstate the frequency with which information is disclosed and may present a rosier, more homogeneous picture of medical practice than an on-site investigation of the same population would. On the other hand, although studies by qualified neutral observers provide a truer picture of a piece of the real world, they often do not permit broad conclusions to be drawn. The results of

⁷ The public sample was stratified by region of the country and within each region by size of the community. Use of random-digit dialing ensures that unlisted telephones are surveyed. Telephone surveys may slightly overrepresent the elderly and will generally significantly overrepresent females. To avoid this latter imbalance in the sample, a quota technique was used. In addition, all responses were weighted before doing the analyses to ensure that results reflected the total population rather than the population with telephones, thereby eliminating the slight bias that arises from the fact that about 2% of the U.S. population do not have telephones.

⁸ The physician sample was drawn according to study specifications by the American Medical Association, which maintains files of all physicians in the country and updates them monthly. This is the most reliable source of data on the total physician population in the country.

surveys are quantifiable, whereas observational studies largely yield qualitative results. The findings from these two types of studies are often complementary but they may also be divergent in some respects. (Differences between the Commission's survey and the observational studies are noted throughout the Report where relevant.)

In general, the Commission's surveys found that the relationship between physicians and patients is dynamic, that disclosures are extensive, that understanding and satisfaction are high, that decisionmaking is shared—and that patients expect their relations with physicians to have these characteristics. This was found to be especially true for office-based (as distinct from clinic- or hospital-based) settings, where doctors and patients are apparently able to establish a relationship over time. Furthermore, as might be expected, the public's experience with the health care system appears to vary depending on whether the patient is young or old, in good or poor health, and well or poorly educated. In contrast, physicians' self-reported behaviors and attitudes were relatively homogeneous. Even though the issue of informed consent has received a great deal of attention in the last decade, there was little variation among physicians by specialty, age, or nature of patients under their care.

The observational studies, on the other hand, found enormous variation in the patient-professional relationship and the decisionmaking process within various hospital settings. Such variation appears to be related to the structure in which care is delivered and the nature of patients' conditions and treatments. In these studies, it was rare for the process described in this Report as ideal to be realized in practice. Because the observational studies were conducted principally in university-affiliated teaching hospitals the findings may not be representative of all hospital care. For example, in non-teaching hospitals patients are more likely to be cared for by fewer doctors (perhaps only one) than in teaching hospitals staffed with a large number of interns and residents, thus lessening the possibility that one doctor will mistakenly assume that another doctor has talked with a patient about treatment.

The Report

In addition to hearing witnesses, the Commission devoted portions of a number of meetings to its own deliberations on the study and helpful comments were received from former Commissioner Renée C. Fox, Professor of Sociology at the University of Pennsylvania, and Professor Jay Katz of Yale Law School. Drafts of this Report were discussed at several Commission meetings. On May 14, 1982, a draft was reviewed and the central conclusions were approved. On August 12,

1982, a final draft was discussed and approved, subject to editorial corrections, by the Commissioners who had reviewed the earlier draft and by four newly appointed members.

The Commission has divided this Report into four parts. The first traces the history of informed consent in the law and in medical practice and briefly sketches recent changes in the nature of health care and in society's expectations for the patient-professional relationship. This is followed by a discussion of the values underlying informed consent. In Part Two, the ethical and legal obligations of health care professionals are discussed against a backdrop of what is known about actual practice. Part Three explores several means to bring goals and realities closer together. Attention is directed to innovative approaches in patient-professional communication and decisionmaking that appear to be practically as well as theoretically sound. Legal rules, along with professional attitudes and behavior as they are shaped by education and training, are examined for the roles they could play in providing patients with an effective basis for participation in decisionmaking. Recognizing that some people are unable to make some or all decisions on their own behalf, the Commission in Part Four of the Report sets forth principles and procedures for health care decisions that others must make for patients who lack decisionmaking capacity.

Values

I

Informed Consent as Active, Shared Decisionmaking

1

The complexities of modern life make it difficult for individuals to be masters of their own fate. Perhaps in no sphere of everyday activity is this more acute than in health care. This often frustrating lack of control can be traced to several recent developments: the increasing reliance on advanced technology, the high degree of specialization, the consequent segmentation of care among an imposing array of health care professionals who are often strangers to the patient. But these latter-day developments have only magnified the sense of awe people have always felt when confronted with the mysteries of life, illness, and death that are health care's most basic concerns.

Traditionally, many cultures, including this one, have responded by according healers a unique deference and authority in their relationships with patients.¹ Yet this authori-

¹ Historically, the law of informed consent developed in the context of claims by patients against physicians. The rationale of existing law would, however, support the application of informed consent requirements to nonphysician practitioners who function as independent providers of health care. As nurses and other nonphysician health professionals move into such roles, these legal requirements will become incumbent upon them as well. The law has thus far had little occasion to address in any detail the distinctive legal obligations regarding informed consent, if any, of nurses and other nonphysician health care professionals in their myriad other professional roles and functions.

Insofar as this Report addresses the distinctively ethical as well as legal requirements of informed consent, the Commission wishes to make clear that its discussion is directed to all health care professionals, including those who work as members of health care teams rather

ty is not, and has not been, absolute. Ancient writings indicate limits on the authority of the physician.² Within the Anglo-American tradition, the law has for centuries recognized the obligation of physicians to seek the consent of their patients prior to initiating treatment.³ And in the past quarter-century, American courts, supported by legal and ethical commentary, have articulated a legal doctrine of "informed consent" that requires health care practitioners not simply to seek the consent of their patients, but also, through a process of disclosure and discussion between practitioners and patients, to make such consents "informed."⁴ Thus, the law requiring informed consent has become an important means by which society regulates relationships between patients and health care professionals.

To what degree does this legal requirement of informed consent advance the ability of patients to maintain control of and be responsible for decisions regarding their lives and their health? How closely does the practice of informed consent in day-to-day health care accord with the theory? Can public policy promote a system in which patients can cope more successfully with the complexities of modern medicine? And quite apart from legal requirements, how can health care providers be encouraged to recognize and to satisfy their distinctive moral obligations to their patients?

Current requirements for informed consent owe much to the legal system, but the values underlying these requirements

than primarily as independent practitioners. While they may not currently have the same legal duties as independent practitioners, they are subject to ethical obligations to respect and serve the interests of their patients. In this Report, therefore, such individuals are encompassed within the meaning of the terms "professionals," "providers," and "practitioners," which are used here interchangeably except where specifically modified. Some of the informed consent statutes specifically indicate the types of health care providers to whom they apply, such as physician's assistants, nurses, podiatrists, etc. See Alan Meisel and Lisa D. Kabnick, *Informed Consent to Medical Treatment: An Analysis of Recent Legislation*, 41 U. PITT. L. REV. 407, 410-11 n.12 (1980).

² Laurence B. McCullough, *Historical Perspectives on the Ethical Dimensions of the Patient-Physician Relationship: The Medical Ethics of Dr. John Gregory*, 5 ETHICS IN SCI. AND MED. 47-53 (1978).

³ The earliest reported case dealing with consent to medical treatment is generally acknowledged to be Slater v. Baker & Stapleton, 95 Eng. Rep. 860 (K.B. 1767). However, nonconsensual medical treatment involves either a harmful or offensive touching of the person and has therefore long been remediable, at least in theory, under the writ of trespass. See generally Fowler Harper and Fleming James, *THE LAW OF TORTS*, Little, Brown, & Co., Boston (1956) §§ 3.1-3.3 at 211-20.

⁴ Alan Meisel, *The Expansion of Liability for Medical Accidents: From Negligence to Strict Liability by Way of Informed Consent*, 56 NEB. L. REV. 51, 79-80 (1977).

are not merely legal artifacts. Rather, they are deeply embedded in American culture and the American character; they transcend partisan ideologies and the politics of the moment. Fundamentally, informed consent is based on respect for the individual, and, in particular, for each individual's capacity and right both to define his or her own goals and to make choices designed to achieve those goals.⁵ But in defining informed consent (and its exceptions) the law has tempered this right of self-determination with respect for other values, such as promotion of well-being in the context of an expert-layperson relationship.⁶

The values underlying informed consent are widely shared by people in all segments of American society. Regardless of race, income, education, age, or gender, the vast majority of people surveyed by the Commission felt that patients have a right to information and ought to participate in decisions regarding their health care. Furthermore—despite vastly different views held by many foreign cultures and subcultures within the United States regarding the etiology of illness and the roles of healers and patients—a desire for information, therapeutic choice, and respectful communication appears to be common in all groups.⁷

Despite this consensus on the values underlying informed consent, the doctrine itself is only dimly perceived—and perhaps even misunderstood—by many people. In the Commission's survey, physicians and the public were asked in an open-ended format: "What does the term informed consent mean to you?" (Each portion of every answer was coded separately to see which particular elements of the informed consent doctrine were mentioned; the percentages that follow add up, therefore, to more than 100.) Among the public, 21% said they did not know what informed consent meant; those who gave a substantive answer said:

⁵ Jay Katz, with the assistance of A. M. Capron and Eleanor S. Glass, *EXPERIMENTATION WITH HUMAN BEINGS*, Russell Sage Foundation, New York (1972) at 540-88; Jay Katz and A. M. Capron, *CATASTROPHIC DISEASES: WHO DECIDES WHAT?*, Russell Sage Foundation, New York (1975) at 82-85, 90; George J. Annas, Leonard H. Glantz, and Barbara F. Katz, *INFORMED CONSENT TO HUMAN EXPERIMENTATION: THE SUBJECT'S DILEMMA*, Ballinger Publishing Co., Cambridge (1977) at 33-38; A. M. Capron, *Informed Consent in Catastrophic Disease Research and Treatment*, 123 U. PA. L. REV. 340, 364-76 (1974).

⁶ Alan Meisel, *The "Exceptions" to the Informed Consent Doctrine: Striking a Balance Between Competing Values in Medical Decision-making*, 1979 WIS. L. REV. 413, 417-29 *passim*.

⁷ Robert A. Hahn, *Culture and Informed Consent: An Anthropological Perspective* (1982), Appendix F, in Volume Three of this Report. The nature of communication and decisionmaking are analyzed in several cultures, including "core" American, Navajo, Italian-American, Vietnamese refugee, and mainland Puerto Rican.

- it meant the patient was informed (44%, although only 10% mentioned risks and less than 1% mentioned alternatives);
- it meant that the patient agreed to treatment, often adding that it meant letting the doctor do whatever was "necessary," "best," or "whatever he sees fit" (44%);
- it meant that the patients made a treatment decision, such as "to give someone consent to do whatever I wish" (19%);
- it involved patient understanding (11%);
- it was a form (7%); and
- it was consent to termination of treatment, such as "giving a person permission to kill you," or "legally put in writing patient request not to be put on life support" (6%).

The most frequent responses given by physicians were:

- generally informing patient about condition and treatment (59%);
- disclosing treatment risks to patient (47%);
- patient understanding his or her condition and treatment (34%);
- patient giving permission for treatment (26%); and
- patient understanding treatment risks (23%).

Only 14% of physicians mentioned treatment alternatives and only 9% indicated that informed consent had something to do with the patient making a choice or stating a preference about his or her treatment. Furthermore, 4% mentioned consent forms, 3% said it was a legal doctrine, and 3% said it was meaningless.

In this Report, the Commission focuses primarily on the ethical and practical dimensions of informed consent, and in particular on the source and extent of professional obligations of health care practitioners to respect and enhance their patients' capacities for wise exercise of their autonomy. The focus is not particularly on the law, and the Report recommends few changes in existing legal or regulatory norms. Yet because informed consent arose as a distinctively legal doctrine, and because many misunderstandings and misapprehensions concerning informed consent derive from the doctrine's origins in the law, it is useful to begin by tracing the legal evolution of informed consent requirements.

Legal Background

Development of the Law. The precursors of the modern doctrine of informed consent are found in the venerable English common law regarding battery, which forbade harmful

or offensive nonconsensual touching, however benign in motive or physical effect.⁸ No special exceptions were made for medical care, except in emergency situations.⁹ Thus, under the common law, a medical intervention in which the practitioner touched the body of the patient would constitute a technical battery unless the patient consented to the intervention.¹⁰

The nature of the consent required to avoid liability for battery was not especially exacting. It could be given explicitly in words, manifested by actions, or, in some instances, implied from the circumstances.¹¹ The law was not overly concerned with the quality of the patient's understanding of what was being consented to, nor did it impose any strenuous obligations on the physician to disclose what was involved, beyond perhaps the name or cursory description of the procedure.¹² Although the law imposed no affirmative obligation to go beyond that simple disclosure, the practitioner was expected to refrain from fraudulent or deceptive statements, because they could invalidate the patient's consent and subject the physician to potential liability.¹³

Few of the early cases concerning nonconsensual medical procedures (including American cases in the first decades of this century) gave much explicit attention to disclosure by the physician.¹⁴ Rather, they focused on unauthorized procedures,¹⁵

⁸ William L. Prosser, *HANDBOOK OF THE LAW OF TORTS* (4th ed.), West Publishing Company, St. Paul, Minn. (1971) § 10 at 36, § 32 at 165.

⁹ *Id.*, § 18 at 103.

¹⁰ *Id.*, § 18 at 102, § 32 at 165.

¹¹ See generally Annotation, 76 A.L.R. 562, 566-70 (1932) (collecting cases) and 139 A.L.R. 1370, 1374-75 (1942) (collecting cases).

¹² See Meisel, *supra* note 4, at 80-81. Prior to the promulgation of the informed consent requirement in 1957, ordinary consent was required for medical treatment. The term consent denotes that the person giving consent understands the nature of the "touching" that will occur. See Marcus L. Plant, *An Analysis of Informed Consent*, 36 *FORDHAM L. REV.* 639 (1968); *RESTATEMENT (SECOND) OF TORTS*, American Law Institute Publishers, St. Paul, Minn. (1979) at § 892(1).

¹³ See, e.g., *Wall v. Brim*, 138 F.2d 478, 479 n.7 (5th Cir. 1943); *Hunt v. Bradshaw*, 242 N.C. 517, 88 S.E.2d 762 (1955); *Waynick v. Reardon*, 236 N.C. 116, 72 S.E.2d 4 (1952); *Paulsen v. Gundersen*, 218 Wis. 578, 260 N.W. 448 (1935).

¹⁴ There are a few cases before the first modern informed consent case in 1957 that paid some attention to doctors making disclosure to patients. The earliest, and perhaps the most important, is *Hunter v. Burroughs*, 123 Va. 113, 96 S.E. 360 (1918), in which the court spoke of the doctor's duty to warn a patient of the danger of possible bad consequences of using a remedy. See also *Wall v. Brim*, 138 F.2d 478 (5th Cir. 1943); *Pratt v. Davis*, 224 Ill. 300, 79 N.E. 562 (1906), *aff'g* 118 Ill. App. 161 (1905).

¹⁵ See generally Annotation, 56 A.L.R.2d 695, 704-07, 716-17 (1957) (collecting cases); Annotation, 139 A.L.R. 1370, 1370-71 (1942) (collecting cases); Annotation, 123 A.L.R. 1115, 1148 (1939) (collecting cases);

instances in which the provider (usually a surgeon) exceeded the agreed scope of the operation¹⁶ or transgressed a specific prohibition made by a patient.¹⁷ This period gave birth to the most well known judicial expression of a patient's right of self-determination, proclaimed in 1914 by Judge Cardozo in the *Schloendorff* case: "Every human being of adult years and sound mind has a right to determine what shall be done with his own body; and a surgeon who performs an operation without his patient's consent commits an assault for which he is liable in damages."¹⁸ Two aspects of this celebrated case are worth noting. First, it was not concerned with the question of the information a patient needs to exercise this right to self-determination. Second, the ringing judicial affirmation of the patient's right to consent came in a decision denying recovery of damages.

Not until the latter half of this century did the courts begin to marry the provider's traditional duty to secure consent with a new affirmative obligation of disclosure, perhaps best understood as a "duty to warn," resulting in a new legal doctrine of "informed consent."¹⁹ This magical phrase was first

Annotation, 76 A.L.R. 562, 562-66 (1932) (collecting cases).

¹⁶ See generally Annotation, 56 A.L.R.2d 695, 709-16 (1957) (collecting cases); Annotation, 76 A.L.R. 562, 564-66 (1932) (collecting cases).

¹⁷ *Corn v. French*, 71 Nev. 280, 289 P.2d 173 (1955); *Meek v. City of Loveland*, 85 Colo. 346, 276 P. 30 (1929); *Throne v. Wandell*, 176 Wis. 97, 186 N.W. 146 (1922); *Markart v. Zeimer*, 67 Cal. App. 363, 227 P. 683 (Ct. App. 1924).

¹⁸ *Schloendorff v. Society of New York Hosp.*, 211 N.Y. 125, 105 N.E. 92, 95 (1914).

¹⁹ This judicial development was presaged by the articulation of consent requirements in the context of research with human subjects following the revelations of Nazi atrocities during World War II. See, e.g., the Nuremberg Code (1946-49), which provides in part that the "voluntary consent of the human subject is absolutely essential" and that the "person involved...should have sufficient knowledge and comprehension of the elements of the subject matter involved as to enable him to make an understanding and enlightened decision." The Code specifies that these elements include "the nature, duration, and purpose of the experiment; the method and means by which it is to be conducted; all inconveniences and hazards reasonably to be expected; and the effects upon his health or person which may possibly come from his participation in the experiments." Several of these elements have been incorporated in informed consent requirements regarding nonexperimental health care. See also the "Principles for Those in Research and Experimentation" adopted by the General Assembly of the World Medical Association in 1954, which requires that "each person who submits to experimentation be informed of the nature of, the reason for, and risk of the proposed experiment" and that written consent be obtained. Some slight recognition of these principles existed prior to the Nuremberg trials. See Hubert Winston Smith, *Antecedent Grounds of Liability in the Practice of Surgery*, 14 ROCKY MOUNTAIN L. REV. 233, 263-65, 286-93 (1946): "The surgeon should make

invoked in a 1957 California decision, *Salgo v. Leland Stanford, Jr., University Board of Trustees*,²⁰ and was further elaborated in two opinions by the Kansas Supreme Court in *Natanson v. Kline*.²¹

Since the Natanson landmark in 1960, claims alleging lack of informed consent have been raised before the highest courts of most states.²² These courts have adopted various definitions of the legal prerequisites for recovery. Today, most states view failure to secure informed consent as a variety of medical malpractice, subject to the norms governing negligence law.

a full disclosure of material facts to the patient including risks and alternative treatments, and obtain his enlightened consent before applying any novel or experimental treatment, or administering unproven remedies, or drugs now held in question because of toxic reactions or threat of tissue damage." *Id.* at 265.

Informed consent in the context of research with human subjects is now subject to extensive government regulation as well as professional codes; see generally Chapter Two of the Commission's study, COMPENSATING FOR RESEARCH INJURIES, Government Printing Office, Washington (1982). Remarkably, none of the seminal judicial decisions rely on, or even cite, statements in the Nuremberg or other research codes. Nonetheless, although they developed along separate, parallel tracks the two areas—*informed consent for research and for therapy*—are today basically the same, and commentators and federal regulators draw on the extensive case law from therapeutic settings in elaborating the rules that are appropriate for disclosure and consent in research settings. For a thorough analysis of the role of informed consent in medical research, see Robert J. Levine, ETHICS AND REGULATION OF CLINICAL RESEARCH, Urban & Schwarzenberg, Baltimore (1981) at 69-116.

²⁰ *Salgo v. Leland Stanford Jr. Univ. Bd. of Trustees*, 154 Cal. App. 2d 560, 317 P.2d 170 (1957).

²¹ 186 Kan. 393, 350 P.2d 1093, *opinion on denial of motion for rehearing*, 187 Kan. 186, 354 P.2d 670 (1960).

²² As of 1982, 37 states had recognized a legal right of recovery for lack of informed consent. See Appendix L in Volume Three of this Report. The number of successful claims (awarding damages to injured patients for not obtaining their informed consent) appears to be relatively small. As to the proportion of malpractice suits involving informed consent, the HEW medical malpractice commission reported that as of 1971 there had been only 90 American appellate decisions in which consent was a major issue. Sylvia Law and Steven Polan, PAIN AND PROFIT: THE POLITICS OF MALPRACTICE, Harper & Row Publishers, New York, (1978) at 112. Law and Polan also cite a study undertaken by the National Association of Insurance Commissioners that reported that, in a survey of claims resolved over a 12-month period in 1975-76, informed consent was raised as an issue in only 3% of the cases. *Id.* at 113. Further, in no reported case have damages been awarded to a plaintiff solely for dignitary harm in the absence of accompanying physical injury. *But see* note 35 *infra*.

Although a few states will no longer allow health professionals to be sued in battery for failure to obtain consent,²³ many more keep the battery action as a partner to suits for negligent nondisclosure.²⁴ In these states, when no consent at all was obtained or when the procedure actually performed differed substantially from the procedure consented to, the appropriate suit is in battery; when consent to the performed procedure was obtained but disclosure was deficient, the appropriate suit is in negligence.

States have also differed in whether the applicable "standard of care" regarding what must be disclosed is based on professional custom (which typically requires that the patient produce expert testimony on such a standard) or on some notion of the "materiality" of the information to be disclosed (which allows a case to go to the jury without the patient needing to prove professional custom through expert testimony, a standard decidedly more favorable to the injured patient in most circumstances.)²⁵ Some of the cases suggest that a legal hybrid has been created, drawing on the law of battery, of negligence, and of fiduciary obligations.²⁶

²³ In many states, abolition of battery as the appropriate cause of action for informed consent actions has been achieved judicially. See, e.g., *Trogn v. Fruchtmann*, 58 Wis.2d 596, 207 N.W.2d 297 (1973). In one state, the change has been legislatively mandated. See ARIZ. REV. STAT. ANN. § 12-562(B)(1976). This change has not escaped scholarly criticism. See, e.g., Capron, *supra* note 5, at 403-29, 348-49; Joseph Goldstein, *For Harold Lasswell: Some Reflections on Dignity, Entrapment, Informed Consent, and the Plea Bargain*, 84 YALE L.J. 683 (1975); Plant, *supra* note 12; Marcus L. Plant, *The Decline of "Informed Consent,"* 35 WASH. & LEE L. REV. 91 (1978); Leonard L. Riskin, *Informed Consent: Looking for the Action*, 1975 U. ILL. L. F. 580, 585-92.

²⁴ See, e.g., *Cornfeldt v. Tongen*, 262 N.W.2d 684 (Minn. 1977).

²⁵ Comment, *Informed Consent in Medical Malpractice*, 55 CALIF. L. REV. 1396, 1405-06, 1410 (1967); Note, *Restructuring Informed Consent: Legal Therapy for the Doctor-Patient Relationship*, 79 YALE L.J. 1533, 1572-76 (1970). One of the strongest objections to the "professional" standard is that it is unclear that there is any custom in the medical profession to disclose the kind of information envisioned by the informed consent doctrine to patients, *Canterbury v. Spence*, 464 F.2d 772, 783 (D.C.Cir. 1972), and that there are strong biases in medical practice and training against making disclosure. Theodore J. Schneyer, *Informed Consent and the Danger of Bias in the Formation of Medical Disclosure Practices*, 1976 WIS. L. REV. 124.

²⁶ See, e.g., *Hales v. Pittman*, 118 Ariz. 305, 576 P.2d 493, 497 (1973). See generally Capron, *supra* note 5, at 404-29; Allan H. McCoid, *A Reappraisal of Liability for Unauthorized Medical Treatment*, 41 MINN. L. REV. 381, 434 (1957); Plant, *supra* note 12, at 650-56; Riskin, *supra* note 23, at 600-04.

A trilogy of major cases decided in 1972 in the Federal appellate court of the District of Columbia²⁷ and the state supreme courts of California²⁸ and Rhode Island²⁹ made it appear that the traditional professional custom standard of care might soon be supplanted by the materiality or patient-based approach. However, since then this trend has slowed and perhaps been reversed.³⁰ Indeed, a number of state legislatures have incorporated the professional custom standard in legislation, usually at the urging of state and local medical societies.³¹ This development was particularly prevalent during the so-called malpractice insurance crisis of the mid-1970s. Although a detailed review of the current state of the law would be a diversion from the Commission's central concerns,³² a discussion of some of the major influences on its development will help assess how well the current legal doctrine of informed consent accords with both the ethical justifications for the doctrine and the day-to-day realities of health care.

The Influence of the Litigation Process. The distinctive role and function of the courts in American society have been major influences in shaping informed consent. Courts do not

²⁷ *Canterbury v. Spence*, 464 F.2d 772 (D.C.Cir.), *cert. denied*, 409 U.S. 1064 (1972).

²⁸ *Cobbs v. Grant*, 8 Cal.3d 229, 104 Cal. Rptr. 505, 502 P.2d 1 (1972).

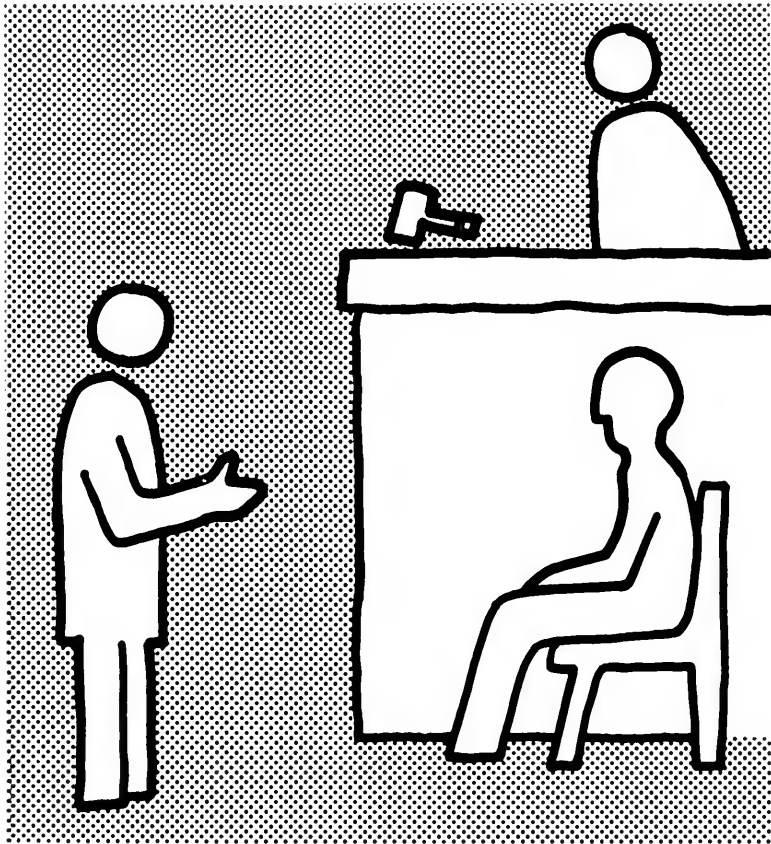
²⁹ *Wilkinson v. Vesey*, 110 R.I. 606, 295 A.2d 676 (1972).

³⁰ This approach had been suggested in scholarly literature prior to these cases. See Jon R. Waltz and Thomas W. Scheuneman, *Informed Consent to Therapy*, 64 Nw. U. L. Rev. 628 (1970); Comment, *supra* note 25; Note, *supra* note 25. When the three significant cases were decided in 1972, the intermediate appellate courts of three states had adopted the patient-based approach, though no state supreme courts had. See *Hunter v. Brown*, 4 Wash. App. 899, 484 P.2d 1162, *aff'd*, 81 Wash. 2d 465, 502 P.2d 1194 (1972); *Mason v. Ellsworth*, 3 Wash. App. 298, 474 P.2d 909 (1970); *Cooper v. Roberts*, 220 Pa. Super. 260, 286 A.2d 647 (1971); *Berkey v. Anderson*, 1 Cal. App.3d 790, 82 Cal. Rptr. 67 (1969). Between 1972 and 1978, a total of 10 jurisdictions had adopted the patient-based approach, Annotation, 88 A.L.R.3d 1008, 1034-35 (1978), compared with 17 states that either stayed with or later adopted the standard based on professional custom. *Id.* at 1024-28. However, beginning in the mid-1970s, a number of states enacted statutes changing the standard back to a professional one. Thus as of this writing, 26 states have adopted a professional standard, 9 states have a patient-oriented standard, and 3 states have no law on the subject.

³¹ Between 1975 and 1977, about half the states enacted legislation relating to requirements for informed consent. See Appendix L in Volume Three of this Report; see also Arnold J. Rosoff, *INFORMED CONSENT: A GUIDE FOR HEALTH CARE PROVIDERS*, Aspen Systems Corp., Rockville, Md. (1981) at 75-186; Meisel and Kabnick, *supra* note 1.

³² The current law of informed consent, including variations among the states, is canvassed in detail in Appendix L in Volume Three of this Report.

exist to reflect philosophically on the state of the world; nor is their role to issue gratuitous, albeit perhaps apt, advice to professionals on how to conduct their relations with patients. Rather, courts are supposed to decide concrete cases, brought by individuals seeking redress for their injuries or enforcement of their rights.



In the context of informed consent, such cases typically involve allegations by an injured patient that a practitioner's improper failure to warn of specific risks led the patient to accept medical procedures that resulted in harm the patient would have avoided if warned. The courts must determine whether such allegations are true and, if so, whether the practitioner should be legally liable to the injured patient. Only by understanding this process and the practical difficulties in carrying it out can the development of the legal doctrine of informed consent be appreciated.

First, the medical malpractice cases that find their way to court invariably involve medical interventions that did not go well.³³ Not only has the patient been physically injured by the intervention, but the patient is sufficiently displeased by the outcome so as to initiate legal action, with its well-known costs and tribulations, which may include the destruction of any positive relationship between patient and professional. When there was a strong preexisting bond between patient and professional, and when the patient was prepared for the possibility of an adverse outcome, litigation is less likely.³⁴ Thus, the courts' perspective is necessarily shaped by their near-exclusive experience with injured, unhappy patients. The far more numerous instances in which care is provided without serious misadventure do not come before them. This may help explain the sometimes differing perspectives of judges, who see only the bad outcomes, and health care professionals, who see the good as well as the bad.

Second, and more specific to informed consent, courts see only those cases in which particular allegedly undisclosed risks associated with medical procedures have led to actual injuries.³⁵ This fact, although perhaps obvious in itself, has

³³ This is an almost inevitable consequence of treating actions for lack of informed consent as a species of negligence rather than as battery, *see note 26 supra*, since negligence actions traditionally require physical harm to person or property and do not permit an award of damages for dignitary affronts alone. Prosser, *supra* note 8, § 30 at 143. *See also note 35 infra*.

³⁴ "[If] patient-physician rapport is high, [the patient] is less likely to sue his doctor in the first instance." R. Crawford Morris and Alan R. Moritz, DOCTOR AND PATIENT AND THE LAW (5th ed. 1971), quoted in Wilkinson v. Vesey, 110 R.I. 606, 295 A.2d 676, 690 (1972).

³⁵ This is referred to as the "materialized risk" requirement, which holds that a patient suffers no legally remediable wrong unless there has been some bodily injury. *See, e.g., Canterbury v. Spence*, 464 F.2d 772, 790 (D.C.Cir. 1972); *Cornfeldt v. Tongen*, 262 N.W.2d 684, 699 (Minn. 1977). This requirement has received severe criticism for failing to "recognize that a citizen can be wronged without being harmed, that his dignity as a human being has been violated and that an assault has taken place the moment the [doctor] commences therapy...even if beneficial..." Goldstein, *supra* note 23, at 691. Occasionally, patients have recovered in lawsuits merely for the dignitary affront involved in nonconsensual treatment. *See, e.g., Lloyd v. Kull*, 329 F.2d 168 (7th Cir. 1964) (\$500 for unauthorized removal of a mole); *Rolater v. Strain*, 39 Okla. 572, 137 P. 96 (1913) (\$1000 for unauthorized removal of a foot bone); *Mohr v. Williams*, 95 Minn. 261, 104 N.W. 12 (1905); *cf. Bailey v. Belinfante*, 218 S.E.2d 289 (Ga. App. 1975) (plaintiff sought damages but did not recover for allegedly nonconsensual treatment by dentist), but none of these cases involved allegations of inadequate disclosure, merely the failure to obtain consent. In the absence of bad results, a patient may only be awarded nominal damages for injury to dignity. *See, e.g., McCandless v. State*, 3 App. Div.2d 600, 606-07, 162 N.Y.S.2d 570, 575-76, *aff'd*, 4 N.Y.2d 785, 149

important consequences for the nature of informed consent litigation. Most significantly, in such cases attention tends to focus almost automatically on the particular procedure employed and on the risk that resulted in injury. The inquiry concerns whether that particular risk was disclosed, rather than whether the overall course of care, and the extended process of disclosure, discussion, and decisionmaking regarding care, were properly respectful of the patient's right of self-determination. Thus, the very nature of the court's task explains the law's oft-remarked preoccupation with the risks of particular procedures,³⁶ often to the exclusion of other aspects of the medical decisionmaking process.

Third, courts must grapple with difficulties posed by the impact of hindsight on the litigation process. Such problems arise in a number of contexts, and if not resolved satisfactorily may endanger the integrity of the courts' truth-seeking function.

Two closely related instances of such difficulties involve the centrally important determinations of whether information that was not disclosed was "material" to the patient (that is, "when a reasonable person in what the physician knows or should know to be the patient's position, would be likely to attach significance to the risk or cluster of risks in deciding whether or not to undergo the proposed therapy"³⁷) and whether the provider's failure to disclose this information "caused" the patient to undertake the course of action that resulted in injury. In both instances, the patient's own testimony about what would have been important to know and how that information would have affected his or her decision may be colored by hindsight, as well as by the patient's recognition that different reconstructions of hypothetical past decisions may help determine whether the case is won or lost. Thus, while injured patients will possess unique insight into their own values and choices, the courts have understandably tried to limit the impact of possibly speculative and potentially self-serving testimony.³⁸

N.E.2d 530, 173 N.Y.S.2d 30 (1957), in which a patient in a state mental hospital was awarded \$10,000 for an unauthorized abortion performed on her. The damages were, however, reduced by the appellate court in light of testimony that her condition was improved by this termination of pregnancy.

³⁶ See, e.g., Jay Katz, *Informed Consent—A Fairy Tale?: Law's Vision*, 39 U. PITT. L. REV. 137, 172 (1977).

³⁷ This formulation was originally put forth by Professor Jon Waltz and Thomas Scheuneman in their classic article on informed consent and adopted, more or less verbatim, in the seminal informed consent case of *Canterbury v. Spence*, 464 F.2d 772, 788 (D.C.Cir. 1972). See Waltz and Scheuneman, *supra* note 30, at 640.

³⁸ See *Canterbury v. Spence*, 464 F.2d 772, 791 (D.C.Cir. 1972).

Accordingly, for both determinations of the materiality of information concerning risks and the existence of proximate cause, most courts have been drawn to what is known as an "objective standard." This requires juries to consider the issues as if they were an "average, reasonable person" in the position of the particular patient.³⁹ To the degree that the decision of the average, reasonable patient would differ from the perhaps idiosyncratic decision of a particular patient, the law's objective standard fails to support that particular patient's right of self-determination.⁴⁰ Nevertheless, a more subjective standard, better attuned to the values of each person, could pose serious practical difficulties in litigation.⁴¹

Although this standard attempts to protect against the dangers of hindsight, the physicians' burdens may still be increased since it is impossible to control fully the degree to which a jury may actually consider any special circumstances and needs of a particular plaintiff. In assessing whether the particular risk that resulted in injury should have been disclosed, the jury cannot magically forget that the risk in fact materialized. A jury, as the finder-of-fact in the case before it, is not in a position to explore all the practical implications of requiring disclosure of a particular risk to future patients facing comparable decisions. Consequently, the judgments in individual cases may seem to impose overly burdensome disclosure requirements. It would be unfortunate, in the Commission's

³⁹ See, e.g., *Canterbury v. Spence*, 464 F.2d 772, 788 (D.C.Cir. 1972); *Sard v. Hardy* 379 A.2d 1014, 1022 (Md. Ct. App., 1977); Rev. Code Wash. Ann. § 7.70.050(c).

⁴⁰ "In holding that the materiality of information is to be judged by what the law's mythical 'reasonable person' would want to know, these courts retreated from the logic of their own reasoning." Capron, *supra* note 5, at 407; see also Goldstein, *supra* note 23; Joseph King, *In Search of a Standard of Care for the Medical Profession: The "Accepted Practice" Formula*, 28 VAND. L. REV. 1213, 1265 (1975); Riskin, *supra* note 23, at 589.

⁴¹ Although acknowledging the practical difficulties attendant upon the use of a subjective test of causation, the North Carolina Supreme Court nevertheless adopted the test because "[t]he detriments of the objective standard are more severe." The court continued by stating:

In determining liability by whether a reasonable person would have submitted to treatment had he known of the risk that the defendant failed to relate, no consideration is given to the peculiar quirks and idiosyncracies of the individual. His supposedly inviolable right to decide for himself what is to be done with his body is made subject to a standard set by others. The right to base one's consent on proper information is effectively vitiated for those with fears, apprehensions, religious beliefs, or superstitions outside the mainstream of society.

opinion, if these legal interventions resulted in physicians feeling compelled to recite formally a parade of all risks remotely associated with each alternative treatment. Such recitations can be so overwhelming that patients are unable to distinguish truly significant information and to make sound decisions. A more appropriate course, albeit a more demanding one, would be for the courts to consider the practical implications of requiring disclosure of a particular risk—and of all comparable risks—to all patients facing comparable decisions.

The fourth influence of the litigation process on the evolution of informed consent law is that courts must determine whether required disclosures were in fact made.⁴² Here again, reliance on after-the-fact testimony by patient or provider may be less than satisfactory. As in many other legal contexts, written documentation of disclosure and consent can provide useful evidence—hence, the ubiquitous “informed consent form.”⁴³ Unfortunately, all too often such forms can become a substitute for, rather than merely a record of, a continual process of disclosure, discussion, and consent. If providers come to believe (probably incorrectly⁴⁴) that their obligation to obtain the patient’s informed consent can be satisfied by securing a signature—even if a patient is drowsy, drugged, or confused or the form is abstruse, jargon-ridden, or largely unintelligible—the law’s inclination to rely on written

⁴² Informed consent cases almost inevitably lead to “testimonial contests” in which patients claim that they were not warned of the risks that befell them, and doctors claim that warnings were issued. *See, e.g.,* *Bloskas v. Murray*, 618 P.2d 719, 720-21 (Colo. Ct. App. 1980); *Beck v. Lovell*, 361 So.2d 245, 248-49 (La. Ct. App. 1978); *Schroeder v. Lawrence*, 359 N.E.2d 1301, 1302 (Mass. 1977). This problem also arose in older “consent” cases before the development of the informed consent requirement. *See, e.g.,* *Beatty v. Cullingworth*, 44 CENT. L. J. 153 (Q.B. 1896)(unreported).

⁴³ Because consent forms are often conclusorily worded—that is, the patient acknowledges that he has received information or “adequate” information about risks, benefits, alternatives, etc., but the form does not actually recite this information—at best they will protect the physician against a suit for battery, but not for negligent failure to disclose. Note, 44 BROOKLYN L. REV. 241, 260 (1978). Actually providing full information to patients is not always the goal of consent forms; rather, “avoiding this risk [of liability] seems to be a primary concern of those who draft what are strangely called ‘informed consent forms’....” Goldstein, *supra* note 23, at 692.

⁴⁴ Merely obtaining a patient’s signature on a consent form does not provide airtight insulation against liability. *See, e.g.,* *Demers v. Gerety*, 85 N.M. 641, 515 P.2d 645, 649 (Ct. App. 1973). Although no informed consent statutes require that consent be obtained in writing, some statutes confer a “presumption of validity” on a written consent. It is not clear, however, that such a presumption works any substantial change in the common law. *See* Meisel and Kabnick, *supra* note 1, at 469-76.

documentation may pervert its central purpose in requiring informed consent.

Finally, the structure of lawsuits requires the naming of particular defendants who will bear financial responsibility in the event of an adverse judgment, either individually or, more typically, through their liability insurers. Injured patients may bring claims against all persons associated with their care, but claims are typically directed against parties with "deep pockets," usually institutions and individual physicians. This pattern does not necessarily reflect the activities of other members of the health care team, particularly nurses, with regard to informing patients and securing their consent.

Thus, the litigation process has shaped the legal doctrine of informed consent. The nature of the cases coming before the courts led to a particular perspective on the character, failings, and potential of relationships between patients and health care providers. The existence of an injury led courts to concentrate on whether there had been disclosure of the particular risks of the medical procedure rather than to an evaluation of the process of patient-professional communication as a whole. The need to avoid giving undue weight to a patient's after-the-fact, speculative, and potentially self-serving testimony regarding materiality and causation led to an objective standard that can contradict individual patients' particular values or desires. And the need to identify legal responsibility and potential financial liability led to a particular view of the appropriate roles of members of the health care team. Taken together, these have brought the current law to an uneasy compromise among ethical aspirations, the realities of medical practice, and the exigencies of the litigation process.⁴⁵

Law, Ethics, and Medical Practice. The realities of court decisions on informed consent thus fall short of the law's professed commitment to the value of self-determination. Since "the courts imposed primarily a duty-to-warn on physicians,"

⁴⁵ Several of the major judicial opinions articulating (and broadening) the legal right to informed consent came in appellate decisions reversing judgments at the trial court level, typically on the ground that the district court's instructions to the jury improperly confined the jury's ability to find in favor of the plaintiff. Thus, the appellate courts, which are somewhat more removed from the exigencies of trial work, have been more willing to expand the scope of required disclosure. Further, the practical result of these appellate decisions is not the award of damages, but rather the return of the case for retrial under the proper (broadened) legal standard. Thus, the ultimate questions of liability and damages still have to be determined by a jury. Even under the broadened standard the jury may decide that the provider met the obligation of disclosure or that the lack of disclosure did not, in light of the medical indications favoring the procedure, "cause" the patient's decision to undergo the procedure, thereby resulting in injury.

thereby avoiding a judicial recognition of the proposition that patients have a decisive role to play in the medical decision-making process, they have merely reinforced "physicians' traditional monologue of talking *at* and not *with* patients."⁴⁶ As a result they have missed the opportunity to move toward what is needed: "a new and unaccustomed dialogue between physicians and their patients...in which both, appreciative of their respective inequalities, make a genuine effort to voice and clarify their uncertainties and then to arrive at a mutually satisfactory course of action."⁴⁷

The Commission, while recognizing the difficulty of the task, believes that "shared decisionmaking" is the appropriate ideal for patient-professional relationships that a sound doctrine of informed consent should support.⁴⁸ The Commission doubts that this will occur, however, if primary reliance is placed on the courts. This is not to say that present legal requirements for informed consent should be abandoned or reduced in scope. Current law serves the important purpose of encouraging health care professionals to disclose important facts to patients and not to proceed with medical interventions unless patients have consented. The law also serves a critical moral and educative role in proclaiming (even if not always fully enforcing) the value of self-determination. These functions can and should continue. The Commission's skepticism relates solely to the likelihood that an expansion of the existing law could control ever more minutely the relationships of patients and health care professionals.

⁴⁶ Jay Katz, *Disclosure and Consent: In Search of Their Roots*, in Aubrey Milunsky and George J. Annas, eds., *GENETICS AND THE LAW II*, Plenum Press, New York (1980) at 122.

⁴⁷ *Id.*

⁴⁸ *Id.* at 124. Dr. Katz cautions emphatically

that translating such a prescription into practice is an inordinately hard task—it is opposed by thousands of years of tradition; it demands unrelenting vigilance, for the propensity to view patient[s]...as children who need to be led, however gently, is ever-present; it calls for a commitment that takes patience and time. Perhaps such a prescription asks for too much, perhaps even patient[s]...may not wish to interact with professionals on that basis.

Id. Further, he observes, the required "prescription...[of] nurtur[ing] the patient[s]' autonomous, adult functioning through a persistent dialogue...goes counter to current practices that exploit the natural regression resulting from illness and stress." *Id.* at 125-26. Finally, the possibilities of achieving shared decisionmaking based on mutual respect and trust are further undercut by the pervasiveness of uncertainty in medical practice and by physicians' attitudes toward it: "[T]he prevailing climate of professional conduct is first to pay lip service to uncertainty and then to proceed, while interacting with self and patients, as if uncertainty did not exist." *Id.* at 126.

The litigation process itself seriously limits the law's ability to reach into an intimate relationship so as to foster a genuine dialogue between health care professionals and their patients.⁴⁹ Not only is the Commission doubtful that laws or regulations can fully bring about shared decisionmaking between patient and professional, but it is concerned that efforts to do so may have unintended and deleterious side effects.

Nevertheless the Commission does not believe that the ideal of better informed consent should be abandoned. In subsequent portions of this Report the Commission attempts to define the ideal more precisely and to suggest a number of means in addition to statutes and judicial decisions that could move day-to-day medical practice closer to shared decision-making.

The Context of Consent

The Commission believes that an analysis of "the ethical and legal implications of requirements for informed consent to...undergo medical procedures"⁵⁰ is best undertaken in the context of a broader examination of relationships between patients and health care professionals in American society. At issue is the definition of the patient-professional relationship, as well as the appropriate role of formal and informal modes of social regulation in shaping it. Clearly, the resolution of these issues requires more than a simple review of the existing law of informed consent. Thus, the remainder of this Report considers patterns of communication between patients and health care professionals and how decisions are made. These inquiries are framed by the Commission's ultimate question about this aspect of its work: how can a fuller, shared understanding by patient and professional of their common enterprise be promoted, so that patients can participate, on an informed basis and to the extent they care to do so, in making decisions about their health care?

Historical Development. While the law has proclaimed, if not always given effect to, such propositions as "Anglo-

⁴⁹ Courts may not, in any event, be inclined to enforce truly shared decisionmaking, even if they were able to do so. Law has often been reluctant to intrude on the autonomy of the medical profession, out of deference to medical expertise, respect for the values of life and health served by the medical profession, and perhaps an unspoken recognition that rules created for health professionals may someday be applied to the legal profession as well. The very history of informed consent litigation, as well as on other areas of medical malpractice, provides ample (although not unmixed) evidence for these views.

⁵⁰ 42 U.S.C. § 300v-1 (a)(1)(A) (1981) the statutory mandate adopted in 1978, under which the Commission examines this issue.

American law starts with the premise of thorough-going self-determination"⁵¹ and "each man is considered to be his own master,"⁵² recent scholarship has suggested that such sentiments have played little role in traditional health care and are indeed antithetical to the proclaimed norms of the medical profession.⁵³ Medical skepticism of patients' capacities for self-determination can be traced to the time of Hippocrates:

Perform [these duties] calmly and adroitly, concealing most things from the patient while you are attending to him. Give necessary orders with cheerfulness and sincerity, turning his attention away from what is being done to him; sometimes reprove sharply and emphatically, and sometimes comfort with solicitude and attention, revealing nothing of the patient's future or present condition.⁵⁴

These attitudes continued to be reflected both in professional codes of ethics and in influential scholarly writings on medical ethics throughout the nineteenth and early twentieth centuries, and indeed survive to this day.⁵⁵ Studies of the records of daily medical practice (rather than normative statements of professional ethics) have found distinct "indigenous medical traditions" of truth-telling and consent-seeking, grounded on the theory that such knowledge "had demonstrably beneficial effects on most patients' health."⁵⁶ But little evidence exists that such traditions combined in anything like the modern doctrine of informed consent. Nor did they derive from or imply any commitment by the medical profession to patient autonomy. Indeed, when patients' wishes regarding treatment were respected it was largely because providers recognized their limited therapeutic capabilities and the substantial risks accompanying medical interventions (for example, surgery without antiseptic) as well as the impracticability of forcing treatments on resisting patients.⁵⁷

Contemporary Trends. Recent changes in health care practices, as well as broader societal changes in contemporary American life, have led to an intense reexamination of

⁵¹ *Natanson v. Kline*, 186 Kan. 393, 350 P.2d 1093 (1960).

⁵² *Scott v. Bradford*, 606 P.2d 554, 556 (Okla. 1980).

⁵³ See Jay Katz, *Disclosure and Consent in Psychiatric Practice: Mission Impossible?*, in Charles K. Hofling, ed., *LAW AND ETHICS IN THE PRACTICE OF PSYCHIATRY*, Brunner/Mazel, Inc., New York (1980) at 91.

⁵⁴ Hippocrates, *Decorum*, in *HIPPOCRATES*, Harvard University Press, Cambridge, Mass. (W.H.S. Jones trans. 2d ed. 1967), quoted in Katz,, *supra* note 46, at 124.

⁵⁵ See Katz, *supra* note 53, at 91, 97-100.

⁵⁶ Martin S. Pernick, *The Patient's Role in Medical Decisionmaking: A Social History of Informed Consent in Medical Therapy* (1981), Appendix E, in Volume Three of this Report.

⁵⁷ *Id.*

relationships between patients and health care practitioners. Gradually, a new understanding of the proper levels and limits of health care is emerging; from this flow changes in the relative rights and obligations of patients and professionals concerning matters such as disclosure and consent for medical interventions.

Perhaps the most significant single factor in this process is the emergence of the scientific, technological approach to medical care over the course of the past century. The rapidly evolving technical prowess of medicine has, of course, brought with it improved health, greater quality and length of life, and new sources of hope for the ill. This revolution in the capacities of medicine has also had profound effects on the structure of the health care delivery system and on the nature of the patient-professional relationship.

Several of these changes are particularly relevant to informed consent. First, health care is now provided in a vast array of settings, ranging from home visits by traditional family doctors to clinics, health maintenance organizations, and multispecialty group practices, to nursing homes and other long-term or chronic care facilities, to high-technology tertiary care centers. Care is frequently provided by teams of highly specialized professionals whose individual responsibilities may be defined less by the overall needs of the patient than by particular diseases or organ systems. When this occurs there may be no single professional in effective command of the entire care of the patient, no one who knows the patient well and to whom the patient may turn for information, advice, and comfort. In such instances the health care system's increased capacity and determination to overcome a disease or defect may be accompanied by a diminished capacity and inclination to care for the patient in more human terms.⁵⁸

Such situations pose a far more serious threat to patient well-being and autonomy than any formal disclosure of remote risks on informed consent forms could possibly remedy. Indeed, the Commission believes that serious efforts by health care institutions to ensure that patients have one identifiable and reliable source of information concerning their care would do far more to remedy the current ills of the health care system than would legal prescriptions with which compliance can be neither assumed nor enforced.⁵⁹

⁵⁸ Dissatisfaction by both patients and some professionals with these depersonalizing tendencies of modern medicine is suggested by the renaissance of interest in holistic medicine and the rise of the self-care movement.

⁵⁹ The problems of not having one person coordinating care are illustrated in this quote from a patient with leukemia:

I kept fighting through all the fevers and transfusions. I felt I could only survive it by insisting on control. And there would

The expanded potential of medicine has also widened the range of choices about health care. Increasingly, the question is not simply whether to accept a single intervention that is available for a particular condition, but which intervention to choose. Often the alternatives vary markedly in their prospects for success, their intrusiveness, their potential side effects, and their other implications for patients' ability to conduct their lives as they see fit. A determination of what is "indicated" is thus inextricably intertwined with the needs and values of the particular patient.

These changes in medicine have been accompanied by broader trends in American society and culture that have reinforced their impact. Since the early 1960s there has been an extraordinary emphasis on the rights of citizens to direct the course of their lives, from voting rights to consumer rights. This stress on the individual has been coupled with a skepticism toward claims of specialized expertise and a suspicion of powerful institutions and the "establishment." Health care has not escaped its share of criticism in the process.

Some commentators have seen in these trends the basis for a new view of the role of medicine and the nature of the patient-provider relationship:

The traditional paternal model of medicine was premised on trust in the physician's technical competence and moral sensitivity and was characterized by patient dependency and physician control. This model is being replaced gradually by one in which patients are increasingly involved in decisionmaking concerning their own medical care. The rise of consumerism and the associated emergence of "rights" language in medicine has encouraged some individuals to view medicine as a

be plenty of chances to test my resolve. The personnel assigned to monitor various functions never coordinated their blood sample requirements on a given day, so they'd come two or three times to leech my tender, collapsing veins. I finally put my foot down.

"You're not going to take more blood," I shouted. "You take it once a day. Get together and find out how much you want and for what purpose, and, goddam it, in the absence of an emergency, don't you touch my veins. Also, no one's going to draw blood except the intravenous nurse team," I said, "because that's all they do, and they know how to do it."

I got my way in both instances, thereby saving myself considerable pain.

"serving" profession and to regard themselves not as patients but as "medical consumers." Such "medical consumers" sometimes wish to invert the traditional model of medicine and to make the physician a passive agent, a hired technician who practices under the direction and control of his "client." However, despite these changes which affect some patients and some physicians, many patients and physicians continue to interact in a fairly traditional, paternalistic physician-patient relationship.⁶⁰

The survey done for the Commission lends support to the conclusion that changes are occurring in the relationship between physicians and patients. Compared with previous studies, the current results demonstrate a clear sense of physicians' responsibilities for making disclosures and reaching mutual decisions.⁶¹ Although the results from the separate surveys of the public and of physicians indicate substantial agreement on these expectations, some lack of congruence remains. Moreover, the observational studies done for the Commission make it apparent that in actual relationships even more divergence occurs between laypeople's and professionals' expectations.

The role of the health care professional thus appears to be in a "phase of incomplete redefinition," as one Commission witness noted.⁶² During this time "judgments of conscientious persons have become divergent and perplexed" and societal consensus does not exist.⁶³ No longer are the proper ends and limits of health care commonly understood and broadly accepted; a new concept of health care, characterized by changing expectations and uncertain understanding between patient and practitioner, is evolving. The need to find an appropriate balance of the rights and responsibilities of patients and health care professionals in this time of change has been called "the critical challenge facing medicine in the coming decades."⁶⁴

⁶⁰ Mark Siegler, *Searching for Moral Certainty in Medicine: A Proposal for a New Model of the Doctor-Patient Encounter*, 57 BULL. N.Y. ACAD. MED. 56, 60 (1981).

⁶¹ The legal doctrine of informed consent has been severely criticized by medical professionals for going too far in its requirements for disclosure. See note 5 in Chapter Seven *infra*. Such criticism has diminished substantially in recent years. Furthermore, there is considerable evidence that physicians today actually do disclose a great deal more information to patients than they did 10-20 years ago. See Chapter Four *infra*.

⁶² Siegler, *supra* note 60, at 61.

⁶³ *Id.*

⁶⁴ *Id.*

The Commission's View

Two models of the patient-professional relationship have dominated the debate surrounding this challenge. For the sake of simplicity, while recognizing the caricatures involved, these may be referred to as "medical paternalism" and "patient sovereignty." Medical paternalism is based on a traditional view of health professionals—typically physicians—as the dominant, authoritarian figure in the relationship, with both the right and the responsibility to make decisions in the medical best interests of the patient. In reaction to this view, some have sought to take over the physician's dominant position. Proponents of maximal patient sovereignty assign patients full responsibility for and control over all decisions about their own care. According to this view, practitioners should act as servants of their patients, transmitting medical information and using their technical skills as the patient directs, without seeking to influence the patient's decisions, much less actually make them.

Both positions attempt to vest exclusive moral agency, ethical wisdom, and decisionmaking authority on one side of the relationship, while assigning the other side a dependent role. In the view of the Commission, neither extreme adequately reflects the current nature and needs of health care. The debate has increasingly become an arid exercise, which the Commission believes should be replaced by a view that reflects the tremendous diversity of health care situations and relationships today. In this Report, the Commission attempts to shift the terms of the discussion toward how to foster a relationship between patients and professionals characterized by mutual participation and respect and by shared decision-making. The Commission believes such a shift in focus will do better justice to the realities of health care and to the ethical values underlying the informed consent doctrine.

Although described in a single phrase, the Commission's view is intended to encompass a multitude of different realities, each one shaped by the particular medical encounter and each one subject to change as the participants move toward accommodation through the process of shared decisionmaking:

The nature of the patient involved—his personality, character, attitude, and values—and the factors which led him to seek a medical encounter with this particular physician are central components of the process. Similarly, the personality, character, attitude, values, and technical skills of the physician affect the accommodation. Further, the quality of the interaction between patient and physician—the chemistry of the interaction—modify the process. Of course, the nature of the medical problem, including its type, acuteness, gravity,

and its potential for remediation, will be a major determinant of whether a physician-patient accommodation is achieved. For example, the entire process will be modified profoundly and telescoped if the patient is acutely or critically ill and alternative medical resources are unavailable. Finally, other considerations which may affect the achievement of a physician-patient accommodation include the clinical setting, *e.g.*, a hospital, doctor's office, or the patient's home; the organization of the medical service, Health Maintenance Organization, or fee-for-service; and also, occasionally, the claims of relevant third party interests such as those of family, insurers, or the state.⁶⁵

At each point, the patient and physician will arrive at a joint decision in which the physician agrees to care for the patient and the patient agrees to be treated by the physician. The particular resolution of rights and responsibilities reached at a given point of the relationship may change with time and circumstances. The resiliency of the relationship will depend importantly on the extent of trust and confidence exchanged between patient and professional.⁶⁶

Whether society should accept whatever accommodation the parties agree to regarding the communication process and the allocation of decisionmaking authority is a complex issue. It raises the question of whether patient-professional relationships are best seen as purely contractual ones, subject to modification solely on the basis of agreement by the parties, or are instead invested with a certain public interest that justifies the imposition by society of limits on the acceptable range of consensual arrangements. The contractual view has strong roots in American traditions of voluntarism and individual responsibility. Yet for reasons of history, tradition, expectations, and disparities in educational, class, and health status, patients and professionals often start out on substantially unequal footing, raising serious questions about the ability of many patients to have an effective role in shaping the relationship.

Through law, American society has regulated relationships between patients and health care practitioners for almost a century. The control of advertising by doctors (to prevent the deception of unknowing patients) and the licensing of practitioners (to prohibit quackery and establish minimum standards of expertise) are some of the earliest examples. Medical malpractice law and criminal law also establish some limits on the freedom of practitioners in the interests of patients. Informed consent is merely one of the newer ways that society

⁶⁵ *Id.* at 62.

⁶⁶ *Id.* at 63.

places some limits on the range of relationships between patients and practitioners.

The Commission concludes that considerable flexibility should be accorded to patients and professionals to define the terms of their own relationships. The resolution favored by the Commission is a presumption that certain fundamental types of information should be made available to patients and that all patients competent to do so have a right to accept or reject medical interventions affecting them. Similarly, a professional who has been as flexible about possible avenues of treatment as his or her beliefs and standards allow is not generally obligated to accede to the patient in a way that violates the bounds of acceptable medical practice or the provider's own deeply held moral beliefs.

Nevertheless, in light of the disparities between the positions of the parties, the interaction should, at a minimum, provide the patient with a basis for effective participation in sound decisionmaking regardless of the particular form of the accommodation. 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.⁶⁷ 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.⁶⁸ 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.

The Commission encourages, to perhaps a greater degree than is explicitly recognized by current law, the ability of patients and health care professionals to vary the style and extent of discussion from that mandated by this general presumption. Such variations might take any of several directions: in one relationship, the patient might prefer not to be

⁶⁷ The Commission's focus in this discussion on the process of reaching agreement is quite deliberate. For perhaps understandable reasons, much of the scholarly legal and philosophical literature concentrates on the "hard case," the case in which no agreement can be reached: when it comes to the crunch, who ultimately has the power to decide? Although such questions cannot be ignored, the Commission's effort in this Report is to readjust the balance toward fuller consideration of those less dramatic issues that arise routinely in the day-to-day practice of responsible medicine and nursing but that have received less attention and emphasis.

⁶⁸ This image of reaching out to a patient is captured well in the following: "The skillful doctor, metaphorically speaking, throws out a rope to the patient drowning in illness and by encouraging the patient to hold on furthers the healing process." Abram, *supra* note 59, at 116.

burdened by detailed discussion of risks unlikely to arise or to affect the decision; in another relationship, a patient might request unusually detailed information on unconventional alternative therapies; in a third, a patient with a longstanding and close relationship of trust with a particular physician might ask that physician to proceed as he or she thinks best, choosing the course of therapy and revealing any information that the physician thinks would best serve the interests of the patient. Inherent in allowing such variations is the difficulty of ensuring they are genuinely agreeable to both parties and do not themselves arise out of an imbalance in status or bargaining power.

The health professional's expert knowledge, focused through the particular diagnosis and prognosis for the patient, usually confers on that person the natural role of leader and initiator in building this shared understanding. The patient, on the other hand, is especially well placed to assess the overall effects of the medical condition and possible treatments, in light of his or her own particular goals and values. Thus each party brings to the relationship special knowledge and perspectives that can help to clarify for both parties what is actually at issue in any decision to be reached.

The Commission is aware that its description of mutual participation and shared decisionmaking sets a high ideal. Both professional and patient in this dialogue are liable to misunderstandings and confusions, false hope or despair, unvoiced fears, anxiety, and questions. Even when each is sensitive to the presence of these barriers to full understanding and seeks to surmount them in the interest of agreeing on their common venture—that is, treating the patient successfully—difficulties will persist. Yet it remains a goal worth striving toward. In this Report the Commission not only fills out the contours of the concept sketched here but also explores its roots in basic values and in contemporary opinion and its implications for the education of health professionals, the delivery of care, the attitudes of patients and providers, and the rules of society as expressed through the law.

The Values Underlying Informed Consent

2

What are the values that ought to guide decisionmaking in the provider-patient relationship or by which the success of a particular interaction can be judged? The Commission finds two to be central: promotion of a patient's well-being and respect for a patient's self-determination.¹ Before turning to the components of informed consent (Part Two of this Report) or the means for promoting its achievement (Part Three), these central values will be explored. They are in many ways compatible, but their potential for conflict in actual practice must be recognized.²

¹ Although these principles have been discussed in judicial decisions and legal commentary on informed consent, the concern of the Commission with patient-provider communication and with decisionmaking in health care in general causes it to consider the issue in a way that is broader and more complex than the legal doctrine. The implications of this discussion for law are noted at appropriate points, however, and conclusions about those implications are given in Part Three.

² Pursuit of these two values is constrained in various ways, most notably by society's overall interest in equity, justice, and maximum social welfare. These issues are the central concerns of the Commission's forthcoming report *SECURING ACCESS TO HEALTH CARE*. Because these goals need not be central to the decisionmaking process of patients and providers, this report does not take up the complications arising from conflicts between legitimate societal goals and individual patient goals. The Commission's forthcoming report on decisions about life-sustaining therapy explores the relationship between societal and individual concerns in the context of a particular set of health care decisions.

Serving the Patient's Well-Being

Therapeutic interventions are intended first and foremost to improve a patient's health. In most circumstances, people agree in a general way on what "improved health" means. Restoration of normal functioning (such as the repair of a fractured limb) and avoidance of untimely death (such as might occur without the use of antibiotics to control life-threatening infections in otherwise healthy persons) are obvious examples. Health care is, in turn, usually a means of promoting patients' well-being. The connection between a particular health care decision and an individual's well-being is not perfect, however. First, the definition of health can be quite controversial: does wrinkled skin or uncommonly short stature constitute impaired health, such that surgical repair or growth hormone is appropriate? Even more substantial variation can be found in ranking the importance of health with other goals in an individual's life. For some, health is a paramount value; for others—citizens who volunteer in time of war, nurses who care for patients with contagious diseases, hang-glider enthusiasts who risk life and limb—a different goal sometimes has primacy.

Absence of Objective Medical Criteria. Even the most mundane case—in which there is little if any disagreement that some intervention will promote health—may well have no objective medical criteria that specify a single best way to achieve the goal. A fractured limb can be repaired in a number of ways; a life-threatening infection can be treated with a variety of antibiotics; mild diabetes is subject to control by diet, by injectable natural insulin, or by oral synthetic insulin substitutes. Health care professionals often reflect their own value preferences when they favor one alternative over another; many are matters of choice, dictated neither by biomedical principles or data nor by a single, agreed-upon professional standard.

In the Commission's survey it was clear that professionals recognize this fact: physicians maintained that decisional authority between them and their patients should depend on the nature of the decision at hand. Thus, for example, whether a pregnant woman over 35 should have amniocentesis was viewed as largely a patient's decision, whereas the decision of which antibiotic to use for strep throat was seen as primarily up to the doctor. Furthermore, on the question of whether to continue aggressive treatment for a cancer patient with metastases in whom such treatment had already failed, two-thirds of the physicians felt it was not a scientific, medical decision, but one that turned principally on personal values. And the same proportion felt the decision should be made jointly (which 64% of the doctors claimed it usually was).

Patient's Reasonable Subjective Preferences. Determining what constitutes health and how it is best promoted also requires knowledge of patients' subjective preferences. In pursuit of the other goals and interests besides health that society deems legitimate, patients may prefer one type of medical intervention to another, may opt for no treatment at all, or may even request some treatment when a practitioner would prefer to follow a more conservative course that involved, at least for the moment, no medical intervention. For example, a slipped disc may be treated surgically or with medications and bed rest. Which treatment is better can be unclear, even to a physician. A patient may prefer surgery because, despite its greater risks, in the past that individual has spent considerable time in bed and become demoralized and depressed. A person with an injured knee, when told that surgery has about a 30% chance of reducing pain but almost no chance of eliminating it entirely, may prefer to leave the condition untreated. And a baseball pitcher with persistent inflammation of the elbow may prefer to take cortisone on a continuing basis even though the doctor suggests that a new position on the team would eliminate the inflammation permanently. In each case the goals and interests of particular patients incline them in different directions not only as to how, but even as to whether, treatment should proceed.

Given these two considerations—the frequent absence of objective medical criteria and the legitimate subjective preferences of patients—ascertaining whether a health care intervention will, if successful, promote a patient's well-being is a matter of individual judgment. Societies that respect personal freedom usually reach such decisions by leaving the judgment to the person involved.

The Boundaries of Health Care. This does not mean, however, that well-being and self-determination are really just two terms for the same value. For example, when an individual (such as a newborn baby) is unable to express a choice, the value that guides health care decisionmaking is the promotion of well-being—not necessarily an easy task but also certainly not merely a disguised form of self-determination.

Moreover, the promotion of well-being is an important value even in decisions about patients who can speak for themselves because the boundaries of the interventions that health professionals present for consideration are set by the concept of well-being. Through societal expectations and the traditions of the professions, health care providers are committed to helping patients and to avoiding harm. Thus, the well-being principle circumscribes the range of alternatives offered to patients: informed consent does not mean that patients can insist upon anything they might want. Rather, it is a choice among medically accepted and available options, all of which

are believed to have some possibility of promoting the patient's welfare, including always the option of no further medical interventions, even when that would not be viewed as preferable by the health care providers.

In sum, promotion of patient well-being provides the primary warrant for health care. But, as indicated, well-being is not a concrete concept that has a single definition or that is solely within the competency of health care providers to define. Shared decisionmaking requires that a practitioner seek not only to understand each patient's needs and develop reasonable alternatives to meet those needs but also to present the alternatives in a way that enables patients to choose one they prefer. To participate in this process, patients must engage in a dialogue with the practitioner and make their views on well-being clear. The majority of physicians (56%) and the public (64%) surveyed by the Commission felt that increasing the patient's role in medical decisionmaking would improve the quality of health care.³

Since well-being can be defined only within each individual's experience, it is in most circumstances congruent to self-determination, to which the Report now turns.

Respecting Self-Determination

Self-determination (sometimes termed "autonomy") is an individual's exercise of the capacity to form, revise, and pursue personal plans for life.⁴ Although it clearly has a much broader application, the relevance of self-determination in health care decisions seems undeniable. A basic reason to honor an individual's choices about health care has already emerged in this Report: under most circumstances the outcome that will best promote the person's well-being rests on a subjective judgment about the individual. This can be termed the instrumental value of self-determination.

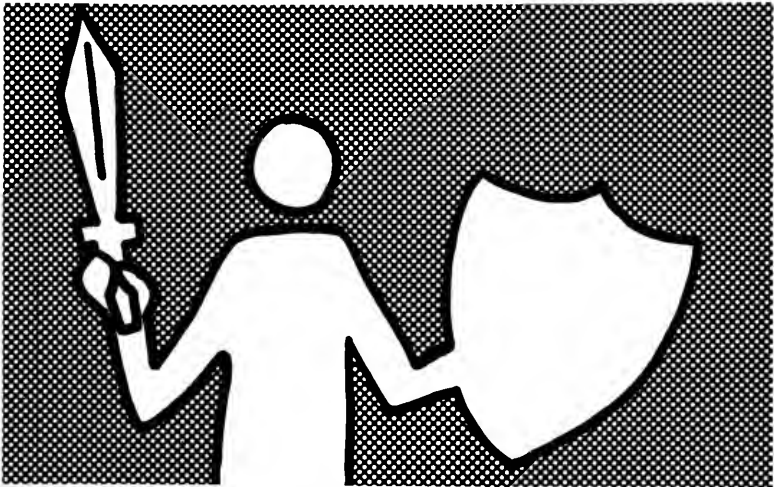
More is involved in respect for self-determination than just the belief that each person knows what's best for him- or herself, however. Even if it could be shown that an expert (or a computer) could do the job better, the worth of the individual, as acknowledged in Western ethical traditions and especially

³ Many physicians and patients said they believed an increased patient role would give the patient a better understanding of the medical condition and treatment, would improve physician performance in terms of the honesty and scope of discussion, and would generally improve the doctor-patient relationship. However, a number of physicians claimed that greater patient involvement would improve the quality of care because it would improve compliance and would make patients more cooperative and willing to accept the doctor's judgment.

⁴ Gerald Dworkin, *Autonomy and Informed Consent* (1982), Appendix G, Volume Three of this Report, at section 5.

in Anglo-American law, provides an independent—and more important—ground for recognizing self-determination as a basic principle in human relations, particularly when matters as important as those raised by health care are at stake. This noninstrumental aspect can be termed the intrinsic value of self-determination.

Intrinsic Value of Self-Determination. The value of self-determination readily emerges if one considers what is lost in its absence. If a physician selects a treatment alternative that satisfies a patient's individual values and goals rather than allowing the patient to choose, the absence of self-determination has not interfered with the promotion of the patient's well-being. But unless the patient has requested this course of conduct, the individual will not have been shown proper respect as a person nor provided with adequate protection against arbitrary, albeit often well-meaning, domination by others. Self-determination can thus be seen as both a shield and a sword.



Freedom from interference. Self-determination as a shield is valued for the freedom from outside control it is intended to provide. It manifests the wish to be an instrument of one's own and "not of other men's acts of will."⁵ In the context of health care, self-determination overrides practitioner-determination even if providers were able to demonstrate that they could (generally or in a specific instance) accurately assess the treatment an informed patient would choose. To permit action on the basis of a professional's assessment rather than on a patient's choice would deprive the patient of the freedom not to be forced to do something—whether or not that person would

⁵ Isaiah Berlin, *Two Concepts of Liberty*, in *FOUR ESSAYS ON LIBERTY*, Clarendon Press, Oxford (1969) at 118-38.

agree with the choice. Moreover, denying self-determination in this way risks generating the frustration people feel when their desires are ignored or countermanded.

The potential for dissatisfaction in this regard is great. In the Commission's survey, 72% of the public said that they would prefer to make decisions jointly with their physicians after treatment alternatives have been explained. In contrast, 88% of the physicians believe that patients want doctors to choose for them the best alternative. Despite these differences in perception, only 7% of the public reports dissatisfaction with their doctors' respect for their treatment preferences.⁶

Creative self-agency. As a sword, self-determination manifests the value that Western culture places on each person having the freedom to be a creator—"a subject, not an object."⁷ Within the broad framework of personal characteristics fixed during the years of development, individuals define their own particular values.⁸ In these ways, individuals are capable of creating their own character and of taking responsibility for the kind of person they are. Respect for self-determination thus promotes personal integration within a chosen life-style.

This is an especially important goal to be nourished regarding health care. If it is not fostered regarding such personal matters, it may not arise generally regarding public matters. The sense of personal responsibility for decisionmaking is one of the wellsprings of a democracy. Similarly, when people feel little real power over their lives—in the economy, in political affairs, or even in their daily interactions with other people and institutions—it is not surprising that they are passive in encounters with health care professionals.

If people have been able to form their own values and goals, are free from manipulation, and are aware of information relevant to the decision at hand, the final aspect of self-determination is simply the awareness that the choice is their own to make. Although the reasons for a choice cannot always be defined, decisions are still autonomous if they reflect someone's own purposes rather than external causes unrelated to the person's "self." Consequently, the Commission's concept

⁶ This finding should be viewed cautiously since it is well known that surveys overstate the extent of actual satisfaction, as measured during on-site interviews immediately following doctor-patient encounters.

⁷ Berlin, *supra* note 5.

⁸ This is not to deny, of course, people's interdependence nor the ways in which each person's values are influenced by others. But people either incorporate or reject such influences into their own conception of what is good. In this view, self-determination lies in the relation between people's values and their actual desires and actions. An individual is self-determined or autonomous when that person is the kind of person he or she wants to be. Self-determination does not imply free will in the sense of a will free of causal determination.

of health care decisionmaking includes informing patients of alternative courses of treatment and of the reasoning behind all recommendations. Self-determination involves more than choice; it also requires knowledge.

The importance of information to self-determination emerged in the Commission's study of treatment refusals in hospitals. There it was found that, regarding routine treatments, information was frequently so lacking that patient self-determination was compromised.

Often patients were not told what treatment or procedure had been ordered for them, much less asked to decide whether or not to accept it. The purpose of the procedure was frequently obscure and the risks commonly went unmentioned. Presentation of alternatives was extraordinarily rare. The main concern of the patients we interviewed was not to select the best treatment from those available, but to find out what was being selected for them and why.⁹

Implications of Self-Determination. Despite the importance of self-determination, its exercise is sometimes impermissible and at other times impossible. That is, society sometimes must impose restrictions on the range of acceptable patient choices; at other times, patients either cannot, or at least do not, exercise self-determination.

External limitations. Two restrictions are recognized on the range of patient decisions that should be respected. First, some objectives are so contrary to the public interest or the interests of others that society bars the use of medical interventions toward these ends. For example, physicians may

⁹ Paul S. Appelbaum and Loren H. Roth, *Treatment Refusal In Medical Hospitals* (1982), Appendix D, in Volume Two of this Report. Although this lack of information and resulting patient noninvolvement in decisionmaking seems to have been a cause of treatment refusal they also occurred in many cases in which patients did not refuse treatment. Nonprovision of relevant information was also observed in the other on-site study.

One caveat must be noted, however. The Appelbaum-Roth team observed house-staff/patient interactions extensively but generally did not have a chance to observe interactions between attending physicians and patients. One would expect that discussions of major treatments and procedures, especially major surgical procedures, which were more often left to the attendings, might correspond more closely to the doctrine of informed consent. However, the investigators' conclusions are probably valid for the discussions about diagnostic procedures, medications, and adjunctive therapies as discussed in the other observational study conducted for the Commission. See Charles W. Lidz and Alan Meisel, *Informed Consent and the Structure of Medical Care* (1982), Appendix C, in Volume Two of this Report.

not assist patients in criminal activity (such as defacing fingertips so they will not leave identifiable fingerprints). The professional norms or moral integrity of health care professionals (individually, or collectively in health care institutions) may also conflict with the desires of a patient. When this occurs, the practitioner must first reexamine his or her own beliefs and preconceptions. If the proposed intervention would actually compromise the provider's integrity or standards, the patient will either have to accept the limitation on available interventions or seek another health care provider. Finally, a particular treatment preferred by a patient occasionally calls on very scarce resources that society (or some legitimate resource-controlling segment of the health care system) has decided to allocate to another use. Even as a "sword," self-determination does not invest a patient with rights to demand use of resources that have legitimately been allocated to others—as in the case, for example, of a patient who cannot have elective surgery on a desired date because all beds in a hospital are being used by disaster victims.

A second limitation on self-determination arises when a person's decisionmaking is so defective or mistaken that the decision fails to promote the person's own values or goals. This can happen in many ways: someone could fail to understand relevant information, such as the risks of a particular treatment, or unconsciously distort unpleasant information, such as the frightening diagnosis of cancer, and so forth. For example, a man in the prime of a full and rewarding life who has great plans for the future suddenly suffers a myocardial infarction in the middle of a poker game in which he has already won handsomely. Yet he refuses to permit himself to be transported to a hospital because he wants to play out his hand. The quality of his decisionmaking capacity is certainly in doubt. If his expressed wishes are respected nonetheless, the results in terms of self-determination would be mixed. Self-determination would be promoted in the sense that he has made the decision for himself, as opposed to having someone else make it, but self-determination would be contravened in that the decision is not the one that would best advance the man's apparent wish to live a long, full life.

Self-determination is valuable in both its roles—in letting an individual be his or her own decisionmaker and in securing each person's own goals. In situations where there is a choice of respecting the individual's decision or overriding it—that is, of favoring one aspect of self-determination at the expense of the other—overriding an individual decision is usually justified on the ground of promotion of well-being rather than of respect for self-choice.¹⁰

¹⁰ Likewise, self-determination is not an adequate guiding principle regarding decisions for persons who suffer permanent or chronic

The absence of contemporaneous choice. Sometimes people anticipate that they will be unable to participate in future decisions about their own health care. A patient, for example, may be under anesthesia during surgery at a time when diagnostic tests force a decision about a further operation. Similarly, patients with an early diagnosis of senile dementia of the Alzheimer's type can expect that their physical functioning might continue long after they are mentally incapable of deciding about care. Through an "advance directive" such people can specify the types of care they want (or do not want) to receive or the person they want to make such decisions if they are unable to do so.¹¹ Honoring such a directive shows respect for self-determination in that it fulfills two of its three underlying values.

First, following a directive, particularly one that gives specific instructions about types of acceptable and unacceptable interventions, fulfills the instrumental role of self-determination by providing reassurance that a course of conduct promotes the patient's subjective, individual evaluation of well-being. Second, honoring the directive shows respect for the patient as a person. To disregard it would be nearly as great an insult as to disregard the wishes of a patient who expresses them at that time.

An advance directive does not, however, provide self-determination in the sense of active moral agency by the patient on his or her own behalf.¹² Although any discussion between patient and health care professional leading up to a directive would involve active participation and shared decisionmaking, that would have been in the past by the time the decision actually needs to be made about the patient's health care. At that point, there is no "self," in the active, mental sense, to determine what should be done.

mental impairment, such as those who are severely mentally retarded or demented, who are incapable of forming a set of values or of applying them in particular decisions. The decisions for these patients rest instead on an assessment of what would promote their "best interests" (*i.e.*, well-being); *see pp.* 178-80 *infra*.

For an interesting example of some of the difficulties that may exist in determining whether an individual's choice reflects his or her long-term goals and values, *see* Albert R. Jonsen, Mark Siegler, and William J. Winslade, *CLINICAL ETHICS*, Macmillan Publishing Co., New York (1982) at 78-81.

¹¹ In the Commission's survey, 36% of the public reported that they have given instructions to someone about how they would like to be treated if they become too sick to make decisions, although only 23% of those instructions are in writing.

¹² *See generally* Paul Ramsey, *THE PATIENT AS PERSON*, Yale University Press, New Haven (1970).

Consequently, self-determination is involved when a patient establishes a way to project his or her wishes into a time of anticipated incapacity. Yet it is a sense of self-determination lacking in one important attribute: active, contemporaneous personal choice. Hence a decision not to follow an advance directive may sometimes be justified even when it would not be ethical to disregard a competent patient's contemporaneous choice.¹³

Active participation. Because patient noninvolvement in treatment decisions occurs frequently in medical care,¹⁴ it is important to understand whether it is compatible with patient self-determination. First and foremost, patients must be aware that they are entitled to make a decision about treatment rather than merely acquiescing in a professional's recommendation. Some patients feel, for example, that making a particular treatment decision will cause them great distress, or that the complexity and uncertainty of certain decisions make them poor decisionmakers and that trusted physicians or family members would be more likely to choose the treatment most in accord with the patients' own goals and values. Alternatively, some patients simply wish others to decide so that they can spend their time and energy on other matters. This, too, could constitute a transfer of the right to decide.

In contrast, some patients defer to physicians because they believe they have no business interfering in the exercise of medical judgment. Such patients do not think they are transferring their "right to decide" to a physician because they do not in the first place believe they have any right to decide about medical treatment. This is not an exercise of self-determination. Rather, self-determination occurs when patients understand decisions are theirs to make—and also to countermand if they are dissatisfied.¹⁵ In other words, self-determination requires that patients either make a choice or actually give the decisionmaking authority to another, not merely fail to act out of fear or ignorance of their rights.¹⁶

¹³ In some states, advance directives made pursuant to a statute may achieve "binding" legal effect (subject, usually, to considerable room for interpretation). See pp. 155-66 *infra*. In such a case, whatever the moral justifications, one may not be legally justified in disregarding the directions.

¹⁴ One of the observational studies conducted for the Commission concludes that "on balance the normative patient role in [health care decisionmaking] is one of passive acquiescence." Lidz and Meisel, *supra* note 9, at section 6.

¹⁵ A possible exception to this requirement would be an irrevocable grant of decisionmaking power to another, as when Odysseus, wishing both to hear and to resist the lure of the Sirens' call, had himself tied to the mast of his ship and instructed his crew not to release him however much he might entreat them to do so.

¹⁶ The critical element is the patient's attitude toward "involvement"

In recognizing that a self-determining person may waive active involvement in each decision, the Commission does not intend to belittle the moral ideal of the free, self-governing person who attempts to make decisions responsibly by applying his or her own values to relevant facts during deliberations about alternative actions. The ideal certainly justifies encouraging patients to play an active part in treatment decisions and argues for structuring medical practices and institutions in ways that facilitate and encourage effective patient participation. Nevertheless, it remains a moral *ideal*—people may strive to meet it but will often fall short of it. The principle of self-determination, the bedrock on which the Commission's concept of shared decisionmaking in health care rests, is best understood as respecting people's right to define and pursue their own view of what is good, which is compatible with people freely giving to others the authority to make particular health care decisions for them.

in the decision, not the mere existence of some "delegation," for all decisions about matters as complex as medical care require a large measure of delegation. Self-determination is not lacking simply because a patient does not insist that the physician review the reasoning and empirical evidence that led up to the physician's recommendation (and its alternatives, if any), including each standardized laboratory test, each anatomical or metabolic finding, and so forth. Rather, patients' decisions are always the end points of a long series of earlier choices made by physicians and others (where many of the steps in action and reasoning are so ingrained that those involved do not even recognize them for the choices they are). What is at issue, then, is merely the *degree* of delegation of decisionmaking authority by the patient to the professional, not the *fact* of delegation. While some patients want to explore every hypothesis, others want to know only the final recommendation; both may be exercising appropriate self-determination.

Goals and Realities

II

Decisionmaking Capacity and Voluntariness

3

Effective patient participation in health care decisionmaking rests on three foundations that correspond to the traditionally accepted elements of legally effective informed consent: decisionmaking capacity and voluntariness, which are treated in this Chapter, and information, which is discussed in Chapter Four. Throughout, the goals articulated by the Commission are compared with the realities of present practice, as evidenced by the Commission's studies and other empirical reports.

Capacity to Make Particular Decisions

For patients to participate effectively in making decisions about their health care, they must possess the mental, emotional, and legal capacity to do so. In the Commission's view, decisionmaking capacity is specific to a particular decision and depends not on a person's status (such as age) or on the decision reached, but on the person's actual functioning in situations in which a decision about health care is to be made. Some patients clearly possess such a capacity; others just as clearly lack it. In obvious instances of decisionmaking incapacity—for example, with infants and young children, the comatose, the severely mentally handicapped, and the severely mentally ill¹—the responsibility of the health care professional is to recognize the incapacity and to find another way to reach a decision that will advance the patient's goals and interests. Such alternative means of decisionmaking are discussed in Part Four of this Report.

¹ This Report does not address the distinctive issues posed by consent to mental health care or consent to health care by the mentally ill, whether or not institutionalized.

In other instances, a patient's capacity to decide on a course of treatment will be less clear-cut. Professionals may initially be uncertain of a particular patient's decisionmaking capacity. In such cases, the situation should be evaluated over time, as care providers assess the patient's understanding of information and reasoning about possible treatment. Efforts can also be made to enhance the patient's capacity by counseling, providing more information, minimizing untoward effects of psychoactive drugs, and giving other forms of support. Ultimately, however, someone must decide whether the patient is capable of making a particular decision that should then have binding force.

Questions of capacity to make health care decisions may be raised from several perspectives. The law treats the issue under the heading of "competence" and generally presumes that adults can make decisions for themselves unless they have been formally judged to be incompetent.² Consent granted by a competent adult normally authorizes a practitioner to provide health care, whereas consent granted by an incompetent individual is usually not legally sufficient to authorize professionals to proceed. Similarly, a competent individual's refusal of treatment as a rule has legal effect and must be respected,³ but the refusal of a treatment by an incompetent patient lacks such legal effect (although it may be taken into account in deciding how to proceed).

The legal tests and standards governing determinations of incompetence are discussed elsewhere in this Report,⁴ and are not the primary concern here. Rather, the objective is to explain why the patient's capacity to make health care decisions is important to a sound decision, and to investigate the foundations of that decisionmaking capacity.⁵

Importance of Capacity. The doctrine of informed consent is founded on the premise that self-determination ought not be blind. That is, patients' interests and well-being are best served when patients understand their medical situation and participate in deciding on treatment or care. This premise is to some degree an empirical proposition and to some degree a statement of faith. Insofar as the premise is an empirical one, there are clearly patients to whom it does not apply. That is to say, some patients (for a variety of reasons) are simply unable to make decisions that will advance their own interests. Following the directives of such patients can be seriously

² See, e.g., *Lotman v. Security Mutual Life Ins. Co.*, 478 F.2d 868 (3d Cir. 1973).

³ See, e.g., *In re Brooks' Estate*, 32 Ill. 2d 361, 205 N.E.2d 435 (1965).

⁴ See pp. 169-72 *infra*.

⁵ The terms "decisionmaking capacity" and "incapacity" are being used in this discussion to avoid the sometimes confounding legal overtones associated with the terms competence and incompetence.

injurious to their well-being and may fail to respect their own long-term values and objectives.

By not applying informed consent norms to patients who are incapable of joining with professionals to decide on their health care, society seeks to enhance their well-being by protecting them from substantial harms (or loss of benefits) that could result from serious defects in their decisionmaking abilities. The Commission believes that most people would desire such protection if they lost their capacity to participate effectively in medical decisionmaking, and concludes that such societal protection of the well-being of its members is, in principle, appropriate.

Society's protection does, however, impose certain costs—costs that become particularly clear when the action results in the countermanding or disregard of the expressed preferences of a patient deemed to lack capacity to make a particular decision. At least to some degree, such protection infringes on the patient's ability to determine his or her own fate. Thus, a conclusion about a patient's decisionmaking capacity necessarily reflects a balancing of two important, sometimes competing objectives: to enhance the patient's well-being and to respect the person as a self-determining individual. Commentators have sometimes failed to recognize this balancing element, viewing "capacity" or "competence" as having intrinsic meaning apart from consideration of particular circumstances or situations. Although this view may be appropriate in some instances (with, for example, the comatose or infants and small children), the Commission believes it is inadequate in more ambiguous or troublesome instances. The Commission concludes, therefore, that determinations of incapacity to participate in medical decisionmaking should reflect the balance of possibly competing interests.

Elements of Capacity. In the view of the Commission, any determination of the capacity to decide on a course of treatment must relate to the individual abilities of a patient, the requirements of the task at hand, and the consequences likely to flow from the decision. Decisionmaking capacity requires, to greater or lesser degree: (1) possession of a set of values and goals⁶; (2) the ability to communicate and to understand information; and (3) the ability to reason and to deliberate about one's choices.

The first, a framework for comparing options, is needed if the person is to evaluate possible outcomes as good or bad. The framework, and the values that it embodies, must be

⁶ At certain outer limits, an individual's goals may be so idiosyncratic that they give rise to questions about the person's capacity for decisionmaking. Assessment of incapacity is further explored in Chapter Eight *infra*.

reasonably stable; that is, the patient must be able to make reasonably consistent choices. Reliance on a patient's decision would be difficult or impossible if the patient's values were so unstable that the patient could not reach or adhere to a choice at least long enough for a course of therapy to be initiated with some prospect of being completed.

The second element includes the ability to give and receive information, as well as the possession of various linguistic and conceptual skills needed for at least a basic understanding of the relevant information. These abilities can be evaluated only as they relate to the task at hand and are not solely cognitive, as they ordinarily include emotive elements.⁷ To use them, a person also needs sufficient life experience to appreciate the meaning of potential alternatives: what it would probably be like to undergo various medical procedures, for example, or to live in a new way required by a medical condition or intervention.⁸



Some critics of the doctrine of informed consent have argued that patients simply lack the ability to understand medical information relevant to decisions about their care.⁹

⁷ See Paul S. Appelbaum and Loren H. Roth, *Clinical Issues in the Assessment of Competency*, 138 AM. J. PSYCHIATRY 1462 (1981).

⁸ Albert R. Jonsen, Mark Siegler, and William J. Winslade, *CLINICAL ETHICS*, Macmillan Publishing Co., New York (1982) at 56-57.

⁹ "[I]nformed consent may create delay, apprehension, and restrictions on the use of new techniques that will impair the progress of medicine. It is questionable whether the 'average prudent man' will

Indeed, some empirical studies purport to have demonstrated this by showing that the lay public often does not know the meaning of common medical terms,¹⁰ or by showing that, following an encounter with a physician, patients are unable to report what the physician said about their illness and treatment.¹¹ Neither type of study establishes the fact that patients cannot understand. The first merely finds that they do not currently know the right definitions of some terms; the second, which usually fails to discover what the physician actually did say, rests its conclusions on an assumption that information was provided that was subsequently not understood. In the Commission's own survey, physicians were asked: "What percentage of your patients would you say are able to understand most aspects of their treatment and condition if reasonable time and effort are devoted to explanation?" Overall, 48% of physicians reported that 90-100% of their patients could understand and an additional 34% said that 70-89% could understand.¹²

The third element of decisionmaking capacity—reasoning and deliberation—includes the ability to compare the impact of alternative outcomes on personal goals and life plans. Some

understand and comprehend . . ." Milton Oppenheim, *Informed Consent to Medical Treatment*, 11 CLEV.-MAR. L. REV. 249, 261 (1962). See also George Robinson and Avraham Merav, *Informed Consent: Recall by Patients Tested Postoperatively*, 22 ANNALS THORACIC SURGERY 209, 212 (1976); Amelia L. Schultz, Geraldine P. Pardee, and John W. Ensinnck, *Are Research Subjects Really Informed?*, 123 W. J. MED. 76, 78 (1975). Some claim that patients can never truly comprehend what a procedure entails until they have experienced it. See, e.g., Franz J. Ingelfinger, *Informed (But Uneducated) Consent*, 287 NEW ENG. J. MED. 465, 465 (1972).

¹⁰ For example, in one of the observational studies conducted for the Commission, one patient asked whether his spleen had anything to do with having children. For a discussion of patient misunderstanding of medical terms, see, e.g., B.M. Korsch and V.F. Negrette, *Doctor-Patient Communication*, 227 SCIENTIFIC AMERICAN 66 (1972); F.C. Tring and M.C. Hayes-Allen, *Understanding and Misunderstanding of Some Medical Terms*, 7 BRIT. J. MED. EDUC. 53 (1973); and Samuel Gorovitz, *DOCTORS' DILEMMAS: MORAL CONFLICT AND MEDICAL CARE*, Macmillan Publishing Co., New York (1982) at 19-20.

¹¹ See, e.g., Robinson and Merav, *supra* note 9, at 210-212; Gorovitz, *supra* note 10, at 40.

¹² Obstetricians were most likely (57%) and subspecialists least likely (38%) to report that more than 90% could understand. Office-based physicians were more likely than hospital-based doctors to think that their patients could understand. Older doctors were more likely than younger doctors (53% versus 38%) to feel that 90-100% of patients could understand, and physicians who treated few patients with serious illness were more likely than physicians who treated more patients with serious illness to report that patients could understand (55% versus 36%).

ability to employ probabilistic reasoning about uncertain outcomes is usually necessary, as well as the ability to give appropriate weight in a present decision to various future outcomes.

Standards for Assessing Capacity. The actual measurement of these various abilities is by no means simple. Virtually all conscious adults can perform some tasks but not others.¹³ In the context of informed consent, what is critical is a patient's capacity to make a specific medical decision. An assessment of an individual's capacity must consider the nature of the particular decisionmaking process in light of these developments: Does the patient possess the ability to understand the relevant facts and alternatives? Is the patient weighing the decision within a framework of values and goals? Is the patient able to reason and deliberate about this information? Can the patient give reasons for the decision, in light of the facts, the alternatives, and the impact of the decision on the patient's own goals and values?

To be sure, a patient may possess these abilities but fail to exercise them well; that is, the decision may be the result of a mistaken understanding of the facts or a defective reasoning process. In such instances, the obligation of the professional is not to declare, on the basis of a "wrong" decision, that the patient lacks decisionmaking capacity, but rather to work with the patient toward a fuller and more accurate understanding of the facts and a sound reasoning process.

How deficient must a decisionmaking process be to justify the assessment that a patient lacks the capacity to make a particular decision? Since the assessment must balance possibly competing considerations of well-being and self-determination, the prudent course is to take into account the potential consequences of the patient's decision. When the consequences for well-being are substantial, there is a greater need to be certain that the patient possesses the necessary level of capacity. When little turns on the decision, the level of decisionmaking capacity required may be appropriately reduced (even though the constituent elements remain the same) and less scrutiny may be required about whether the patient possesses even the reduced level of capacity. Thus a particular patient may be capable of deciding about a relatively inconsequential medication, but not about the amputation of a gangrenous limb.

¹³ Bernard Gert and Charles Culver, *What Would It Mean to Be Competent Enough to Consent to or Refuse Participation in Research?—Philosophical Overview*, in Natalie Reating, ed., *Competency and Informed Consent: Papers and Other Materials Developed for the Workshop "Empirical Research on Informed Consent with Subjects of Uncertain Competence,"* National Institutes of Mental Health (Jan. 12-13, 1981).

This formulation has significant implications. First, it denies that simply by expressing a preference about a treatment decision an individual demonstrates the capacity to make that decision. The "expressed preference" standard does nothing to preclude the presence of a serious defect or mistake in a patient's reasoning process. Consequently, it cannot ensure that the patient's expressed preference accords with the patient's conception of future well-being. Although it gives what appears to be great deference to self-determination, the expressed preference standard may actually fail to promote the values underlying self-determination, which include the achievement of personal values and goals. For these reasons, the Commission rejects the expressed preference standard for decisions that might compromise the patient's well-being.¹⁴

The Commission also rejects as the standard of capacity any test that looks solely to the content of the patient's decision. Any standard based on "objectively correct" decisions would allow a health professional (or other third party) to declare that a patient lacks decisionmaking capacity whenever a decision appears "wrong," "irrational," or otherwise incompatible with the evaluator's view of what is best for the patient. Use of such a standard is in sharp conflict with most of the values that support self-determination: it would take the decision away from the patient and place it with another, and it would inadequately reflect the subjective nature of each individual's conception of what's good. Further, its imprecision opens the door to manipulation of health care decisionmaking through selective application.

Logically, just as a patient's disagreement with a health care professional's recommendation does not prove a lack of decisionmaking capacity, concurrence with the recommendation would not establish the patient's capacity. Yet, as testimony before the Commission made clear, coherent adults are seldom said to lack capacity (except, perhaps, in the mental health context) when they acquiesce in the course of treatment recommended by their physicians. (Challenges to patients' capacity are rarer still when family members expressly concur in the decision.) This divergence between theory and reality is less significant than it might appear, however, since neither the self-determination nor the well-being of a patient would usually be advanced by insisting upon an inquiry into the patient's decisionmaking capacity (or lack thereof) when patient, physician, and family all agree on a course of

¹⁴ Of course, extreme care must be exercised lest pronouncements of "what the patient really wants" become a cover for "what I think is best for the patient." Properly circumscribed, however, a choice made on behalf of a patient who lacks capacity may be a truer example of one fundamental interest undergirding self-determination than following the patient's preference would be.

treatment. Even if the course being adopted might not, in fact, best match the patient's long-term view of his or her own welfare, a declaration of lack of capacity will lead to a substitute making a decision for the patient (which means full self-determination will not occur), yet will rarely result in a different health care decision being made (which means no change in well-being). Substitution of a third party for an acquiescent patient will lead to a different outcome only if the new decisionmaker has a strong commitment to promoting previously expressed values of the patient that differ significantly from those that guided the physician. If, as would usually be the case, the substitute would be a family member or other individual who would defer to the physician's recommendation, there would be little reason to initiate an inquiry into capacity. The existing practice thus seems generally satisfactory.¹⁵

Questions of patient capacity in decisionmaking typically arise only when a patient chooses a course—often a refusal of treatment—other than the one the health professional finds most reasonable.¹⁶ A practitioner's belief that a decision is not "reasonable" is the beginning—not the end—of an inquiry into the patient's capacity to decide. If every patient decision that a health professional disagreed with were grounds for a declaration of lack of capacity, self-determination would have little meaning. Even when disagreement occurs, an assessment of the patient's decisionmaking capacity begins with a presumption of such capacity. Nonetheless, a serious disagreement about a decision with substantial consequences for the patient's welfare may appropriately trigger a more careful evaluation. When that process indicates that the patient understands the situation and is capable of reasoning soundly about it, the patient's choice should be accepted. When it does not, further evaluation may be required, and in some instances a determination of lack of capacity will be appropriate.¹⁷

¹⁵ Plainly, this conclusion rests on practical and prudential, rather than theoretical, considerations. A system could be instituted in which all patients facing significant decisions receive a thorough evaluation of their decisionmaking capacity. Those showing psychiatric morbidity that might undermine their decisionmaking capacity could then be channeled through an alternative process designed to protect their interests and well-being. Though this would undoubtedly result in "better" decisions for some patients, it would impose substantial additional costs and burdens on the health care system.

¹⁶ Loren H. Roth, Alan Meisel, and Charles W. Lidz, *Tests of Competency to Consent to Treatment*, 134 *AM. J. PSYCHIATRY* 279 (1977).

¹⁷ The procedural and substantive standards that apply in this assessment are discussed in Chapter Nine *infra*. The factors that prompt an inquiry about a patient's capacity are related, but not

Voluntariness in Decisionmaking

A second requirement for informed consent is that the patient's participation in the decisionmaking process and ultimate decision regarding care must be voluntary. A choice that has been coerced, or that resulted from serious manipulation of a person's ability to make an intelligent and informed decision, is not the person's own free choice. This has long been recognized in law: a consent forced by threats or induced by fraud or misrepresentation is legally viewed as no consent at all.¹⁸ From the perspective of ethics, a consent that is substantially involuntary does not provide moral authorization for treatment because it does not respect the patient's dignity and may not reflect the aims of the patient.

Of course, the facts of disease and the limited capabilities of medicine often constrict the choices available to patient and physician alike. In that sense, the condition of illness itself is sometimes spoken of as "coercive" or involuntary. But the fact that no available alternative may be desirable in itself, and that the preferred course is, at best, only the least bad among a bad lot, does not render a choice coerced in the sense employed here. No change in human behavior or institutional structure could remove this limitation. Such constraints are merely facts of life that should not be regarded as making a patient's choice involuntary.

Voluntariness is best regarded as a matter of degree, rather than as a quality that is wholly present or absent in particular cases. Forced treatment—the embodiment of coercive, involuntary action—appears to be rare in the American health care system.¹⁹ Health care professionals do, however, make limited intrusions on voluntary choice through subtle, or even overt, manipulations of patients' wills when they believe that patients would otherwise make incorrect decisions.

Forced Treatment. The most overt forms of involuntariness in health care settings involve interventions forced on patients without their consent (and sometimes over their express objection) and those based on coerced consent. Although rare

necessarily equivalent, to those that govern the resolution of the inquiry.

¹⁸ See generally RESTATEMENT (SECOND) OF TORTS, American Law Institute Publishers, St. Paul, Minn. (1979) at § 892B; see also Robert E. Powell, *Consent to Operative Procedures*, 21 MD. L. REV 181, 203 (1961). Indeed, many of the eighteenth, nineteenth, and early twentieth century legal cases often cited as precursors of the modern doctrine of informed consent imposed liability for unauthorized medical procedures on precisely these grounds. See notes 13 to 15 in Chapter One *supra*.

¹⁹ Charles W. Lidz and Alan Meisel, *Informed Consent and the Structure of Medical Care* (1982), Appendix C, in Volume Two of this Report, at section 4.

in mainstream American health care, such situations do arise in certain special settings, and therefore require brief discussion. Society currently legitimates certain forced medical interventions to serve important social goals such as promoting the public health (with, for example, compulsory vaccination laws), enforcing the criminal law (removing bullets needed as evidence for criminal prosecutions), or otherwise promoting the well-being of others (sedating uncontrollable inmates of mental institutions on an emergency basis, for example, to protect other inmates or staff).²⁰

Although it is typically not viewed as forced treatment, a good deal of routine care in hospitals, nursing homes, and other health care settings is provided (usually by health professionals such as nurses) without explicit and voluntary consent by patients. The expectation on the part of professionals is that patients, once in such a setting, will simply go along with such routine care. However, the Commission's study of treatment refusals found that in a hospital setting it was the routine tests that were most likely to be refused. At least some patients expected that participation was voluntary and refused tests and medications ordered without their knowledge until adequate information was provided about the nature, purpose, and risks of these undertakings. Lack of information in such cases may not only preclude voluntary participation but also raise questions about a patient's rationality, and hence competence.

When a situation offers the patient an opportunity to refuse care, then patient compliance or acquiescence may be viewed as implicit consent. But when the tacit communication accompanying such care is that there is no choice for the patient to make, and compliance is expected and enforced (at least in the absence of vigorous objections), the treatment can be properly termed "forced." The following conversation between a nurse and a patient regarding postoperative care, obtained in one of the Commission's observational studies, illustrates forced treatment that follows routinely from another decision (surgery) that was made voluntarily.

Nurse: Did they mention anything about a tube through your nose?

Patient: Yes, I'm gonna have a tube in my nose.

Nurse: You're going to have the tube down for a couple of days or longer. It depends. So you're going to be NPO, nothing by mouth, and also you're going to have IV fluid.

²⁰ Of course, not all forced interventions that employ medical procedures in such institutions are necessarily intended to promote the well-being of others. Drawing the line between the protection of others and the abuse of inmates is a difficult task. See, e.g., Rogers v. Okin, 778 F. Supp. 1342 (D.Mass. 1979).

- Patient: I know. For three or four days they told me that already. I don't like it, though.
- Nurse: You don't have any choice.
- Patient: Yes, I don't have any choice, I know.
- Nurse: Like it or not, you don't have any choice. (laughter) After you come back, we'll ask you to do a lot of coughing and deep breathing to exercise your lungs.
- Patient: Oh, we'll see how I feel.
- Nurse: (Emphasis) No matter how you feel, you have to do that!²¹

The interview ended a few minutes later with the patient still disputing whether he was going to cooperate with the postoperative care.

Coerced Treatment. Unlike forced treatment, for which no consent is given, coerced treatment proceeds on the basis of a consent that was not freely given. As used in this sense, a patient's decision is coerced when the person is credibly threatened by another individual, either explicitly or by implication, with unwanted and avoidable consequences unless the patient accedes to the specified course of action.²² Concern about coercion is accordingly greatest when a disproportion in power or other significant inequality between a patient and another individual lends credibility to the threat of harm and when the perceived interests of the individuals diverge.²³

²¹ Lidz and Meisel, *supra* note 19.

²² In this respect, threats should be distinguished from warnings of unpleasant occurrences that may be the natural consequences of certain decisions. A physician's discussion of the natural history of a disease does not constitute threats, while a statement that a physician will discharge the patient from the hospital if the patient requests a second opinion (or asks too many questions, or complains excessively about hospital food) probably does. In many cases, the distinction depends on whether the professional can bring about the unwanted consequences, but this is not always true. For example, a surgeon who tells a breast cancer patient of an inability to continue in charge of her care if she rejects surgery in favor of chemotherapy or radiation is probably not issuing a threat, although in some circumstances the suggestion that a health professional would abandon a highly dependent patient if medical advice were not followed might constitute an improper and coercive threat.

²³ These concerns are particularly acute in certain settings, such as so-called total institutions, where whole populations are placed in a special condition of inequality and dependency on powerful others, even for ordinary care and sustenance. Choices made in such settings are particularly subject to coercive influences, and careful scrutiny of their voluntariness is often warranted.

The disparity in power between patient and health care professional may be slight or substantial, depending on the nature of the patient's illness, the institutional setting, the personalities of the individuals involved, and several other factors. In nonemergency settings, a patient typically can change practitioners or simply forego treatment, thus avoiding the potential for coercion. Further, although health care professionals do have interests distinct from and sometimes in conflict with those of their patients, strong social and professional norms usually ensure that priority is accorded to patients' welfare. To be sure, coercion can be exercised with benevolent motives if practitioner and patient differ in their assessments of how the patient's welfare is best served. Nonetheless, there is little reason to believe that blatant forms of coercion are a problem in mainstream American health care. When isolated instances of abuse do arise, the law provides suitable remedies.

A patient's family and other concerned persons may often play a useful role in the decisionmaking process. Sometimes, however, they may try to coerce a particular decision, either because of what they perceive to be in the patient's best interests or because of a desire to advance their own interests. In such instances, since the health care professional's first loyalty is to the patient, he or she should attempt to enhance the patient's ability to make a voluntary, uncoerced decision and to overcome any coercive pressures.²⁴

Manipulation. Blatant coercion may be of so little concern in professional-patient relationships because, as physicians so often proclaim, it is so easy for health professionals to elicit a desired decision through more subtle means. Indeed, some physicians are critical of the legal requirement for informed consent on the grounds that it must be mere window dressing since "patients will, if they trust their doctor, accede to almost any request he cares to make."²⁵ On some occasions, to be sure, this result can be achieved by rational persuasion, since the professional presumably has good reasons for preferring a recommended course of action. But the tone of such critics suggests they have something else in mind: an ability to package and present the facts in a way that leaves the patient with no real choice. Such conduct, capitalizing on disparities in knowledge, position, and influence, is manipulative in character and impairs the voluntariness of the patient's choice.²⁶

²⁴ The role of the family is discussed in more detail in Chapter Five *infra*.

²⁵ Henry K. Beecher, *Some Guiding Principles for Clinical Investigation*, 195 J.A.M.A. 1135, 1135 (1966). See also Norman Fost, *A Surrogate System for Informed Consent*, 233 J.A.M.A. 800 (1975); Ingelfinger, *supra* note 9, at 466.

²⁶ "In spite of...federal requirements that clients participating as

Manipulation has more and less extreme forms. At one end of the spectrum is behavior amounting to misrepresentation or fraud. Of particular concern in health care contexts is the withholding or distortion of information in order to affect the patient's beliefs and decisions. The patient might not be told about alternatives to the recommended course of action, for example, or the risks or other negative characteristics of the recommended treatment might be minimized. Such behavior is justly criticized on two grounds: first, that it interferes with the patient's voluntary choice (and thus negates consent) and, second, that it interferes with the patient's ability to make an informed decision. At the other end of the spectrum are far more subtle instances: a professional's careful choice of words or nuances of tone and emphasis might present the situation in a manner calculated to heighten the appeal of a particular course of action.

It is well known that the way information is presented can powerfully affect the recipient's response to it. The tone of voice and other aspects of the practitioner's manner of presentation can indicate whether a risk of a particular kind with a particular incidence should be considered serious. Information can be emphasized or played down without altering the content. And it can be framed in a way that affects the listener—for example, "this procedure succeeds most of the time" versus "this procedure has a 40 percent failure rate." Health professionals who are aware of the effects of such minor variations can choose their language with care; if, during discussions with a patient, they sense any unintended or confused impressions being created, they can adjust their presentation of information accordingly.

Because many patients are often fearful and unequal to their physicians in status, knowledge, and power, they may be particularly susceptible to manipulations of this type. Health care professionals should, therefore, present information in a form that fosters understanding. Patients should be helped to understand the prognosis for their situation and the implications of different courses of treatment. The difficult distinction,

'subjects' in research give 'informed consent,' and in spite of the legal releases required for such procedures as surgery, it is my impression that clients are more often bullied than informed into consent, their resistance weakened in part by their desire for the general service if not the specific procedure, in part by the oppressive setting they find themselves in, and in part by the calculated intimidation, restriction of information, and covert threats of rejection by the professional staff itself." Eliot Freidson, *THE PROFESSION OF MEDICINE*, Dodd, Mead & Co., New York (1970) at 376. See also Jon R. Waltz and Thomas W. Scheuneman, *Informed Consent to Therapy*, 64 Nw. U. L. REV. 628, 645-46 (1970).

both in theory and in practice, is between acceptable forms of informing, discussion, and rational persuasion on the one hand, and objectionable forms of influence or manipulation on the other.

Since voluntariness is one of the foundation stones of informed consent, professionals have a high ethical obligation to avoid coercion and manipulation of their patients. The law penalizes those who ignore the requirements of consent or who directly coerce it. But it can do little about subtle manipulations without incurring severe disruptions of private relationships by intrusive policing, and so the duty is best thought of primarily in ethical terms.

The Communication Process

4

The final element of effective patient participation in health care decisionmaking is the actual communication between patient and professional of the facts, values, doubts, and alternatives on which decisions must ultimately be based. This process should transcend the professional's legal "duty to warn" of the risks associated with a proposed medical intervention. Indeed, from the Commission's perspective, the law's near-exclusive focus on the disclosure of risks—which has often led to standardized forms and recitations of risks, but not to a full dialogue with patients—has had an unfortunate impact on the very objectives the informed consent process is designed to achieve.¹ Further, this preoccupation with risks is undoubtedly responsible for much of the medical community's skepticism about informed consent. In this section, therefore, the Commission seeks to reorient the discussion of "informing"—and of patient-professional communication generally—in directions more likely to produce the objective of all health care: improved well-being and self-determination.²

Two major objectives are promoted through the communication process between patient and professional. The first is therapeutic: in many circumstances, patients knowledgeable about their condition and involved in the decisionmaking process are likely to emerge from therapy in better health. A number of recent studies indicate that informed patients tend

¹ Jay Katz, *Informed Consent—A Fairy Tale?: Law's Vision*, 39 U. PITT. L. REV. 137 (1977).

² As well as looking beyond an excessive preoccupation with disclosure of risks, this section seeks to take account of the diversity of situations and individual preferences that characterize the real world of medical practice. Accordingly, the discussion is based in significant part on the substantial body of empirical literature on informed consent and professional-patient communications.

toward greater compliance with certain therapeutic regimens, reduced levels of anxiety, faster recovery from surgery, and enhanced ability to protect their own well-being—by detecting errors in dosage or type of medication, for example, or by recognizing untoward side effects.³

Second, patients making informed decisions are likely to better advance their own life plans. As discussed in Chapter Two, for self-determination to be meaningful, patients must have some understanding of the alternatives and what they entail. The obligation of health care professionals, who typically will have a greater command of this information than patients, is to communicate that information in an understandable fashion.

The Nature and Scope of Disclosure

Much confusion has arisen, both in legal contexts and in the medical and philosophic literature, over the nature and scope of the information to be disclosed and discussed.⁴ Although the content and extent of the information to be discussed will inevitably depend on the circumstances of the particular case, the ethical standard for assessing the adequacy of discussion is constant. Professionals should discuss with patients the facts and associated uncertainties that will give patients a working understanding of their situation and of available treatment alternatives, so they can participate effectively in the decisionmaking process. This will include consideration of patients' values and objectives, as well as their ability and desire to participate in the decisionmaking process.

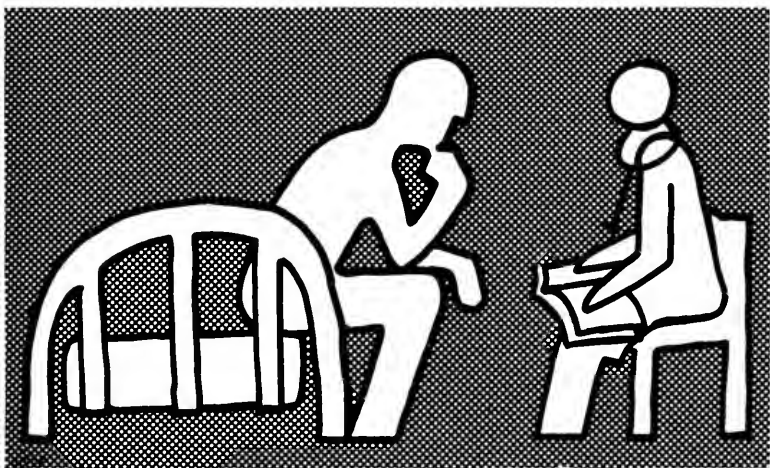
To the extent these characteristics of an individual differ from those of the law's hypothetical "reasonable person," professionals should tailor the "standard" presentation. Obviously, for such tailoring to take place, practitioners must be aware of the special needs of particular patients. For legal purposes, an important question concerns whether the burden of communicating such special needs is placed squarely on patients (who typically are the best judges of their own values and objectives), or whether health care professionals should notice certain "apparent" special needs and try to elicit others through discussions with patients (or, in some cases, with members of their families). The professional's responsibility may be especially compelling given that certain procedures are objectionable to identifiable population groups (such as blood

³ See full discussion pp. 99-102 *infra*.

⁴ Many medical writers, *see* note 5 in Chapter Seven *infra*, assume that the law of informed consent requires that patients be given a detailed "mini-course in medical science." *Cobbs v. Grant*, 8 Cal. 3rd 229, 104 Cal. Rptr. 505, 502 P.2d 1, 11 (1972), as the California Supreme Court characterized it in the course of rejecting such a view.

transfusions for Jehovah's Witnesses) and that different patients assess the desirability of various medical procedures in very different ways (as with surgery for breast cancer, or "last ditch" therapies for cancers that are terminal). Whatever the legal resolution of this burden, from an ethical perspective professionals should in good faith try to elicit and discuss the values of their patients insofar as those values affect choices to be made among medical alternatives.

Professionals should recognize, and lawyers and courts should perhaps be reminded, that patients' interests are not well served by detailed technical expositions of facts that are germane neither to patients' understanding of their situations nor to any decisions that must be made. Such recitations are not legally required, nor should they be. Overwhelming patients with a mass of unintelligible technical data that they are ill-prepared to comprehend or use, particularly at what may be a stressful time, can be as destructive of the communication process and its goal of enhanced understanding as giving too little information is. Similarly, reciting "all the facts" in a blunt, insensitive fashion can also destroy the communication process, as well as the patient-professional relationship itself. The professional's goal should be a tactful discussion, sensitive to the needs, intellectual capabilities, and emotional state of the particular patient at that time, in terms that the patient can understand, assimilate, and work with as part of the ongoing decisionmaking process. To be sure, translating medical jargon and discussing issues of concern to patients requires time and considerable intellectual and emotional effort. But those are the necessary costs of achieving the objective and are properly regarded as part of practitioners' professional responsibility.



The current tendency toward excessively technical recitations of medical data may reflect, at least in part, the medical profession's understandable reaction to the fear of lawsuits in

the event an undisclosed, remote risk should result in injury to a patient. This illustrates one important counterproductive effect of the law's focus on the "duty to warn" aspect of informed consent. Reconciling the requirement that all material facts be disclosed with the objective of facilitating an intelligent discussion of the most salient issues is clearly no simple task, either for the law that must formulate disclosure standards or for practitioners who must apply those standards to the myriad individual circumstances that arise in medical practice. Nor is the conflict between full disclosure and intelligent discussion unique to the law of informed consent. Indeed, this conflict represents an important limitation on the law as an instrument of social control.

In the Commission's survey, professionals and the public were asked several questions about disclosure in general and about who is responsible for making sure patients are adequately informed. Nearly all the public (97%) said that patients should have the right to all available information about their condition and treatment that they wish. Somewhat surprisingly (since patients report that they want virtually all information), when asked "Who do you think is the best judge of the amount of information that should be disclosed to the patient?," 45% of the public said the patient and 44% said the physician. In addition, 56% of the public thought that some patients should be told less about their treatment than others.⁵ Few people (2%) complained that doctors tell patients too much about either routine care or serious illness. However, 38% felt that patients are told too little about routine care and 33% felt the same about serious illness.⁶

Physicians were asked: "How often do you find yourself in a situation where you must make a conscious and deliberate evaluation of how much to tell a patient about his condition or treatment?" Far from being a rare occurrence, 27% said "several times a day," 25% said "daily," 20% said "weekly," 25% said "rarely," and 3% said "never."⁷ In an open-ended

⁵ People in poor health, the elderly, and those with little education or low income were most likely (up to 58%) to view the doctor as the best judge. People with a life-threatening illness, those in poor health, those over 35, those with high incomes, and college graduates were more likely (up to 65%) to feel that some people should have less information than others.

⁶ Young people, women, people without a usual source of medical care or health insurance, the college-educated, and those with high incomes were more likely than others to feel that doctors give too little information about routine care and serious illness. Overall, 11% of the public were uncertain whether doctors give the right amount of information about serious illness.

⁷ Internists were most likely and obstetricians/gynecologists least likely to deliberate frequently about how much to tell a patient. Among specialists and subspecialists, 9% reported they deliberate as

question, physicians were asked: "What are the primary factors that influence how much you tell a patient about his condition or treatment?" The patient's ability to understand (56%) and to cope with the information (31%), the seriousness of the condition (30%), and the patient's desire to know (25%) were the reasons given most frequently.⁸ Time constraints were mentioned by only 2% of the sample.

In terms of responsibility, physicians felt it is primarily their responsibility to make sure that the patient is fully informed (77%) rather than the patient's responsibility to ask for information (3%), although 19% said the doctor and patient are equally responsible. The public, on the other hand, especially those in poor health and with little education, generally placed more of a burden of responsibility on the patient (20%). In general, however, the public agreed with the physicians that it is the latter's responsibility to make sure patients are fully informed.

When asked whether their physicians keep them informed about questions and decisions relating to their medical care that they (the public) consider important, 37% said they are informed on all important issues and another 30% said they are informed on most issues.⁹

seldom as weekly and 11% reported that they rarely evaluate the amount of information to disclose. Physicians who are hospital-based and those who treat a high percentage of patients with serious illness were more likely than office-based physicians or those who treat fewer seriously ill patients to report frequent conscious evaluations.

⁸ Some significant variations were found within subgroups of physicians concerning the factors that influence how much information is disclosed. Although the patient's ability to understand was the factor most often cited by all physicians, those treating primarily poor patients were significantly more likely than those with few poor patients (71% versus 52%) to mention patient understanding. Foreign medical graduates were most likely to mention seriousness of the patient's condition (37% versus only 14% of graduates of U.S. public medical schools with major research support). Foreign medical graduates and physicians treating primarily poor patients were the least likely to mention a patient's desire for information as a factor that influenced disclosure (15% of foreign graduates compared with at least 25% of U.S. graduates, and 17% of those with a majority of their patients being poor compared with 27% of physicians treating few poor patients).

⁹ People without a usual source of care felt least well informed. Those in poor health, the elderly, the poor, nonwhites, those with no health insurance, and the poorly educated felt best informed, perhaps because their expectations were lower. Those most satisfied with their doctor's willingness to answer questions about their condition and treatment were people who had had a life-threatening illness, who usually got their medical care in a doctor's office, or who were in poor health, elderly, female, white, or with little education. These

What, then, are the substantive issues to be discussed by professional and patient? These have been variously formulated by courts and commentators, and one version has been incorporated in the federal regulations governing the conduct of research with human subjects.¹⁰ In addition, recent surveys have identified a number of elements as particularly important to patients.¹¹ Without seeking to provide the last word on this much-discussed subject, the Commission believes the core elements fall under three headings: (1) the patient's current medical status, including its likely course if no treatment is pursued; (2) the intervention(s) that might improve the prognosis, including a description of the procedure(s) involved, a characterization of the likelihood and effect of associated risks and benefits, and the likely course(s) with and without therapy; and (3) a professional opinion, usually, as to the best alternative. Furthermore, each of these elements must be discussed in light of associated uncertainties.

Current Medical Status. Inaccurate or incomplete information about illness limits patients' understanding of the effects and of what is at stake in any effort to alter the natural course of diseases. For patients to make effective use of available information, not only must it be understandable, but patients must recognize the uncertainties inherent in the information itself and in any effort to prognosticate on the basis of it.

In the Commission's survey, 56% of physicians said they always discuss their diagnosis and prognosis with the patient and another 42% said they usually do. According to the public, 52% of their physicians always explain their diagnosis and prognosis; 26% report their physicians usually do. The frequency with which this is done differed in the various subgroups examined.¹²

In a different version of this question, given to half the samples,¹³ 99% of physicians reported they initiate such

same groups were most likely to report high satisfaction with their doctor's honesty in discussions.

¹⁰ U.S. Department of Health and Human Services, *Protection of Human Subjects*, 46 Fed. Reg. 8366, 8389-90 § 46.116 (Jan. 26, 1981).

¹¹ See, e.g., Ruth Faden *et al.*, *Disclosure of Information to Patients in Medical Care*, 19 MED. CARE 718 (1981).

¹² Those who had had a life-threatening illness, who had high incomes, who received their care in a doctor's office, or who were young, female, white, in excellent health, or college-educated were significantly more likely to report that their physicians always or usually explained such information (for example, 87% of the college-educated versus 64% of those with less than a high school education). Although almost none of the physicians reported they rarely or never discussed diagnosis and prognosis, up to 10% of the public with no usual source of care, the elderly, and the least well educated reported that their physicians rarely or never discussed these items.

¹³ Questions on specific items of information that could be disclosed

discussion as a matter of course, though only 75% of the public felt this was a professional obligation. Here, too, there were variations by subgroups in the population, with more than 80% of those with life-threatening illness, the young, the college-educated, and people in excellent health feeling that physicians should initiate discussion.

Since informed consent has, in terms of legal requirements, sometimes been equated with a duty to disclose according to the standards of the medical community, it is interesting to learn that on certain points physicians and the public are in substantial agreement. For example, 17% of physicians claimed that all their patients want candid assessments of their diagnosis and prognosis, even unfavorable ones, and an additional 69% perceived that most of their patients felt that way. Of the public, 94% reported that they would "want to know everything." Indeed, the public displayed an unflinching desire for facts about their conditions, even dismal facts. When asked specifically whether they would want to know about a diagnosis of cancer, 96% of the public said yes (with almost no variation across subgroups). When asked "If you had a type of cancer that usually leads to death in less than a year, would you want your doctor to give you a realistic estimate of how long you had to live, or would you prefer that he not tell you?," 85% (again, with little variation) said they would want a realistic estimate.

When, however, physicians were asked "If you had a patient with a fully confirmed diagnosis of lung cancer in an advanced stage, which of the following would you be most likely to tell your patient?," they showed much less willingness to be candid. Only 13% said they would "give a straight statistical prognosis for his class of disease"; 33% said they would say they "couldn't tell how long he might live, but would stress that it could be for a substantial period of time"; 28% would say they "couldn't tell how long, but would stress that in most cases people live no longer than a year"; and 22% would "refuse to speculate on how long the patient might live." Thus it would still appear that physicians are more reluctant to disclose a limited prognosis than patients would like. Nonetheless, the Commission's survey indicates that physicians generally disclose information about patients' diagnosis and prognosis, and that both physicians and the public feel this should be

were asked in two different ways in the Commission's survey (by splitting the samples of physicians and the public) in order to determine not only the frequency with which physicians say they disclose certain information (and patients report such disclosures) but also whether physicians initiate discussion about various pieces of information as a matter of course or wait to be asked (and whether patients think physicians *should* initiate discussion).

done. These results are consistent with findings from other surveys that have demonstrated a recent trend toward more complete and frank disclosure and even toward more open discussion specifically regarding "bad news."¹⁴

Treatment Alternatives and the Professional's Recommendation. In order for medical intervention to be warranted, the patient must stand to gain more from some intervention than if none were undertaken at all. As noted previously, the benefit to be gained must be assessed in terms of the patient's own values and goals. Thus, a practitioner should be cautious not to rule out prematurely an alternative that might offer what a particular patient would perceive as a benefit even if the practitioner sees it differently.

The patient's condition and the range of available alternatives will necessarily shape the course of the discussion. In some instances, there may be only one medically recognized treatment, so that the decision is primarily between that treatment and no treatment at all. In such cases, discussion will naturally focus on the benefits and risks associated with that treatment compared with the likely course of the untreated disease. Time is an important dimension here: can an intervention be put off, and with what consequences, to allow for greater diagnostic certainty and to permit the patient to reflect on the decision and to engage in any desired activities with which the intervention might interfere?

More commonly, there will be a range of medically acceptable responses to a given disease or health condition. The decision then has two components: *whether* to treat and *how* to treat. Here the discussion will typically require a comparison of several treatment options and an airing of the preferences of both professional and patient.

Since the judgment about which choice will best serve well-being properly belongs to the patient, a physician is obliged to mention all alternative treatments, including those he or she does not provide or favor, so long as they are supported by respectable medical opinion. For example, an internist has an obligation to discuss a surgical option with a patient who might benefit from it. In any case, the physician would ideally offer to refer the patient to a physician who does offer or favor the alternative treatment.

¹⁴ For example, a survey conducted in 1961 found that 90% of physicians preferred not to inform patients of a diagnosis of cancer. See D. Oken, *What to Tell Cancer Patients: A Study of Medical Attitudes*, 175 J.A.M.A. 1120 (1961). By 1977, 97% of physicians said they routinely disclosed cancer diagnoses. D.H. Novak *et al.*, *Changes in Physicians' Attitudes Towards Telling the Cancer Patient*, 241 J.A.M.A. 897 (1979). See also Arnold J. Rosoff, *INFORMED CONSENT: A GUIDE FOR HEALTH CARE PROVIDERS*, Aspen Publications, Rockville, Md (1981) at 340-76.

Similarly, a physician ought not withhold information about a treatment from a patient simply because the physician judges its potential benefits not to be worth its costs.¹⁵ Increasingly, however, even when physicians fulfill their obligation to describe alternatives, the expense of some alternatives may make them unavailable to most patients. Ordinarily, alternatives should still be described, even though they would not be covered by a patient's insurance plan (if any) or enrollment agreement with a health maintenance organization, lest the patient be deprived of the opportunity to seek other avenues for paying for the treatment or to look for treatment outside the insured or prepaid options.

Plainly, the special rules and expectations generated for the patient-professional relationship by the legal and ethical precepts summarized in the requirement of informed consent find no precise equivalent in commercial relationships in the insurance marketplace. Nonetheless, because of the close connection between health insurance (including prepaid group plans) and health care, both the sellers and the buyers of such insurance should make sure buyers receive a comprehensible explanation of the limitations in what they are purchasing. Otherwise, their subsequent decisions at the time of selecting among treatment alternatives may not in any real sense be either voluntary or informed.

The Commission does not believe that each alternative must be discussed in comprehensive detail. Rather, the professional should initially set forth, in a fairly general way, the nature and implications of the various options. Such a discussion can and should be used to "sound out" what is important to the patient and to identify the options likely to prove most satisfactory in light of the patient's values and preferences. Once the options (including the possibility of no treatment) have been pared down to those that seem most promising to patient and professional, a more detailed evaluation of the risks and benefits is appropriate. Attention should be devoted as well to the time dimension and finality of the choice, and to the possibility of a sequential approach to various alternatives. In this process, the Commission views the discussion of risks and benefits as a step toward a sound decision among alternatives, not a supreme objective in itself.

This Report, like many discussions of informed consent, places considerable stress on the patient's right of self-determination, including the right to choose among available treatments or to reject a particular treatment. Yet the Commission

¹⁵ Nothing in the obligations that arise within the patient-professional relationship precludes physicians, individually or collectively, from taking steps to make the health care system more efficient, including the elimination of treatment options that do not produce a favorable cost-benefit ratio in particular cases.

does not mean to suggest that professionals must take a neutral position among available alternatives. Physicians ordinarily do make recommendations to patients, and many patients would be quite disconcerted if they were rebuffed when they requested a "doctor's opinion." Indeed, a critical aspect of the professional's role is to provide expert advice and judgment, and not solely technical diagnostic or curative skills. But the recommendation should neither be, nor appear to be, coercive; rather, it should function both as a yardstick against which patients can measure their own inclinations and as a stimulus to further questioning and discussion if the recommendation is not one the patient agrees with.¹⁶

Treatment information in practice. The public clearly feels that physicians *should* discuss the nature, risks, and other consequences of the recommended treatment. Although physicians generally report that they do so, the Commission's survey found that patients are less likely to perceive that this information is generally disclosed by their physicians (see Table 1). The greatest disparity was found on the question of discussion of costs associated with treatment. Whereas 70% of the public thought physicians should initiate such discussions, only 38% of doctors reported that they do so. When the expense of treatment is borne by the patient—and a substantial amount of expense *is* borne by the patient, even when he or she is insured—differences in the cost of alternatives can be as important to the patient's "pursuit of a life plan" as differences in risks or side effects. A number of proposals are currently being considered that would increase the amount of cost-sharing by patients; this would make cost information

¹⁶ In making treatment recommendations the health care professional may indicate what his or her own values are. To the extent that a particular recommendation is based on the professional's values, rather than the patient's values, that should be made clear. For example, a physician may recommend that an athlete retire from competition because it is harming his or her health. The athlete, however, may want to remain in professional competition as long as possible. The physician may reply that the patient's view is shortsighted and that health is more important than another year of professional sports. Once having stated the recommendation, however, and having made clear the values that led the physician to the recommendation, the choice remains the patient's. When there are a number of medically appropriate treatment alternatives, the decision among them may also turn on value preferences. For example, a physician who feels strongly that kidney transplant is preferable to renal dialysis is likely to be stating a value preference rather than a purely medical conclusion. In such situations, physicians should recommend that the patient consult with another expert with opposite views before making a final decision. In both examples, clarification of the professional's values is likely to provoke a useful discussion of the patient's values. See, e.g., Robert M. Veatch, *Generalization of Expertise*, 1 THE HASTINGS CENTER STUDIES 29 (1973).

even more important. Even when the patient does not bear the expense directly, providing cost information would permit the patient to consider whether the personal benefit seems commensurate with the cost to society. (Although this may not cause a patient to alter his or her behavior, at least the person will have some idea of why insurance premiums are so high.)

Furthermore, although discussion of costs may, in the short run, be embarrassing to patients and physicians, in the long run

Table 1:

Public and Physicians' Views on Initiation of Discussion and Explanation of Treatment

Subject of Discussion	Public View: Doctors Should Initiate Discussion	Doctors' Report: I Do Initiate Discussion	Public View: My Doctor Always or Usually Explains	Doctors' Report: I Always or Usually Explain
Nature and Purpose of Recommended Treatment	85%	96%	77%	96%
Pros & Cons of Recommended Treatment vs. Alternatives	81%	84%	68%	83%
Likely Side Effects	88%	95%	68%	93%
Probable Impact on:				
Patient's family life	79%	74%	*	78%
Patient's job role	79%	79%	*	86%
Cost of Treatment	70%	38%	45%	47%
Risks of Death or Serious Disability that are:				
1:100	75%	81%	*	82%
1:1000	64%	52%	*	59%
Risks of Temporary Disability that are:				
1:1000	65%	43%	*	57%

* Not asked.

Source: Commission survey conducted by Louis Harris and Associates.

failure to discuss expenses could compromise health—a patient who is reluctant to explain that a prescribed medicine is unaffordable may fail to fill the prescription; an individual who fears that an expensive operation will be recommended may decide not to go to a specialist when referred to one. In the view of the Commission, health care professionals have an obligation to ensure that patients get the cost information that is relevant to the treatment options under consideration.

The observational studies conducted by the Commission are most striking in their findings that in hospital settings often little or nothing is actually discussed with patients regarding either alternative treatments or the recommended treatment. Instead, physicians commonly make decisions and proceed to treat the patient. Beyond this generalization, however, there was tremendous variation in the nature of disclosure and decisionmaking that was related to the structure of the medical care setting, the nature of the patient's illness, and the treatment under consideration.

In the study of treatment refusals in medical, surgical, and specialty wards of a university teaching hospital and a community hospital, it was found that most of the treatment refusals were related to the nature and extent of information provided to patients. In many cases there was a total lack of information concerning diagnostic and therapeutic procedures. Typically these were ordered by physicians without patients being alerted to what was to be done, much less being asked. Although most people went along with these tests and procedures, the lack of information served as a trigger for refusals by patients already primed to resist treatment because of ambivalence about the primary procedure for which they had been hospitalized, delays, previous complications, etc. It was not always obvious to patients why something needed to be done and some refused to proceed until they were given some justification. Thus this lack of information was often a precipitating factor, but not generally the sole cause of refusals. In some cases, patients were told that a test or procedure would be performed, but they were not informed about the purpose or the risks. Patients who knew or discovered that certain procedures were potentially very risky refused treatment until reasonable justification and assurances were provided.

Another source of refusals of treatment was conflicting information given to patients by different health care professionals. This is especially likely to occur in hospitals, where patient care is divided among different people, many of whom are not in direct communication with each other. This resulted in patient uncertainty about who was making decisions about their care and whom, therefore, they should trust. In some cases patients questioned the capabilities of the house officers

and wanted their own primary physician's endorsement before agreeing to a procedure.

Some refusals could be traced to a lack of communication on the part of both the doctor and the patient. For example, one patient refused to take a routinely prescribed laxative because she had severe diarrhea. The doctor had failed to ask the patient about her bowels and the patient was hesitant to volunteer the relevant information. Once the patient told the nurse responsible for dispensing medications why she did not want the laxative (which she had previously been taking despite her diarrhea), the medication was withdrawn.

In the Commission's other observational study, the nature of the communication and decisionmaking process varied for cardiology versus surgery patients, for outpatients versus inpatients, and for acute versus chronic disorders. Differences in the nature of disclosures for surgery and cardiology patients derived from differences in the authority structures and daily routines in the two wards and from the nature of the interventions themselves. Surgery is a single event that is relatively easily described by staff and understood by patients. On the surgical ward, a single, readily identifiable physician was usually clearly in charge. Patients had a greater opportunity to ask questions than in cases where responsibility was more diffuse. Cardiology is organized around an organ malfunction, not around a particular treatment. Cardiac care is therefore more process-oriented and ambiguous and may involve numerous forms of treatment and diagnostic tests. The nature of disclosures for cardiology patients varied with the procedure. For example, patients undergoing exercise stress tests (who were usually outpatients referred to the hospital just for this procedure) were mailed a cover letter and consent form describing the test. Upon arrival at the hospital the nurse asked if they had read the form and had any questions. If they had no questions (which was usually the case), no discussion took place. Presumably the referring physicians had discussed the test somewhat with the patients previously, but those encounters were not observed.

Cardiac catheterization patients, on the other hand, got detailed explanations of the procedure and its risks. The following is a transcript of part of a typical conversation between one physician and patient. Having explained why the procedure should be done and what information it would provide, the physician went on to describe how it was done and what it would feel like, including that the patient would feel very hot for about 20 seconds.

Patient: Oh, seconds only, that's all right. But I do want this explanation because I knew I would get this for 25 years. I guess I've heard a lot of

things about it. Friends of mine have had it and so forth.

Doctor: Yes, some people like it and some people say it's the worse thing that happened to them in their lives. I think I ought to tell you that there's some possibility that we may have to do a transeptum catheterization [and he explained what this consisted of]. There's some potential risks. I think you will find they are terrifying, but I want you to remember we weigh the risks both of doing it and not doing it before we recommend it to you.

Patient: Maybe you shouldn't tell me until tomorrow.

Doctor: Well, I could wait until tomorrow, but I do have to tell you this. I want you to know the risk is low. We are talking about a one in a thousand chance of a major risk. There's some minor ones, too. But they can all be dealt with. Some of the major ones can, too, but they're not very likely. Here are some of them. First of all we have to go into the vessel, and we can injure the vessel, and that can sometimes require surgery, which can be difficult in its own right. The second one is that you might have hardening of the arteries already, and some sort of blockage could result from pushing through them. This can require surgery also to make it better, and even so there's a low risk of a heart attack or of stroke from it. Then another thing is that some people are allergic to the dye, and this can put somebody into shock, and usually we can treat that with medicine, but it's quite serious. Another thing it can do is it can cause an irregular heartbeat, and you can even need an electric shock because it can cause your heart to stop. But of course you would be asleep then, and you wouldn't feel it. Another thing is that if we need to do the transeptal catheterization, that can cause a puncture of the heart and bleeding. The blood can get between the heart and the sac around it, and then we would have to drain that. One of the minor risks is that you can have a hematoma around where we put in the catheter. That's not much of a real problem, but you can get black and blue, and that happens because of the Heparin we put in to prevent the clotting I talked about earlier.

- Patient: You know, I can't remember any of that stuff.
- Doctor: Well, I know it's scary, but I want you to understand that it's my feeling that it is a higher risk not to have it done. But of course ultimately it's your decision, not mine.
- Patient: Do you do this often?
- Doctor: Yeah, this is a big center for that sort of thing, for valve replacements, and we see a lot of these.
- Patient: You see it's all new to me.
- Doctor: And one other thing is that you're going to have to sign a consent form. The nurse'll bring that in later tonight.
- Patient: Well, you have to do it because it's the best procedure.

Several things are worth noting in this exchange. The patient was clearly ambivalent about learning all the details about risks; the doctor was clearly determined to enumerate them and tried to be reassuring. Given the sheer volume of information provided, coupled with the anxiety that probably pervaded the entire situation, it is not surprising that the patient stated immediately that he could not "remember any of that stuff" (though other patients following similar disclosures had actually been able to remember a good deal). The patient was more concerned about whether the procedure would hurt and about the physician's experience with it than in knowing details about the risks. It was the patient who pointed out a key aspect in most of medical care, namely that these things may be routine for the staff but they are new to the patient. The ultimate decision to go ahead with the test was based on the patient's assessment that it was the best procedure and that it was necessary.

The studies further indicated that the extent of disclosure was related both to the nature of the proposed treatment and to the risks involved. For courses of action perceived to constitute "procedures"—typically, surgical and invasive diagnostic interventions—substantial information was provided, particularly when the procedure was recognized to be a risky one. For more routine courses of action, not perceived as formal procedures, less information was provided. This was true even in the case of administration of potentially risky drugs, which might entail greater risks than minor surgical procedures for which more information was disclosed. These practices may reflect the origins of consent requirements in surgical practice.¹⁷

¹⁷ Only a few jurisdictions have ever considered the applicability of informed consent to medications, *see, e.g.*, *Hamilton v. Hardy*, 549 P.2d 1099 (Colo. App. 1976); *Sharpe v. Pugh*, 270 N.C. 598, 155 S.E.2d

In general it was found that surgical outpatients received less unprompted information than inpatients. On the other hand, they asked more questions and sought other sources of information, so that ultimately they may have ended up getting as much information as those in the hospital.

The nature of the disorder was found to affect the amount of information patients receive from physicians about treatments. Chronically ill patients are sometimes so well educated about their illness that they speak in the same jargon as the medical personnel. Their understanding of information relevant to their illness and treatment grows over time. The increase in both informing and understanding that time allows is most apparent in the case of chronic illness.

Furthermore, it was found that much of the information given to patients is not necessarily intended to assist them in participating in the decisionmaking process, though it sometimes



108 (1967); *Marsh v. Arnold*, 446 S.W.2d 949 (Tex. Civ. App. 1969), and none of them has ever explicitly rejected the applicability. In fact, one much-discussed recent case, *Truman v. Thomas*, 165 Cal. Rptr. 308, 27 Cal.3d 285, 611 P.2d 902 (1980), held that an informed consent claim could be founded on a physician's failure to disclose the risks of *not* performing a procedure. One case holds that informed consent requirements do not apply to the dispensation of medications. In *Malloy v. Shanahan*, 421 A.2d 803 (Pa. Super. 1980), in an opinion that did not include an explanation of the court's reasoning, the Pennsylvania Superior Court held that the administration of a drug, not involving any physical touching of the patient, could not constitute a battery and thus was outside the scope of the state's informed consent requirements. The Pennsylvania approach is undesirable in that it substantially undercuts the goals of patient well-being and self-determination that informed consent is intended to serve. Since so much medical care involves the use of drugs, many of which have potentially serious or even lethal side effects, informed consent requirements should be applicable.

has that consequence. People who are newly diagnosed as having a chronic disease are given a great deal of information to help them adjust to a new way of life and comply with the treatment recommendations of the attending medical personnel.

Ideally, information should help patients to cope with their illnesses and should produce better outcomes. It is thus a part of good care and goes beyond merely trying to improve compliance. However, it was found that patients suffering from an acute illness typically are given only enough information so they can agree to the therapeutic recommendation of the medical personnel and so they will not be too surprised by untoward results. According to the nurses in the observational study of informed consent, this is the main purpose of preoperative surgery education.¹⁸

Thus it would appear that in actual practice the nature and extent of information provided to patients regarding treatment alternatives, including the recommended treatment, risks, benefits, and other consequences, varies substantially depending on the nature of the patient's condition and of the proposed treatment as well as on the preferences of the patient and providers.

The Role of Uncertainty. Underlying all three core elements of the professional-patient communication process is the dimension of uncertainty. Few would claim that medicine is an exact science, yet many commentators have remarked on the disinclination of medical professionals to discuss with their patients the uncertainties inherent in diagnosis, prognosis, and potential treatments. Explanations of this attitude range from an insistence on maintaining professional control and dominance to the potential therapeutic efficacy of unquestioning confidence in a treatment by patient and professional alike.¹⁹ (General recognition of this effect is implicit in the nearly

¹⁸ Certainly not all nurses would agree that the goals of preoperative education are so limited. The findings from this study may be peculiar to the particular health care providers in the institution studied or may be peculiar to university hospitals.

¹⁹ The significance of medical uncertainty for the doctor-patient relationship was first discussed by Talcott Parsons, *THE SOCIAL SYSTEM*, Free Press, Glencoe, Ill. (1951) at Chapter Ten and has been elaborated on by Renée C. Fox in many of her writings; see, e.g., *Training for Uncertainty*, in Renée C. Fox, *ESSAYS IN MEDICAL SOCIOLOGY: JOURNEYS INTO THE FIELD*, John Wiley and Sons, New York (1979) at 32-48, *The Evolution of Medical Uncertainty*, 58 *MILBANK MEMORIAL QUARTERLY* 1, 49 (1980), and, with Judith P. Swazey, *THE COURAGE TO FAIL: A SOCIAL VIEW OF ORGAN TRANSPLANTS AND DIALYSIS*, Univ. of Chicago Press, Chicago (1974) at 40. See also G. Honigfeld, *Non-Specific Factors in Treatment II: Review of Social-Psychological Factors*, 25 *DISEASES OF THE NERVOUS SYSTEM* 225 (1964).

universal acceptance of the randomized double-blind design in biomedical research to eliminate "placebo effects.")

Whatever the reasons, numerous studies have indicated that people respond differently to uncertainty, and it seems there may be systematic differences between physicians and patients in how uncertainty affects their decisions regarding medical interventions. The Commission's view of informed consent includes as one facet patients being able to reflect their own attitudes toward uncertainty in their decisions. If they do not know of uncertainties in the diagnosis and treatment, their ability to be self-determining is limited.

Types of uncertainty. Uncertainties about medical decisions derive from a number of sources, some more intractable than others. First, of course, there are limitations in medical knowledge. While biomedical research continually pushes forward the frontiers of knowledge, much remains only imperfectly understood.

Second, there is what may be termed "empirical uncertainty": that uncertainty inherent in any knowledge obtained through the scientific method. The reliability of information based on past experience with a defined, similar group of patients depends upon the determined error of statistical prediction, the adequacy of definition of the group, the accuracy of observations, and the constancy of natural history and medical care over time.

A particularly difficult uncertainty for both doctors and patients derives from the probabilistic nature of much health care. Most treatment recommendations are based on the physician's view of what is most likely to be successful rather than on absolute certainty that a particular treatment will lead to a particular outcome. Implicit is some notion of probability—90% of the time this is successful. Yet most people, physicians and patients alike, see the results of diagnostic tests as completely reliable, even though they know that no test is 100% accurate. Patients especially may draw broad and unwarranted inferences from a similar case they know of, acting as if an example were proof.²⁰

Uncertainty can also arise from limitations in the knowledge of particular health care providers about medical information. Obviously no practitioner can have instant command of the full range of medical knowledge. In some instances such gaps in knowledge may reflect a failure to keep up with fundamentals; in others they may simply indicate a regrettable but unavoidable limitation of human capacity.

²⁰ Richard Nisbett and Lee Ross, HUMAN INFERENCE: STRATEGIES AND SHORTCOMINGS IN HUMAN JUDGEMENT, Prentice-Hall, Inc., Englewood Cliffs, N.J. (1980) at Chapter Three.

A fifth, somewhat different type of uncertainty may be termed "experiential": the limits on an individual's ability to imagine what life under very different circumstances would be like. A previously healthy individual contemplating life as an invalid, for example, or a pregnant woman anticipating her first labor and delivery faces certain inherent limitations in knowing how the new experience will feel.

Each of these areas of uncertainty is to some degree inevitable, but health care professionals can and should take steps to reduce them, where possible, and to help patients deal with those that remain. Continued biomedical research and efforts by professionals to remain informed will reduce the scope of the unknown, both for medicine as a whole and for individual practitioners. Patients can be given some indication of the extent of a professional's knowledge—specialization, prior experience, scholarly inquiry—and of the availability of second opinions by expert consultants. Practitioners can also share the experience of other patients in similar circumstances (consistent with norms of confidentiality), help patients to meet others who faced similar decisions, and work with patients to understand their own resources for coping with and adapting to new situations.

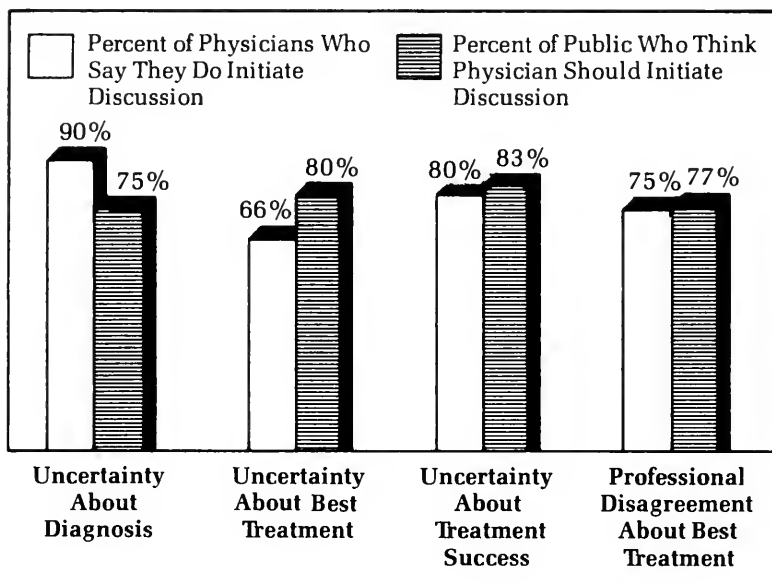
Attitudes toward uncertainty. Both health care professionals and patients may have difficulty dealing with the concept of uncertainty as well as the substance. And for both, uncertainty can evoke uncomfortable emotions. Nonetheless, in the Commission's view, where significant uncertainty exists health care professionals have an obligation to discuss it with patients.

Although there was variation among subgroups of those surveyed by the Commission, physicians on the average reported that they initiate discussion and always or usually discuss uncertainties, and the public feels physicians should raise such issues (see Figure 1). Interestingly, the public is generally less likely to feel that physicians should initiate discussion about uncertainties about diagnoses (75%) than physicians report they actually do (90%). On the other hand, the public is more likely to feel that uncertainties regarding the best course of treatment should be discussed (80%) than are physicians to report bringing up such discussions (66%).²¹

²¹ Of the various subgroups examined, those who had had a life-threatening illness, who received their care in a physician's office, who had high incomes, whose current health was excellent, or who were young, white, or college-educated were more likely to feel that doctors should initiate discussion about these uncertainties. Those in poor health, the elderly, and the least well educated were most likely to say they were "not sure" whether such discussions should be initiated.

Figure 1: Discussion of Uncertainty in Medical Care

Source: Commission survey conducted by Louis Harris and Associates, 1982



Not surprisingly, physicians who regard most (90-100%) of their patients as able to understand most aspects of their conditions and treatments were more likely to discuss uncertainties. Although there was some variation among physician subgroups, the differences were neither as regular nor as pronounced as those among the public.²² Generally physicians who graduated from medical school after 1972 were less likely than older physicians to report that they always or usually discussed uncertainties. Given the burgeoning interest in informed consent and in litigation during the last decade, this is somewhat surprising and serves as a reminder that the law may influence—but does not necessarily control—relationships that are subject to myriad other subtle influences. However, many commentators have noted that medical students and young physicians are themselves unable to deal with

²² Physicians in general or family practice were less likely than others to initiate discussion about most uncertainties, although the one exception was for uncertainty regarding diagnosis, for which obstetricians/gynecologists were least likely to initiate discussion. Surgeons were most likely to report that they always or usually discussed uncertainties with their patients. Office-based physicians were more likely than hospital-based ones to discuss uncertainties.

uncertainty, so much so that they are uncomfortable discussing it with patients.²³ Only after being in practice for some period of time do physicians reconcile their sometimes overwhelming sense of responsibility to heal with the real limits and uncertainties inherent in medicine.

The observational study of informed consent found that when the nature of the patient's problem is fairly certain and a professional consensus exists about the best approach for dealing with that problem (for example, general surgery), patients receive more information about their illness and its treatment than when the nature and etiology of the problem, and thus the best method for dealing with it, are more uncertain (for example, cardiology). Even when there is a high degree of uncertainty about a patient's problem, it was found that medical personnel tried to convey a sense of certainty rather than subtle information about the illness and its treatment.

The study of treatment refusals found that even when physicians did discuss uncertainty, patients often had a difficult time understanding it. They sometimes even claimed to be unaware of information that study observers heard the physicians discuss with them. One patient, for example, who suffered from a "fever of unknown origin" kept refusing to have any more blood tests despite repeated explanations that they were necessary in order to discover the reason for her fever. The patient seemed unable to grasp the idea that her doctor really did not know why she had a fever and she wondered why he did not just prescribe an antibiotic. A similar example concerned a patient with pancreatitis whose physician told him honestly he did not know why he had it and what was causing pain even after an operation. Because "no one ever told me why I had it," he said, he refused further diagnostic tests. Here, too, the patient seemed unable to believe that there was something the doctor did not know. It is perhaps not surprising that physicians may sometimes try to make things sound more certain than they really are in order to proceed with tests they consider necessary, to do something concrete for patients, and to avoid undermining people's confidence in them, even though patients in such situations are denied full opportunity to participate meaningfully in decisionmaking.

Mode of Presentation and Barriers to Effective Communication. The way information is presented can greatly affect understanding. Research has identified a number of influences on the success of the communication process and the nature of the message received. These include the particular words used, the structure and framing of the information, the timing of the

²³ Fox, *Training for Uncertainty*, *supra* note 19.

disclosure, and the setting in which the discussion takes place. As already discussed, some kinds of information are inherently more difficult than others to describe and to understand.

The public was asked: "Do you usually come away from your doctor feeling that you have understood the important issues relating to your treatment?" Of all those surveyed, 38% said they felt they understood fully, 14% understood more than adequately, 36% said adequately, and only 10% said their understanding was usually less than adequate. The place of care and type of relationship had significant effects on the degree of self-reported understanding.²⁴ In a follow-up question, when asked "When a patient doesn't understand his medical treatment, how often is this because the doctor did not explain things well?" 12% of the public said "always," 32% said "often," 37% said "sometimes," 8% said "rarely," 3% said "never," and 7% were not sure.²⁵ Thus, it would appear from the Commission's survey that doctors believe most patients have the capacity to understand and that most patients feel they do understand most aspects of their medical care and regard promotion of this understanding as a task of the physician.

The amount of information that is actually understood is more difficult to establish empirically. A number of studies purport to have examined the extent to which patients understand medical information, but unfortunately they all suffer from several methodological shortcomings. The most serious flaw is that "knowledge" is usually equated with "comprehension." The typical study tests patients after they have read consent forms or talked with physicians, in order to determine whether they can repeat information accurately. Some tests are multiple choice in nature, thereby assessing "recognition"; others are open-ended, thereby testing "recall." While some tests are given immediately after disclosure, others are given after a substantial period of time has elapsed to test "retention" of information.²⁶

²⁴ Those receiving care in a doctor's office were more likely than others to feel they fully understood; those with no usual source of medical care were most likely to report inadequate understanding. People in poor health, the elderly, women, and those with less than a high school education were more likely than others to report either that they fully understood or that their understanding was inadequate, with fewer falling in the middle categories of "adequate understanding" on the scale.

²⁵ The college-educated were significantly more likely than those with little education to say it was always or often the doctor's fault (51% versus 31%). People in poor health and the elderly were less likely to blame the doctor for their lack of understanding and more likely to be unsure (up to 19%) whether it was the doctor's fault.

²⁶ See, e.g., the review article by Alan Meisel and Loren H. Roth, *What We Do and Do Not Know About Informed Consent*, 246 J.A.M.A. 2473

Although knowledge is a necessary condition for comprehension it is not sufficient. True understanding involves the ability to use information rationally. Very few empirical studies have attempted to examine how information is used in the decisionmaking process. Little is known about variations in knowledge and understanding that are related to the nature of the patient or the condition for which treatment is being proposed.

For information to have been communicated successfully, it needs not only to have been disclosed, but also attended to, understood, accepted, remembered, and put to use. For patients to use information, they must pay attention to the physicians' communications, select out the details important to them, interpret and integrate new knowledge with information they already have, and later recall and use the information to make decisions.

Not only are there finite limits on people's ability to use information, but patients—*anxious, frustrated, trying to understand unfamiliar yet threatening information*—are at a serious disadvantage when it comes to absorbing what physicians say. At the very first step—*paying attention to what is said*—limitations of the patients' ability to process information are probably most evident. It is difficult for patients to pay attention to details about their therapy when they are thinking, and probably worrying, about the diagnosis given earlier in the interview.²⁷

In addition to the limiting effects of the patient's emotional state, the lack of familiarity with the topic being discussed constrains the patient's ability to attend to essential messages. People cannot possibly remember every word they heard during discussions with health professionals. Rather, they extract what they consider to be the important points. Unfortunately, patients may not know which ideas are most important medically. They may not realize the implications of what is being said because they do not recognize the special meanings of medical phrases, especially ones that do not sound "medical." For example, it has been found that the phrase "admitted

(1981). For specific proposals to test patients' knowledge, see Robert Miller and Henry S. Willner, *The Two-Part Consent Form*, 290 *NEW ENG. J. MED.* 964 (1974); John Grabowski, Charles P. O'Brien, and Jim Mintz, *Increasing the Likelihood that Consent is Informed*, 12 *J. OF APPLIED BEHAV. ANALYSIS* 283 (1979).

²⁷ See, e.g., M.W. Eysenck, *Anxiety, Learning and Memory: A Reconceptualization*, 13 *J. OF RESEARCH IN PERSONALITY* 363 (1979); K.A. Leight and H.C. Ellis, *Emotional Mood States, Strategies and State-Dependency in Memory*, 20 *J. OF VERBAL LEARNING AND VERBAL BEHAV.* 251 (1981).

for a work-up" does not convey to some patients that they will be hospitalized.²⁸

Under these circumstances, patients may direct their attention to the most familiar aspects of what the physician is saying, concentrating on old problems and failing to recognize the severity of new ones. Health care professionals can assist patients by indicating which information is medically important and the reasons why, by avoiding jargon, by timing discussions so as to minimize anxiety, and by holding discussions in a setting that will encourage patients to ask questions.

Practitioners should be particularly careful about how they present information concerning uncertainty. In some instances, there is no neutral or obviously correct formulation; however the information is conveyed, it will carry some distinctive bias that will affect how it is heard. An attempt to be neutral is quite different, however, from deliberately presenting or framing facts to induce a particular reaction. "You are very ill; but, even so, almost everyone survives this operation—only 17% die" is comprehended very differently from "You are not doing too well, and the only operation that might help kills nearly one in every five patients." Such formulations are not necessarily deceptive, but they certainly can be manipulative in the sense of eliciting a different decision from that which might result from other professional-patient discussions.²⁹ A more forthright recognition of these aspects of communication and an effort to present complex information about uncertainty in several ways could achieve a more well rounded understanding of what is at stake. Such an approach would do much to advance the values of patient welfare and self-determination.

Finally, health care practitioners often find their ability to inform patients severely constrained by the limited or nonexistent history of their relationship. Often professionals do not know patients before their current crises and may never have known them as reasonably healthy individuals. Furthermore, when people are ill, they are often frightened and in pain, which can compromise communication. These barriers may be an inevitable concomitant of modern, high-technology, acute-care medicine. Yet their absence in many chronic care situations suggests the real possibility of effective patient participation.

The detrimental effects of having little, if any, previous knowledge of hospitalized patients can be ameliorated by frequent contact, sincere concern, conversations with families, and limited change of professional responsible for the patients'

²⁸ See, e.g., B.M. Korsch and V.F. Negrette, *Doctor-Patient Communication*, 227 *SCIENTIFIC AMERICAN* 66 (1972).

²⁹ See pp. 66-68 *supra*.

care. Moreover, it is important for professionals to indicate not only an interest in learning about patients but also a willingness to provide information and respond to questions and concerns. This message can be conveyed—or contradicted—in subtle ways. Physicians who remain standing when they enter patients' rooms create a different impression than those who sit down by patients' beds to talk.

Justifications for Less Than Full Disclosure. Quite apart from these barriers to effective communication, there may be times when a full communication process is not desirable and should not be required. The law recognizes a number of such situations. These "exceptions to informed consent,"³⁰ when properly invoked, shift all or part of the decisional authority from the patient to someone else. The exceptions fall under several headings:

- (1) legal requirements;
- (2) emergencies;
- (3) incompetency;
- (4) waiver; and
- (5) therapeutic privilege.

Informed consent is not required in certain instances in which medical interventions are directed or authorized by law. These include certain tests performed pursuant to the authority of police officers or of public health officials, such as testing drivers for inebriation or immunizing school children against contagious diseases.³¹ Since consent need not be sought in such circumstances, "informed consent" is a misnomer. Nonetheless, it may still be appropriate to discuss with a person the nature of the procedure and the reasons for it, out of respect for that person, even though such discussion is not intended to assist the individual in making a choice.

The emergency exception applies when immediate treatment is required to preserve life or prevent a serious impairment to health but consent cannot be obtained from a patient (or from someone empowered to authorize treatment on the patient's behalf) and there is no indication that the treatment would be refused were the patient then able to make his or her wishes known. It is sometimes said that consent in such situations is "implied by law," by analogy to situations in which a patient by his or her conduct implies consent without explicitly giving it.³² This terminology is misleading. More accurately, in an emergency the law sets aside the requirement

³⁰ See Alan Meisel, *The "Exceptions" to the Informed Consent Doctrine: Striking a Balance Between Competing Values in Medical Decisionmaking*, 1979 Wis. L. Rev. 413.

³¹ See Rosoff, *supra* note 14, at 19-24, 253.

³² See, e.g., *Dicenzo v. Berg*, 340 Pa. 305, 17 A.2d 15 (1940); *Jackovach v. Yocom*, 212 Iowa 914, 273 N.W. 444 (1931); *Luka v. Lowrie*, 171 Mich.

of consent, based on the presumption that a reasonable person would want emergency aid to be rendered and that a particular patient has such wishes unless he or she has indicated otherwise.

The remaining three exceptions actually comprise modifications in, rather than eliminations of, the usual rules for informed consent. A patient's informed consent is not required in cases of incapacity to make a particular decision. As discussed in Part Four, however, the requirement of consent is not eliminated; rather, a surrogate must exercise the authority on behalf of an incapacitated patient. It may still be appropriate to inform such patients of the nature of their situation and to seek to involve them in the decisionmaking process, even when they do not have the capacity to make legally binding decisions.

The modest attention paid to the fourth exception—waiver—in the courts and scholarly literature is regrettable given its interesting relationship to the value of self-determination that underlies the doctrine of informed consent. As observed in Chapter Two, self-determination encompasses both the moral right to formal control over a decision and the ideal of active participation in the decisionmaking process. Although these two senses of self-determination often go hand in hand, sometimes they do not, as in the case of a waiver, when a patient asks not to be informed of certain matters and/or delegates decisional authority to another person.

The impact of the waiver exception is that if a waiver is properly obtained the patient remains the ultimate decisionmaker, but the content of his decision is shifted from the decisional level to the metadecisional level—from the equivalent of "I want this treatment (or that treatment or no treatment)" to "I don't want any information about the treatment."³³

The legal requirements for effective waiver in the context of informed consent have never been clearly articulated by the courts. There is substantial reason to believe that the courts would respect waivers of certain information (for example, the disclosure of particular risks) or the delegation of certain decisions to others. Yet it is questionable whether patients should be permitted to waive the professional's obligation to disclose fundamental information about the nature and implications of certain procedures (such as, "when you wake up, you will learn that your limb has been amputated" or "that you are irreversibly sterile"). In the absence of explicit legal

122, 136 N.W. 1106 (1912). See generally William L. Prosser, *THE LAW OF TORTS*, West Publishing Co., St. Paul, Minn. (4th ed. 1971) § 18 at 101-03.

³³ Meisel, *supra* note 30, at 459.

guidance, health care professionals should be quite circumspect about allowing or disallowing, encouraging or discouraging, a patient's use of waiver.

The final exception to informed consent, which has been the subject of substantial comment, is called therapeutic privilege and permits professionals to refrain from making a disclosure that could so seriously upset a patient that it would be countertherapeutic.³⁴ The obvious danger with such an exception is the ease with which it can swallow the rule, thereby legitimating wholesale noncompliance with the general obligation of disclosure.³⁵ Accordingly, some courts and commentators hold that the scope of therapeutic privilege should be severely circumscribed, and that, at the least, the privilege should not apply in situations when the potential harm to the patient from full disclosure would result not from the disclosure itself, but from a treatment decision the practitioner fears the patient might make as a result of the information disclosed.³⁶ More plausible claims of therapeutic

³⁴ Ironically, the "privilege" not to disclose was first recognized before there was a well-established legal duty to make disclosure. Alan Meisel, *The Expansion of Liability for Medical Accidents: From Negligence to Strict Liability by Way of Informed Consent*, 56 NEB. L. REV. 51, 99 n.140 (1977). The two earliest articles discussing the privilege—Charles C. Lund, *The Doctor, the Patient, and the Truth*, 19 TENN. LAW REV. 344 (1946); Hubert Winston Smith, *Therapeutic Privilege to Withhold Specific Diagnosis from Patient Sick with Serious or Fatal Illness*, 19 TENN. L. REV. 349 (1946)—appeared at a time when very few cases had imposed upon a physician an affirmative duty of disclosure, and almost a decade before a court first used the term "informed consent." Although one commentator has remarked that "[i]t is not clear where this privilege originated," Note, *Restructuring Informed Consent: Legal Therapy for the Doctor-Patient Relationship*, 79 YALE L. J. 1533, 1564 n.95 (1970), something like the privilege was referred to in *Twombly v. Leach*, 65 Mass. (11 Cush.) 397, 405-06 (1853): "Upon the question whether it be good medical practice to withhold from a patient...a knowledge of the extent and danger of his disease, the testimony of educated and experienced medical practitioners is material and peculiarly appropriate."

³⁵ "The privilege does not accept the paternalistic notion that the physician may remain silent simply because divulgence might prompt the patient to forego therapy the physician feels the patient really needs." *Canterbury v. Spence*, 464 F.2d 772, 789 (D.C.Cir. 1972). As is true of much of the *Canterbury* case, this language is taken from Jon R. Waltz and Thomas W. Scheuneman, *Informed Consent to Therapy*, 64 NW. U. L. REV. 628, 642 (1970). Other courts have not been as restrictive in their formulation of the privilege: "[A] physician may withhold disclosure of information regarding any untoward consequences of a treatment where full disclosure will be detrimental to the patient's total care and best interest." *Nishi v. Hartwell*, 52 Haw. 188, 191, 473 P.2d 116, 119 (1970).

³⁶ See generally A. M. Capron, *Informed Consent in Catastrophic Disease Treatment and Research*, 123 U. PA. L. REV. 340, 387-92 (1974);

privilege might involve certain disclosures to patients previously known to be suicidal or those susceptible to serious physiological effects of stress, and in situations where there is strong reason to believe that a particular disclosure is likely to result in serious self-destructive behavior that could not be justified in terms of the patient's own long-term values and goals.

Despite all the anecdotes about patients who committed suicide, suffered heart attacks, or plunged into prolonged depression upon being told "bad news," little documentation exists for claims that informing patients is more dangerous to their health than not informing them, particularly when the informing is done in a sensitive and tactful fashion. On the contrary, as discussed further below, there is much to suggest that therapeutic privilege has been vastly overused as an excuse for not informing patients of facts they are entitled to know. In light of the values at stake, the burden of justification should fall upon those who allege that the informing process is dangerous to patient health, and information should be withheld on therapeutic grounds only when the harm of its disclosure is both highly probable and seriously disproportionate to the affront to self-determination.

Attitudes toward less than full disclosure. In the Commission's survey an attempt was made to discover how often and why physicians withhold information from patients, the conditions under which the public considers this acceptable, and the justifications for providing information to families when it is not given to patients.

Although physicians reported that they frequently make a conscious and deliberate evaluation of how much to tell patients, relatively few reported that they ultimately withheld information (see Table 2).³⁷ Physicians who judged that 90-100% of their patients are able to understand most information were generally less likely to withhold details. Interestingly, physicians who had graduated from medical school ten years ago or sooner were more likely than older physicians to withhold information about treatment risks and alternatives and about diagnosis and prognosis.

Physicians were also asked: "What are the most common reasons for you to withhold information about condition or treatment?" Patients' inability to cope with the information

Waltz and Scheuneman, *supra* note 35, at 641-43; Comment, *Informed Consent: The Illusion of Patient Choice*, 23 EMORY L.J. 503 (1974); Note, *supra* note 34, at 1564-71.

³⁷ Obstetricians/gynecologists were less likely than other physicians, especially internists, to withhold information. Practice location and the proportion of patients with serious illness influenced the withholding of information in the same way they affected making conscious evaluations; see note 7 *supra*.

Table 2:

Frequency With Which Physicians Report They Withhold Information

Frequency	Information Is Withheld About	
	Diagnosis or Prognosis	Treatment Risks and Alternatives
Once a Day	2%	4%
Once a Week	7%	6%
Once a Month	12%	9%
Few Times a Year	32%	24%
Almost Never	46%	57%

Source: Commission survey conducted by Louis Harris and Associates.

(34%), inability to understand it (28%), and the wishes of the patients' families (21%) were the reasons given most frequently. Only 9% mentioned effects on the patient's health.

Further questioning revealed that in nearly two-thirds of the cases in which physicians withhold "bad news" the decision to do so is rarely or never based upon the patients' wishes.³⁸ Moreover, when members of the public were asked "Have you ever asked a doctor not to tell you 'bad news'?", only 2% said yes, although 5% of those who had received care in a setting other than a doctor's office, or who were in poor health, or who had less than a high school education said yes. These figures on the public's request not to be told "bad news" are substantially lower than the physicians' reports of such requests.

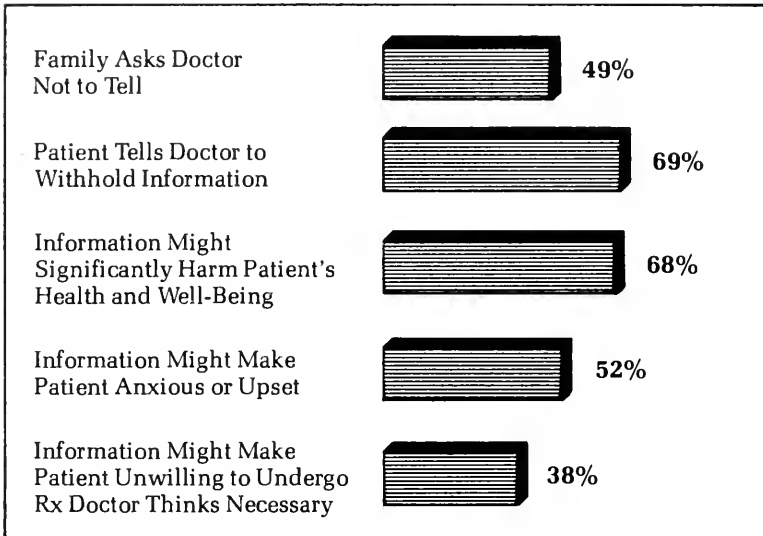
Nevertheless, physicians do believe in disclosing information to patients' relatives—a step that may alert them to potential idiosyncratic objections to an intervention or other special facts but that still falls far short of shared decisionmaking with the patient.³⁹ Of physicians surveyed, 80% said they "usually discussed the withheld information with another family member," 10% said "sometimes," 4% said "rarely," and

³⁸ Physicians were asked: "For those patients to whom you do not disclose 'bad news,' how often is this because they tell you directly they don't want to know it?"; 12% of physicians said "always," 11% said "often," 13% said "sometimes," 45% said "rarely," and 16% said "never." Not surprisingly, physicians treating high proportions of seriously ill patients were most likely to say "always" (17%).

³⁹ The legal status of disclosure to patients' relatives when the therapeutic privilege is invoked is uncertain. See Meisel, *supra* note 30, at 465-67.

Figure 2: Conditions Under Which Public Feels Physician Can Justifiably Withhold Information

Source: Commission survey conducted by Louis Harris and Associates, 1982



3% said "never." In an unusual response 3% said they were "not sure."⁴⁰

The responses of the public, when asked whether a physician would be justified in withholding information about a medical condition or treatment from a patient, more closely parallel existing law than do those in the physician sample (see Figure 2). A majority of the public only disapproved of physicians withholding information when the withholding occurs because the information might make the patient unwilling to undergo treatment believed to be medically necessary. However, more than two-thirds of those responding thought a physician would be justified in withholding information if the patient asked for it to be withheld or if the information might significantly harm the patient's health. About half those in the public sample find nondisclosure acceptable if the patient's family asked that the patient not be told (which 8% of the public reports having done) or if the information might make the patient upset or anxious.⁴¹

⁴⁰ Among specialists and subspecialists, 11% were not sure; among doctors who graduated between 1966 and 1972, 8% were not sure. Obstetricians were the least likely (68%) and surgeons the most likely (88%) to report that they usually did discuss with the family information they had withheld from a patient.

⁴¹ In general, older, less well educated people and those in poor health were more likely to feel that withholding information was justifiable; these groups were also more likely to express uncertainty than others. There is no recognition in law for withholding information from

Effects of disclosure and nondisclosure. Despite the fair amount of conceptual attention paid to the notion of therapeutic privilege, there is very little empirical evidence to indicate whether and in what ways information can be harmful.⁴² Clearly there is a need to define "harmful" or "negative" consequences better and to distinguish between situational anxiety (caused by illness or hospitalization) and anxiety resulting from information. In addition, the mere fact that some information may be "upsetting" in and of itself does not justify withholding information.⁴³

Early empirical studies sought to discover how patients would respond to certain kinds of information that might be provided. Now that the law requires information about risks to be disclosed, a number of studies have sought ways to reduce anxiety associated with such information. Potential as well as actual patients have been asked whether they would want to know about risks of treatment; some patients, after having been informed, have been asked whether the information was upsetting. A study of hypothetical situations found that people often said they would not want information about risks.⁴⁴ However, studies with real patients indicate that although information is sometimes upsetting, virtually all patients went ahead with procedures and thought the information was useful.⁴⁵

Some people have argued that informing patients about therapy can reduce therapeutic effectiveness by undermining the placebo component of treatment.⁴⁶ Clinicians have long realized that patients are cured not only by a specific treatment, but also by the knowledge that they have undergone a treatment and that relief is imminent. Thus the suggestion

patients at the request of a family member. Whether or not a physician is entitled to withhold information that might make a patient upset or anxious depends on whether the concern is merely with upsetting the patient or with causing the patient to reject the doctor's therapeutic advice.

⁴² Meisel and Roth, *supra* note 26.

⁴³ Testimonies of Debra L. Roter and Lawrence W. Green, transcript of the 15th meeting of the President's Commission (Dec. 11, 1981) at 79-96.

⁴⁴ Ralph J. Alford, *Controversy, Alternatives, and Decisions in Complying with the Legal Doctrine of Informed Consent*, 114 *RADIOLOGY* 231 (1975).

⁴⁵ See, e.g., Barbara H. Stanley, *Informed Consent and Competence: A Review of Empirical Research*, in Natalie Reating, ed., *Competency and Informed Consent: Papers and Other Materials Developed for the Workshop "Empirical Research on Informed Consent with Subjects of Uncertain Competence,"* National Institutes of Mental Health (Jan. 12-13, 1981); and Ralph J. Alford, *Informed Consent: A Study of Patient Reaction*, 216 *J.A.M.A.* 1325 (1971).

⁴⁶ Honigfeld, *supra* note 19.

that treatment is efficacious can lead to improvement. Arguably, if a patient is more fully informed about the limitations and risks of treatment, credibility and belief in the therapy can be destroyed, thus losing the therapeutic effects of blind faith. Systematic investigations have found, however, that patients who are informed about the side effects of drugs, for example, are no more apt to report the effects than are patients who are uninformed,⁴⁷ but they are more apt to attribute those effects to the drug.⁴⁸

Not only is there no evidence of significant negative psychological consequences of receiving information, but on the contrary some strong evidence indicates that disclosure is beneficial. Several studies have focused upon the effects of giving patients information about their surgery and its recovery period. Preoperative counseling appears to reduce anxiety and complications during convalescence.⁴⁹ Fewer analgesic medicines and days in hospital are required by those who are counseled than by those who are not. Providing information has also proved useful in burn treatment,⁵⁰ in stress experienced by blood donors,⁵¹ in childbirth,⁵² and in sigmoidoscopy

⁴⁷ See, e.g., several studies by E.D. Myers and E.J. Calvert, *The Effect of Forewarning on the Occurrence of Side Effects and the Discontinuation of Medication in Patients on Amitriptyline*, 122 BRIT. J. OF PSYCHIATRY 461 (1973); *The Effects of Forewarning on the Occurrence of Side Effects and Discontinuation of Medication in Patients on Dathiopin*, 4 J. OF INT'L. MED. RESEARCH 237 (1976); *Knowledge of Side Effects and the Perseverance with Medication*, 132 BRIT. J. OF PSYCHIATRY 526 (1978). See also P.T. Paulson et al., *Medication Data Sheets—An Aid to Patient Education*, 10 DRUG INTELLIGENCE AND CLINICAL PHARMACY 448 (1976).

⁴⁸ Louis A. Morris and David E. Kanouse, *Informing Patients about Side Effects*, 5 J. OF BEHAV. MED. 363 (1982).

⁴⁹ See, e.g., Irving Janis, *PSYCHOLOGICAL STRESS: PSYCHOANALYTICAL AND BEHAVIORAL STUDIES OF SURGICAL PATIENTS*, John Wiley and Sons, New York (1958); J.M. Andrew, *Recovery from Surgery: With or Without Preparatory Instruction for Three Coping Styles*, 15 J. OF PERSONALITY AND SOC. PSYCHOLOGY 223 (1970); L.D. Egbert et al., *Reduction of Post Operative Pain by Encouragement and Instructions to Patients*, 270 NEW ENG. J. MED. 825 (1964); I.F. Wilson, *Behavioral Preparation for Surgery: Benefit or Harm*, 4 J. OF BEHAV. MED. 79 (1981).

⁵⁰ R.L. Wernick, M.E. Jaremko, and P.N. Taylor, *Pain Management in Severely Burned Adults: A Test of Stress Innoculation*, 4 J. OF BEHAV. MED. 103 (1981).

⁵¹ R.T. Mills and D.S. Krantz, *Information, Choice and Reactions to Stress: A Field Experiment in a Blood Bank with Laboratory Analog*, 37 J. OF PERSONALITY AND SOC. PSYCHOLOGY 608 (1979).

⁵² J.M. Levy and R.K. McGee, *Childbirth As Crisis: A Test of Janis' Theory of Communication and Stress Resolution*, 31 J. OF PERSONALITY AND SOC. PSYCHOLOGY 171 (1975).

examinations.⁵³

A number of hypotheses have been advanced to explain the distress-reducing effects of preparatory information. Some people believe that giving people such counseling stimulates preparatory worry prior to surgery, thus providing an "emotional inoculation" that allows the patient to cope better with distress.⁵⁴ Others point to the role of information in producing accurate expectations⁵⁵ or in allowing patients to obtain some control, through predictability, of adverse postsurgical convalescence.⁵⁶

Although information may generally improve postoperative outcomes, people clearly differ in how they use information. For some, preparatory information may reduce their ability to deny the threat; for others, it may sensitize them to specific threats, rather than general fears; for still others, it may be a sign of social support or a way to divert attention, refocus cognitive effort, or elicit certain coping responses. Thus, the meaning of the information to the patient will be the primary determinant of whether it produces positive effects.⁵⁷ Yet even for frightened, denying, or aggressive patients, preparatory information does not necessarily produce negative effects.⁵⁸

Along with claiming that information about risks of treatment may have negative psychological consequences for patients, some critics of informed consent argue that such information will result in the refusal of necessary treatment and in noncompliance with therapeutic regimens. But several studies have investigated the effect of providing information about risks and side effects; none found any change in behavioral compliance due to the disclosure of information.⁵⁹

⁵³ G.R. Saunderson, *The Effectiveness of Two Types of Preparatory Messages on the Responses of Patients Undergoing Sigmoidoscopy Examination*, 14 ABSTRACTS OF HOSPITAL MANAGEMENT STUDIES 48 (1977).

⁵⁴ Irving Janis and L. Mann, *DECISION MAKING*, Free Press, New York (1977) at 388-392.

⁵⁵ J.E. Johnson, *Effects of Accurate Expectations About Sensations on the Sensory and Distress Components of Pain*, 27 J. OF PERSONALITY AND SOC. PSYCHOLOGY 261 (1973).

⁵⁶ See, e.g., S.M. Auerbach *et al.*, *Anxiety, Locus of Control, Type of Preparatory Information and Adjustment to Dental Surgery*, 43 J. OF CONSULTING AND CLINICAL PSYCHOLOGY 809 (1976); J.R. Averill, *Personal Control Over Adversive Stimuli and Its Relationship to Stress*, 80 PSYCHOLOGICAL BULLETIN 286 (1973).

⁵⁷ Andrew, *supra* note 49; Averill, *supra* note 56.

⁵⁸ Wilson, *supra* note 49.

⁵⁹ See, e.g., David E. Kanouse *et al.*, *INFORMING PATIENTS ABOUT DRUGS: SUMMARY REPORT ON ALTERNATIVE DESIGNS FOR PRESCRIPTION DRUG LEAFLETS*, Rand Corporation, Santa Monica, Calif. (1981).

There have been very few studies of treatment refusal generally, or, more specifically, of the effects of risk disclosure on subsequent treatment decisions. Anecdotal reports document that at least some patients refuse treatment because of fear of the therapy. However, in one of the Commission's observational studies, which was the first systematic attempt to determine the frequency of treatment refusals and their causes and outcomes, refusals were found to occur about once per 15-20 patient days. As indicated earlier in this Chapter, most involved minor treatments, not life-threatening procedures. And, perhaps most importantly, the trigger for refusing treatment was not too much but too little information. Patients who refused treatments typically did so because the nature, purpose, and attendant risks of the procedures had not been adequately explained.

The Relationship of Ethical and Legal Standards

From all that has been said, it is clear that the disclosure and communication processes should be geared to the needs of particular patients in given health situations. Professionals should seek to elicit the individual's goals and values and to frame the discussion in those terms, with due regard to the patient's emotional needs and intellectual capacities. To what extent can or should the law aid movement in this direction?

The Development of Legal Rules. To date, no American jurisdiction has adopted legal requirements for informed consent fully congruent with the ethical objectives set forth in this Report.⁶⁰ The reasons for this are partly historical: in most jurisdictions, failure to obtain informed consent is treated as a form of medical negligence or malpractice. To assess whether a particular act or omission constitutes malpractice, the legal system usually relies on professional standards of practice. Thus, in a lawsuit alleging lack of informed consent, the behavior of the defendant has traditionally been assessed in light of the "professional standard" of disclosure—that is, what other physicians would have disclosed in like circumstances.

The law's treatment of informed consent claims as a kind of medical negligence and the resulting adoption of the professional standard of disclosure tacitly assume that full disclosure is a recognized part of accepted medical practice, and that departures from it label the practitioner as failing to live up to the professional standard. This assumption has been extensively criticized by scholars.⁶¹ Although both disclosure

⁶⁰ See generally Katz, *supra* note 1.

⁶¹ See, e.g., Capron, *supra* note 36, at 407-10; Katz, *supra* note 1, at 154-60.

and consent have long been advocated and practiced by some,⁶² medical practice did not join the dual obligations of disclosure and consent in the sense of "informing for decision" until very recently. Thus reliance on a professional standard of disclosure is unlikely to provide much legal encouragement for the ideal of effective patient participation in decisionmaking set forth in this Report. Nevertheless, to the degree that professional attitudes and standards change over time in the direction of greater respect for, and encouragement of, patient participation in decisionmaking, the use of a professional standard will conform more closely with the objectives set forth in this Report.

Since 1970, a number of American jurisdictions have abandoned use of the professional standard and moved at least part of the way toward a legal standard oriented more to the needs of the particular patient. With some variation in specifics, these courts have stressed that the standard of disclosure is properly set by society rather than by the medical profession, and they have adopted a standard that responds to the informational needs of the hypothetical "reasonable patient."

The Commission finds this approach commendable in recognizing that the appropriate standard is societal rather than professional and in redirecting the inquiry toward the needs of the patient. However, a standard based only on the needs of a reasonable patient offers no assurance that either the well-being or the self-determination of a particular patient will be advanced by the workings of the law.

Numerous commentators have urged that the law of informed consent take the next step, moving beyond the reasonable patient standard to one that is more attentive to the informational needs of particular patients.⁶³ The critical issue in this debate concerns the degree to which providers should be legally required to take into account the informational needs of particular patients that differ from those of the "reasonable patient." Some commentators focus on apparent differences; others call upon practitioners to press their patients for a clearer articulation of their individual goals, values, and informational needs, which would then set an individual standard for disclosure. Such an evolution in legal requirements would move the law into closer conformity with the moral obligations of health care professionals that are set forth in this Report.

⁶² Martin S. Pernick, *The Patient's Role in Medical Decisionmaking: A Social History of Informed Consent in Medical Therapy* (1981), Appendix E, in Volume Three of this Report.

⁶³ See note 61 *supra*.

⁶⁴ There are some informed consent cases and statutes that can be read as suggesting a more individualized or subjective approach

No jurisdiction has yet clearly taken this step.⁶⁴ Indeed, in a number of states where courts have adopted the reasonable patient standard, legislatures have reimposed the professional standard by statute.⁶⁵ Their hesitancy to bring legal standards into closer conformity with moral obligations is in part practical and in part political.

Much of the difficulty arises from the fact that moral obligations define a standard of conduct for individuals while legal requirements must also be enforceable. Enforcement typically occurs via litigation conducted long after injuries have occurred, on the basis of evidence that may include selective and self-serving assertions by parties with a considerable stake in the outcome. Such a situation makes reliable determinations of the individual parties' wishes, needs, and intentions regarding the original communication very difficult, which helps explain the law's decided preference for more objective standards, even at the cost of some injustice in particular cases.⁶⁶ Thus there must be some balance between the ethical objectives the law seeks to encourage and the technical demands of a workable litigation process. The Commission recognizes that further evolution of legal standards toward a firmer protection of individual self-determination in medical decisions must be tempered by a recognition of the law's limits as an instrument of social control.⁶⁷

Attitudes toward the Law. In the Commission's survey, several questions to physicians and the public dealt with the legal doctrine of informed consent. The majority of both groups agreed that patients' rights to information should be protected by law (see Figure 3). However, significantly more physicians than patients agreed with the statement "Time spent discussing diagnosis, prognosis, and treatment could be better spent taking care of patients." The public was more likely than physicians to think that the legal requirements for obtaining

toward determining what must be disclosed to patients, though no court has ever expressly held that a health care professional must disclose what the particular patient would have wanted to know. A similar issue exists with respect to the test of causation to be employed. Although courts have not only hinted but actually decided that whether or not the failure to disclose "caused" the patient's injury is to be determined by reference to whether or not a "reasonable" person would have refused the treatment had he or she been properly informed, a few cases and statutes have begun to reject this formulation, focusing instead on whether the particular patient would have refused treatment had disclosure been proper.

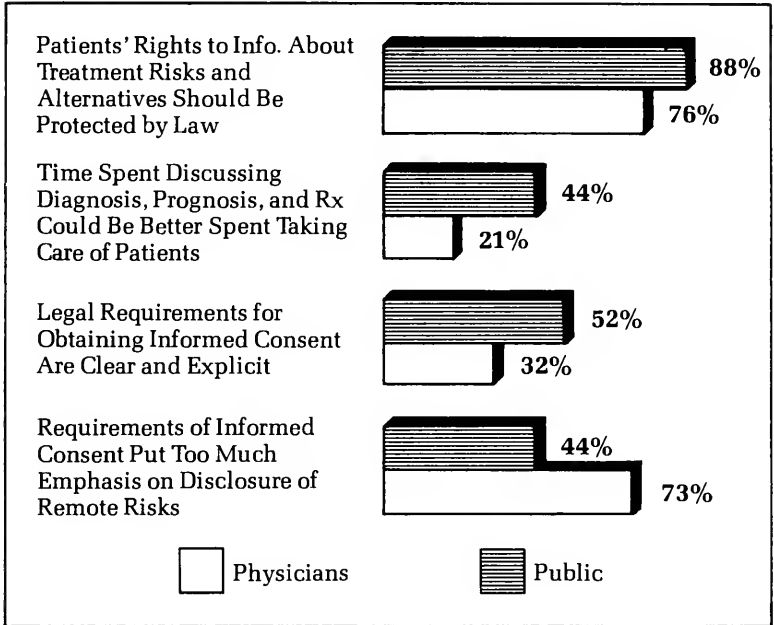
⁶⁵ See Alan Meisel and Lisa D. Kabnick, *Informed Consent to Medical Treatment: An Analysis of Recent Legislation*, 41 U. PITT. L. REV. 407, 423-26 (1980).

⁶⁶ *Canterbury v. Spence*, 464 F.2d 772, 790-91 (D.C.Cir. 1972).

⁶⁷ See Chapter Seven *infra* for a further discussion of possible legal developments.

Figure 3: The Legal Doctrine of Informed Consent: Public and Physician Views

Source: Commission survey conducted by Louis Harris and Associates, 1982



informed consent were clear and explicit (52% versus 32%), and doctors were more likely than the public to feel that the requirements put too much emphasis on disclosure of remote risks (73% versus 44%).

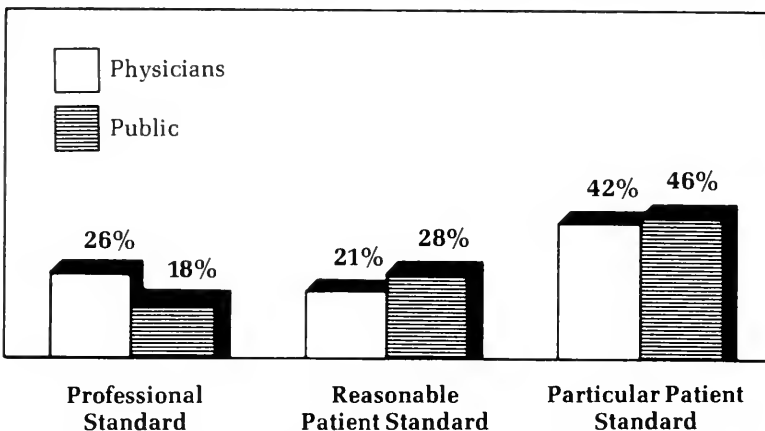
Finally, both groups were asked which disclosure standard was best (see Figure 4). More than 40% of the physicians and the public thought that a standard based on the informational needs of a particular patient was preferable to a reasonable patient or physician standard.

Physicians were then asked whether they knew which standard applied in the state(s) in which they practiced. Only 23% said they did. Surgeons were more likely than any other specialty to say they knew (30%), and older doctors were more likely than younger ones to claim knowledge of their state's standard (27% versus 17%). Overall, of the 23% who claimed to know the standard, 54% of those practicing in states that have a standard gave the correct answer.

The Use of Consent Forms. Consent forms, which were originally intended as documentation of disclosure and con-

**Figure 4: The Best Disclosure Standard:
Public and Physician Views***

Source: Commission survey conducted by Louis Harris and Associates, 1982



*1% of the public and 8% of physicians thought there should be no standard; 7% of the public and 4% of physicians were not sure what standard they preferred.

sent, have in many cases come to substitute for the very processes they are intended to substantiate.⁶⁸ Furthermore, there appears to be substantial variation among health care professionals about when consent forms are required⁶⁹ deriving in many cases from institutional differences in interpretation of the law. And the law is, in fact, often unclear and nonspecific about the requirements for consent.

Several different consent forms are in use. Hospitals often require patients upon admission to sign a blanket consent that purports to give physicians authority to "treat as necessary." The Joint Commission on Accreditation of Hospitals requires that separate consent forms be signed for any procedure or treatment "for which it is appropriate" and that these forms be included in the medical record.⁷⁰ It appears from one of the observational studies conducted for the President's Commission that physicians deem "procedures"—in contrast to "routine care"—as appropriate for written consent. Procedures are

⁶⁸ See, e.g., Bradford H. Gray, *Complexities of Informed Consent*, 437 ANN. AMER. ACAD. POLIT. SOC. SCI. 37 (1978).

⁶⁹ "As a legal matter, consent forms are rarely required. Those state informed consent statutes that deal with consent forms make them permissible, not mandatory. Even the federal regulations governing the conduct of federally funded research do not require consent forms in all instances." Alan Meisel, *More on Making Consent Forms Readable*, 4(1) IRB 9 (Jan. 1982).

⁷⁰ Joint Commission on Accreditation of Hospitals, ACCREDITATION MANUAL FOR HOSPITALS, Chicago, Ill. (1981) at 84-86.

done relatively infrequently and include most invasive measures, as well as major diagnostic tests that carry some risk. Risk itself, however, does not distinguish the procedures for which written consent is thought to be required; written consent is typically not obtained for medications, even when major and frequent risks attend their use.⁷¹

Preprinted "fill-in-the-blank" forms are used for many procedures, especially surgery. The emphasis in these forms is on obtaining permission rather than on giving information, for they state that the general categories of legally material information have previously been "fully explained." Some forms are specially prepared, as in the case of the stress tests for cardiac patients observed in one of the Commission's studies. Here the nature of the test and its attendant risks were substantially different than for invasive procedures, and the form provided the only information patients received unless they chose to initiate a discussion after reading it.⁷²

In the Commission's survey, physicians were asked whether they usually obtained consent—and if so, in what form—for a variety of procedures. The frequency with which consent was obtained varied significantly with the nature of the procedure; virtually all doctors reported getting consent for inpatient surgery, and about half those surveyed reported they did not get consent for prescriptions and blood tests (see Table 3). This finding was substantiated in the Commission's two observational studies.

States' informed consent laws (with the single exception of Texas) do not delineate consent requirements on a procedure-by-procedure basis. Nor does the law on informed consent generally distinguish between oral and written consent in judging validity; that is, written consent is not required where oral consent has been given.⁷³ Indeed, one state's statute and the case law in three states explicitly hold that consent need not be in writing in order to be valid.⁷⁴ However, a signed written consent form is likely to make legal proof of consent significantly easier, at least in the absence of other complicating factors. Physicians' consent practices apparently reflect this assumption.

Physicians and the public were asked whether they agreed with several statements regarding consent forms (see Figure 5).

⁷¹ Charles W. Lidz and Alan Meisel, *Informed Consent and the Structure of Medical Care* (1982), Appendix C, in Volume Two of this Report, at section 4.

⁷² *Id.*

⁷³ *Hernandez v. United States*, 465 F. Supp. 1071, 1073 (D. Kan. 1979); *Maercklein v. Smith*, 129 Colo. 72, 266 P.2d 1095, 1099 (1954).

⁷⁴ Meisel and Kabnick, *supra* note 65, at 468. See *State-by-State Analysis of Informed Consent Laws* (1982), Appendix L, in Volume Three of this Report.

Table 3:

Nature of Consent Obtained for Various Procedures*

Procedure	Written Consent	Oral Consent	Written and Oral Consent	Neither
Inpatient Surgery	81%	3%	15%	0
Minor Office Surgery	26%	58%	9%	7%
Setting Bones	39%	42%	9%	8%
General Anesthesia	83%	3%	12%	1%
Local Anesthesia	21%	57%	7%	15%
Diagnostic X-rays Involving Injections	45%	35%	8%	10%
Blood Tests	2%	52%	0	45%
Prescriptions	1%	43%	2%	54%
Radiation Therapy	63%	18%	11%	4%

* The total number on which figures in this table are based varied for each procedure in order to eliminate physicians who did not perform the particular procedure. Therefore the figures refer to the proportion of physicians performing a procedure who obtained consent.

Source: Commission survey conducted by Louis Harris and Associates.

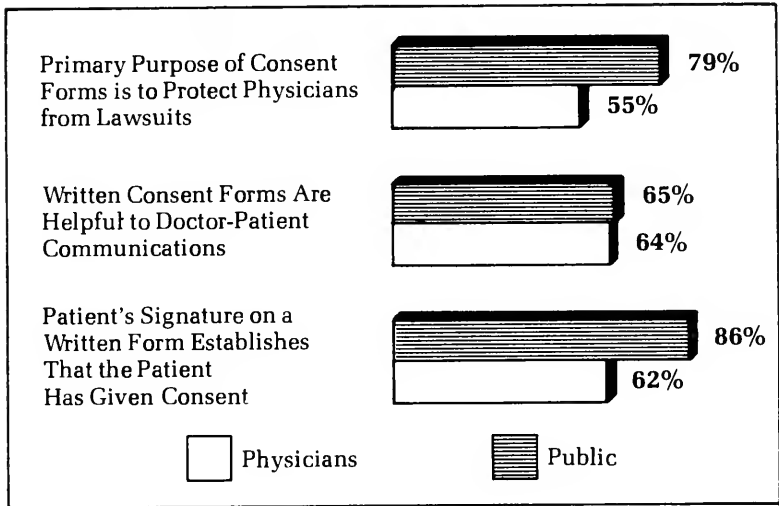
Nearly four-fifths of the public and 55% of the physicians think the primary purpose of consent forms is to protect physicians from law suits.⁷⁵ This finding seems to reflect more the advice of lawyers who represent health care professionals than the ethical basis of informed consent, in which the role of the consent form is to protect patients by ensuring that they have full information and are participating voluntarily. The majority of physicians (64%) and the public (65%) think that consent forms help doctor-patient communications. Concerning written consent forms, 62% of the physicians and 86% of the public think that a patient's signature establishes that the individual has given consent.

Of the 24 states with statutes on informed consent, only 13 make some attempt to define the legal effect of a signed consent form. As noted above, a signed form will always be some evidence that the patient actually consented to the treatment, and a jury could use it, along with other evidence, to support or rebut the existence of actual consent. However, the

⁷⁵ Asking a person to sign a consent form may cause that person to refuse to sign even when he or she would be willing to give oral consent. Cf. Eleanor Singer, *Informed Consent: Consequences for Response Rate and Response Quality in Social Survey*, 43 AM. SOC. REV. 144, 151 (1978).

Figure 5: The Purpose and Effect of Consent Forms: Public and Physician Views

Source: Commission survey conducted by Louis Harris and Associates, 1982



type of rebuttal evidence and the circumstances under which it is allowed vary.⁷⁶

In addition, information that must be included in the consent form in order for it to have legal weight varies by state. In Georgia, for example, the form need not disclose any risks of the proposed procedure; only the general nature of the treatment need be set forth.⁷⁷ Louisiana, on the other hand,

⁷⁶ In some states plaintiffs are allowed to prove they did not understand the standardized consent form they signed. For example, one court stated that "the effect to be given to a standard consent form is governed by the same principles used in evaluating appellant's claim under the informed consent doctrine. Thus, unless a person has been adequately apprised of the material risks and therapeutic alternatives incident to a proposed treatment, any consent given, be it oral or written, is necessarily ineffectual." *Sard v. Hardy*, 379 A.2d 1014, 1019 n.3 (Md. 1977). In that case, a signed form is subject to the same type of rebuttal as would be directed against testimony that oral consent had been given. Other states restrict the type of evidence that may be presented to rebut a signed written consent form. Some allow only strict legal proof of fraud or misrepresentation. In one case, for example, the plaintiff proved that she had not read the consent form that she had signed, but since she presented no legal excuse for not reading the form, she was held to be bound by its terms. *Winfrey v. Citizens & Southern Nat'l Bank*, 149 Ga. App. 488, 254 S.E.2d 725, 726 (1979).

⁷⁷ *Winfrey v. Citizens & Southern Nat'l Bank*, 149 Ga. App. 488, 254 S.E.2d 725, 726 (1979).

requires the form to list the frequency with which a specified set of risks occurs for the particular procedure involved.⁷⁸

In the Commission's survey, 24% of the public reported that they had signed a consent form in the last year. Among those people, 71% thought their doctor explained the form satisfactorily and 29% said the explanation was unsatisfactory. Those in poor health were the most satisfied (92%) and those reporting their health status as fair were the least satisfied (60%). The explanation of such a substantial difference between these two groups (when it would seem more likely that the largest difference would be between those in excellent and those in poor health) is not clear.⁷⁹

When the people who had signed a consent form within the last year were asked "After reading the consent form, did you feel that you fully understood the risks of the treatment you were going to undergo?," 72% said "yes," although this varied by subgroups just as the satisfaction with the explanation did. Finally, these people were asked: "Have you ever refused treatment because of what you learned about the treatment from the written consent form?" Only 5% said they had.⁸⁰

⁷⁸ La. Rev. Stat. Ann. § 40:1299.40(A) (West Cum. Supp. 1980).

⁷⁹ Those surveyed who had no usual source of medical care, the middle-aged (35-50 years old), and those with less than a high school education were all less likely than people who had a usual source of care, the young, the old, and the better educated to view the explanation of the consent form as satisfactory.

⁸⁰ Women were more likely than men to have refused treatment because of what they learned from a consent form (7% versus 3%) and those without any health insurance were the most likely (12%) to have refused treatment on this basis. Refusers were likely to be young, college-educated, in fair or poor health, and people who receive care in a doctor's office.

There is strong evidence that existing consent forms are written in extremely turgid prose and that patients have a great deal of difficulty understanding them, even if they do not admit it. A study conducted for the National Commission for the Protection of Human Subjects found that "overall, no more than 15 percent of the consent forms were in language as simple as is found, for example, in *Time Magazine*. In more than three-fourths of the consent forms, fewer than 10 percent of the technical or medical terms were explained in lay language...." U.S. Department of Health, Education and Welfare, *Protection of Human Subjects—Institutional Review Boards: Report and Recommendations of the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research*, 43 Fed. Reg. 56,174, 56,189 (1978). See also G.R. Morrow, *How Readable Are Subject Consent Forms?*, 244 J.A.M.A. 56 (1980); T.M. Grundner, *On the Readability of Surgical Consent Forms*, 302 NEW ENG. J. MED. 900 (1980).

Physicians were asked in an open-ended question what the effect of consent forms had been: 52% thought they had a positive effect (for example, that they improved patient awareness so patients knew more about their treatment and risks and asked more and better questions, encouraged more communication between doctors and patients, and provided legal protection for doctors and hospitals); 23% felt that consent forms had a negative effect (for example, that they increase patients' fears, reduced compliance, caused patients to avoid necessary treatment, made patients distrust their doctors, increased law suits, and provided no legal protection); 18% thought that informed consent forms had no effect; and 7% were not sure whether they had an effect or not.

The Commission's observational studies suggest that consent forms are typically read and signed after a decision has been made regarding treatment.⁶¹ This is probably as it should be, assuming that the form is presented for signature after discussion and that the patient has participated in making the decision. In the Commission's view, consent forms should summarize discussion, but not be a substitute for it. Ideally, they will stimulate additional questions and discussion, as some physicians in the survey indicated, but they should not be allowed to replace such communication or to cut it off prematurely.

⁶¹ More often than not, however, discussion prior to consent form signing was nonexistent or brief. See Lidz and Meisel, *supra* note 71; Paul S. Appelbaum and Loren H. Roth, *Treatment Refusal in Medical Hospitals* (1982), Appendix D, in Volume Two of this Report.

The preceding portions of this Report have set forth the Commission's vision of the patient-professional relationship as a flexible arrangement, defined in substantial part by the desires of the parties and the demands of the situation. The obligation of the professional is to provide each patient with a basis for effective participation in decisionmaking about his or her own health care. This obligation entails providing information, answering questions, talking over options and doubts, and helping patients to clarify the values and goals relevant to the decision. Such discussion serves to enhance patients' competence and hence the likelihood that the course of action selected represents the patient's voluntary choice. In this portion of the Report, the Commission examines several ways to bring this vision closer to reality.

First, the Commission has examined several innovations in practice (all within the scope of existing law), including increased efforts in patient education to promote self-confidence and the ability to be an active participant in health care decisionmaking; broadened sources of information, such as hospital libraries and pharmacists; and appropriate efforts to engage patients' families in these processes. The Commission finds that there are a number of techniques that could facilitate effective patient participation in health care decisionmaking.

Although the experience with most of these innovations is too slight to justify recommending them as standard practice, the Commission identifies in Chapter Five several that, on the basis of their inherent logic and early results, deserve further study and experimental application. The Federal government now spends many billions of dollars a year on health care, of which some \$5 billion is allocated to health-related research, from basic laboratory science to large-scale studies with patients. The Commission believes that the effectiveness of health care—indeed, its true quality in terms of improving

patients' well-being and satisfying their needs—would be enhanced by the support of behavioral research that shows promise of increasing professional-patient communications and shared decisionmaking. Great advances in medical technology deserve to be matched by improvements in the human side of health care, which has been the central concern of the Commission in this Report. The Commission recommends that the Department of Health and Human Services, and particularly the National Institutes of Health, develop appropriate initiatives and explicitly encourage the pursuit of scientifically sound studies in this field.

The Commission believes that what is ultimately needed to improve mutual respect and participation and shared decisionmaking in health care are changes in traditional attitudes toward the patient-professional relationship. To this end, Chapter Six examines current trends and innovations in medical and nursing education to assess what might be done to encourage and reinforce empathic qualities in health care professionals, to improve communication not only between professionals and patients but also among health care professionals, and to promote the basic values of health care by ensuring that patients are active, informed decisionmakers about their health care. Again, a number of promising avenues exist, and the Commission recommends that those involved in the education and training of health professionals, both within the Federal government and, more importantly, at academic institutions, systematically explore these avenues. At the very least, medical and nursing students should be better educated about the issues and objectives of informed consent that are explored in this Report.

Finally, in Chapter Seven the Commission considers whether changes in the existing law of informed consent might more effectively promote the objectives identified by the Commission and evaluates the costs associated with such changes. Although the law has a useful role in defining certain minimal standards and processes, the intimate and necessarily diverse nature of therapeutic relationships cannot be fully prescribed or enforced by law. The Commission does not believe that the law needs to be modified through new statutes on ordinary physician-patient interactions but regards the concepts developed in this Report as useful for judges in the resolution of cases and for clarification of the common law. Statutory law may be appropriate, however, as a means of ensuring patients greater adherence to their wishes—through “advance directives”—after they lose the capacity for personal participation in decisionmaking.

As discussed in Part Two of this Report, the goals of informed consent and the realities in practice often diverge. Many innovative and practical suggestions have been put forward on how to alter communications between patients and health care professionals to meet the goals of informed consent more fully. In addition to ideas taken from the existing literature, the Commission heard testimony from a number of witnesses concerning ways to improve communications generally and the informed consent process specifically. Suggestions included (1) preparing patients better for effective participation in health care decisionmaking; (2) providing patients with more sources of information; and (3) involving family members more fully in the decisionmaking process.

Preparing the Patient for Effective Participation

To achieve the goals of open communication and shared decisionmaking in medical care, not only must health professionals possess certain interpersonal skills and attitudes, but patients must be willing and able to participate. The Commission views communication between patient and professional, not simply the disclosure of risks, as essential to promoting the value of self-determination discussed in Part Two of this Report and ensuring that patients participate voluntarily, competently, and knowledgeably in decisionmaking about their care.

As discussed in Chapter Four, to participate effectively in the decisionmaking process patients need information. Some experts have argued that the more patients know about health in general, the better able they will be to participate meaningfully in any particular health care decision.¹ Such general

¹ Testimony of Donald Vickery, transcript of 15th meeting of the President's Commission (Dec. 11, 1981) at 21-25.

knowledge would help patients consider whether and when to seek care, realize what information was important to volunteer to health care providers and to ask about, and decide whether or not to consent to particular procedures. Furthermore, specific information about a patient's particular condition may result in a better understanding of the patient's own needs, better compliance with medical regimens, greater involvement in the care process, and improvements in health.²

A variety of techniques have been designed to help patients obtain information they need and want, thereby equipping them for a more active role in their care and for a more equitable partnership between professional and patient. Development of these techniques has been based on several important assumptions:

- (1) patients can participate more in health care decisions³;
- (2) such participation is of value both because it can promote greater commitment to the therapeutic process, thereby enhancing health, and because it promotes the value of self-determination⁴;
- (3) education for health care decisionmaking is useful for all decisions, however minor, and is therefore best seen as a process, not as something to be done once at a moment of crisis⁵; and
- (4) patients can effect changes in the relationship with their physician because health professionals respond to patient-initiated styles of interaction.⁶

The Commission recognizes that, as in all of life, a little knowledge can be a dangerous thing. Patients may be naive and overly optimistic about their situation; they may not

² See, e.g., David M. Levine *et al.*, *Health Education for Hypertensive Patients*, 241 J.A.M.A. 1700 (1979); Testimony of Lawrence W. Green, transcript of 15th meeting of the President's Commission (Dec. 11, 1981) at 89-96; R. Giglio, *Encouraging Behavior Changes by Use of Client Held Records*, 16 MED. CARE 757 (1978); Sheldon G. Greenfield *et al.*, *Peer Review by Criteria Mapping: Criteria for Diabetes Mellitus*, 83 ANNALS OF INTERNAL MED. 761 (1975).

³ The entire field of health education as well as the underlying principles of informed consent rests on the assumption that patients can participate in health care decisionmaking.

⁴ Virtually every patient education intervention is designed to assist patients to care for themselves better, follow therapeutic regimens more closely, and enhance health.

⁵ Vickery, *supra* note 1.

⁶ See, e.g., Debra L. Roter, *Patient Participation in the Patient-Provider Interaction: The Effects of Patient Question Asking on the Quality of Interaction, Satisfaction and Compliance*, 5 HEALTH EDUC. MONOGRAPHS 281 (1977); Testimonies of Debra Roter, Donald Vickery, and Lawrence W. Green, transcript of 15th meeting of the President's Commission (Dec. 11, 1981) at 21-25 and 79-96.

appreciate uncertainties and the probabilistic nature of medical knowledge. However, generally it has been found that having information and understanding its implications increases patients' self-confidence. Educated patients tend to feel more competent about managing their illnesses and freer to interact with the medical staff.⁷ Given the numerous barriers to meaningful professional-patient communications discussed in Chapter Four, presenting information in a way that maximizes understanding is a prerequisite for more equal participation. Health care practitioners should endeavor to provide information to patients in language they can understand and under circumstances that will promote understanding. A layperson can understand medical information better when simple, nonjargon language is used and when important concepts and implications are stated explicitly. For the message to be understandable, health care professionals must be clear in their own minds about which information is most important.⁸ This process of self-scrutiny may have the additional benefit of causing them to rethink, or at least to review, their own diagnosis, prognosis, and recommendations.

Written and audiovisual materials can also aid the communication process. Pamphlets and numerous other aids, both written (stickers, charts, brochures) and audiovisual (tapes, films, computer-assisted instruction, slide shows) have been used to improve patient knowledge and to explain treatment options.⁹ Such aids are useful supplements to, but not replacements for, face-to-face discussion.¹⁰ In general the Commission believes that written materials, including preprinted consent forms, should only augment the continuing process of information exchange.

⁷ This was discussed by several witnesses who testified at the 15th meeting of the President's Commission (Dec. 11, 1981) and is the rationale behind many of the self-care books in the popular market.

⁸ See, e.g., several studies by Philip Ley and his colleagues such as Philip Ley, *Towards Better Doctor-Patient Communications: Contributions from Social and Experimental Psychology*, in A.E. Bennett, ed., COMMUNICATIONS BETWEEN DOCTORS AND PATIENTS, Oxford Univ. Press, London (1976) at 77-98; Philip Ley, *Giving Information to Patients*, in J. Richard Eiser, ed., SOCIAL PSYCHOLOGY AND BEHAVIORAL MEDICINE, John Wiley and Sons, New York (1982) at 339-73.

⁹ See, e.g., H.W. Griffith, D. Hayes, and L.P. Hyde, *Let Printed Aids Work for You and Your Patients*, 21 PATIENT CARE 119 (1973); G.L. Barbour and M.J. Blumenkrantz, *Videotape Aids Informed Consent Decision*, 240 J.A.M.A. 2741 (1978); E.E. Bartlett, *Selection of Education Strategies*, in Lawrence W. Green et al., eds., HEALTH EDUCATION PLANNING: A DIAGNOSTIC APPROACH, Mayfield Pub. Co., Palo Alto, Calif. (1980) at 86-115.

¹⁰ Ruth R. Faden, *Disclosure and Informed Consent: Does It Matter How We Tell It?*, 5 HEALTH EDUC. MONOGRAPHS 198 (1977).

In addition to improving the quality of personal communication and written materials, health care professionals must provide patients with the proper time and setting to absorb the information. A step as simple as allowing patients to take written materials home to read before making a decision (or signing a consent form) can improve understanding.¹¹ It removes the needless pressures of having to make a rapid decision not required by the medical circumstances and permits the patient to raise questions with, and hear questions from, family members on the information in the materials. Discussion with others is helpful not only in providing other sources of information but also in revealing issues the patient is unclear about and may wish to raise again with the health care professional.

Some efforts have been made to "test" patients at the conclusion of the consent process to ascertain whether they had absorbed the essential information.¹² For certain patients and procedures, the Commission was impressed with the benefits of having patients write their own consent forms.¹³ As recounted by one medical witness, patients who have discussed with a physician a particular elective procedure under consideration, including its attendant risks and the alternative treatments and their risks, are asked to go home and write down what they have understood. When they return to the physician's office with this "consent form," specific areas of misunderstanding can be identified and discussed until the physician is sure that all pertinent information has been understood. The Commission believes that this approach deserves further exploration and urges that studies be conducted in a variety of medical specialties to assess the relative efficacy of such a consent process.

The timing of disclosures is also important, especially when the discussion or the medical setting is likely to provoke anxiety. For example, upon hearing a diagnosis of cancer, patients are typically so preoccupied with fear that detailed information is not heard or even desired.¹⁴ What little information is taken in is likely to be distorted. Similarly, a pregnant woman who has been told that her fetus is abnormal might very well fail to absorb other information unless the physician

¹¹ See, e.g., G. Morrow, J. Gootnick and A. Schmale, *A Simple Technique for Increasing Cancer Patients' Knowledge of Informed Consent to Treatment*, 42 *CANCER* 793 (1978); E.B. Silberstein, *Extension of Two-Part Consent Form*, 291 *N. ENG. J. MED.* 155 (1974).

¹² See the discussion on p. 90 and note 25, Chapter Four *supra*.

¹³ This procedure was discussed by Dr. Arnold O. Roberts in his testimony before the Commission on Dec. 11, 1981. It appears particularly promising for elective procedures and other treatment decisions that are not urgent.

¹⁴ See, e.g., M.W. Eysenck, *Anxiety, Learning and Memory: A Reconceptualization*, 13 *J. OF RESEARCH IN PERSONALITY* 363 (1979).

mentions the slight possibility of intervening successfully; a decision made at this point would be based on incomplete information because the woman would be unable to attend to the serious limitations and risks of such interventions.¹⁵ The Commission, therefore, encourages health care professionals, whenever possible, to discuss upsetting diagnoses, risks, uncertainties, and other threatening information over a period of time in several encounters rather than to rely on a single discussion.

A suggestion of this type is considered unrealistic by some.¹⁶ It calls for longer talks with patients by professionals who are often pressured to see many people each hour and who are not adequately reimbursed for discussion time. Given the projected oversupply of physicians (at least in some geographic locations and in some specialties)¹⁷ and the fact that health care services are increasingly being provided by nonphysicians,¹⁸ some of the time pressures that have so far militated against doctors spending more time talking with patients may be alleviated. From the viewpoint of the health care system as a whole, a physician's saving time by failing to educate a patient may be a false economy. Even for the individual practitioner, improved initial communication may save time later by avoiding misinformation or misunderstandings, including those that lead to a malpractice action by a dissatisfied patient.

At the present time, health care professionals are generally reimbursed at higher rates for specific physical interventions (from diagnostic procedures to major surgeries) than they are for communication.¹⁹ Physicians and health planners have long

¹⁵ Robin Marantz Henig, *Saving Babies Before Birth: The New Promise of Fetal Surgery*, NEW YORK TIMES MAGAZINE 16 (Feb. 28, 1982).

¹⁶ Physicians often complain that time pressures are too great to allow a full discussion with every patient. However, in the Commission's survey there was no relationship between reported disclosure behavior or attitudes toward disclosure and patient load (total number of patients seen divided by number of hours worked per week). Furthermore, physicians rarely reported time pressures as a factor they consider in determining how much information to give to patients.

¹⁷ Graduate Medical Education National Advisory Committee, FINAL REPORT, VOL. 1, Health Resources Administration, Hyattsville, Md. (Sept. 1980).

¹⁸ See, e.g., Loretta C. Ford, *A Nurse for All Settings: The Nurse Practitioner*, 27 NURSING OUTLOOK 516 (1979).

¹⁹ As recently noted:

Our current financing mechanisms peg personal physician-patient interactions as "loss leaders" and over-reward the use of tests, procedures, and devices. There are striking financial incentives that coax physicians to go with the technologies as

observed that the third-party reimbursement schedules provide incentives for laboratory tests and diagnostic procedures but disincentives for taking adequate histories. In fact, only by actually undertaking a reimbursable intervention does a practitioner even indirectly receive payment for ensuring that the patient has validly consented. When the time spent with the patient is billed to a third-party payor, its validity is judged only by a standard of therapeutic necessity, which has not traditionally included any independent obligation to help the patient participate in the decisionmaking process.

If the approach to informed consent proposed in this Report is to be implemented in practice, certain incentives in the reimbursement system may have to be readjusted. Notably, nearly 40% of the public in the Commission's survey said they would be willing to pay more if their doctors spent more time explaining routine care. Presumably this proportion would be even higher in cases of serious illness. The Commission notes that changes in reimbursement could be an important element in achieving a pattern of medical practice where decisions are truly shared by patient and professional. It recommends that procedures—whether preventive, diagnostic, or therapeutic—be defined in such a way that appropriate communication and consent is regarded as a necessary part of good patient care, rather than that a separate reimbursable category of information-giving be created.

Developing Other Sources of Information for Patients

The health care professional providing treatment is typically the one to initiate discussions of patients' conditions and possible remedies and in the end is responsible for ensuring that patients are informed decisionmakers. Yet this single professional is not the only source of information available to patients. When practitioners are committed to the goal of patient participation in health-related decisionmaking they may encourage patients to explore the implications of their illnesses and treatments by, for example, talking to other professionals and patients. To the extent that other informa-

the most economic use of their time. Our reimbursement system sends strong signals to physicians to maintain a high-technology practice within their chosen fields.

Thomas W. Maloney and David E. Rogers, *Medical Technology - A Different View of the Contentious Debate Over Costs*, 301 NEW ENG. J. MED. 1413, 1416 (1979). See also William G. Hsiao and William B. Stason, *Toward Developing a Relative Value for Medical and Surgical Services*, HEALTH CARE FINANCING REV. 23 (1979) and Steven A. Schroeder and John A. Showstack, *Financial Incentives to Perform Medical Procedures and Laboratory Tests: Illustrative Models of Office Practice*, 16 MED. CARE 289 (1978).

tion sources can assist the patient to understand, reinforce, and explain what the primary provider has said, patients may be able to make better decisions.

Patients may, of course, on their own initiative seek out other sources of information, including the professional literature, to translate jargon that a health care professional has not made understandable, to follow up on the latest account of a "miracle cure" reported in the press, or to discover alternatives to a treatment suggested by their practitioner. Although such excursions can at times create misunderstanding and confuse patients, they need not do so if they occur in the context of a relationship characterized by mutual respect and open communication. By encouraging patients to bring back any information they discover, health care professionals can correct any misunderstandings while encouraging and harnessing the active participation shown by the patient toward their joint objective—the maximum improvement in the patient's well-being.

To illustrate the available sources of information outside the professional-patient relationship, this section of the Report looks at sources of information on the use of medicines and at hospital medical libraries as general resources for patients.

Pharmacists and Pamphlets for Patients on Medication. One of the areas where patients are most likely to need information is in the use of medication, since drugs are the most common treatment in all medical care. Most visits to the doctor result in a prescription being written; many patients with chronic diseases must take medications over long periods of time; and many patients take several drugs simultaneously, often on the basis of prescriptions written by different specialists.²⁰ The educational aspect of the pharmacist's role—providing basic drug information, reinforcing instructions about how to use drugs, and warning patients about possible side effects and drug interactions—has not been fully taken advantage of. Pharmacy students are trained in communication skills and patient education. As in medicine and nursing, the clinical roles of pharmacists have expanded greatly in recent years and now include patient drug monitoring, drug utilization reviews, consultations on pharmacotherapy, patient education, and other related pharmaceutical services. Pharmacists are trained to work with other health professionals and with patients on the appropriate use of medicines, although relative-

²⁰ See, e.g., Marian Osterweis, Patricia J. Bush, and Alan E. Zuckerman, *Family Context as a Predictor of Individual Medicine Use*, 13A SOC. SCI. & MED. 287 (1979).

ly little attention has been paid to the formal establishment of an educational role for neighborhood pharmacists.²¹

Substantial effort has been devoted, however, to the development of patient package inserts (PPIs) in recent years.²² These small pamphlets are designed to inform patients; they include information on when and how to take a drug, contraindications, side effects, and risks. To date, PPIs have been used by the Food and Drug Administration (FDA) only for a limited number of drugs on an experimental basis.²³ Some physician groups have raised formal objections to PPIs because they fear patients will no longer take what is prescribed if they know all the side effects. Others worried that details on side effects would increase the frequency with which patients perceived them.²⁴

A recent evaluation of PPIs conducted by the Rand Corporation found that patients generally had read the information sheets; though increases in side effects were reported, it was not clear whether the information actually led to an increased perception of symptoms or merely to an increased and more accurate attribution of those symptoms to the drugs. Perhaps most importantly, the Rand study found that PPIs led some patients to discuss more fully with their physicians the reasons for taking a drug and its potential risks and benefits.²⁵ Thus, providing specific information with drugs appears to have opened up avenues for more meaningful doctor-patient communication. Although the FDA recently shelved the PPI program, the American Medical Association has begun a voluntary system under which physicians can purchase information forms on 20 of the most widely prescribed drugs for

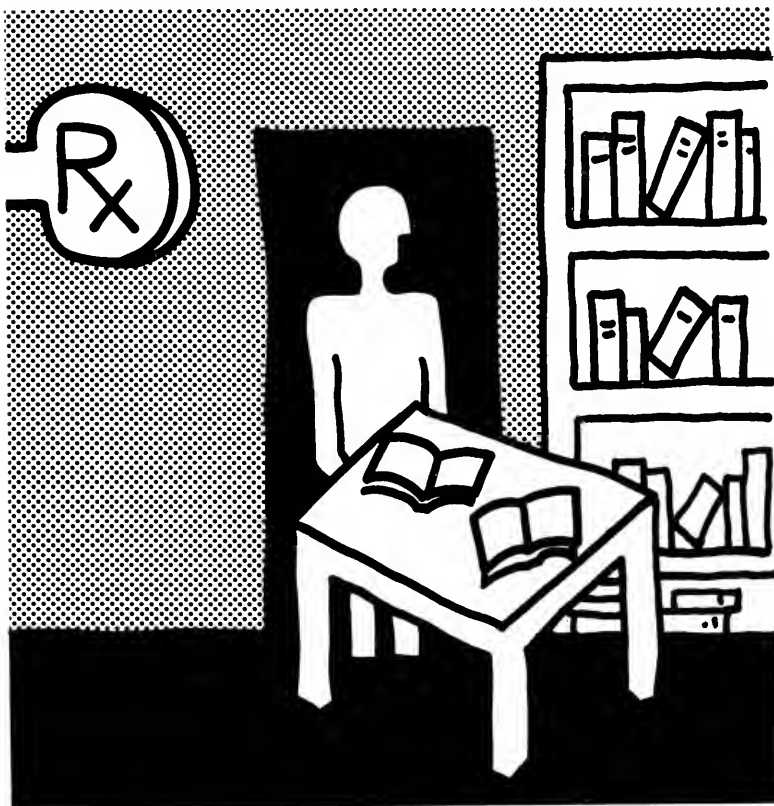
²¹ Letter to the Commission from Howard Ansel, Dean of the University of Georgia School of Pharmacy, April 1982; pamphlet from the American Association of Colleges of Pharmacy, *Pharmacy Education: Responding to the Nation's Health Care Needs*, Bethesda, Md. (1980).

²² Following the introduction of H.R. 14289 by Paul Rogers and S. 1282 by Edward Kennedy requiring that patients be provided with written drug information, the FDA proposed to require that printed information be dispensed with prescription drugs concerning its nature, purpose, proper use, and risks. Under an FDA contract, the Institute of Medicine and the Rand Corporation evaluated the effects of drug leaflets. See also the report of a symposium on drug information sheets published as a special supplement to *DRUG INFORMATION JOURNAL*, Jan. 1977.

²³ See, e.g., David E. Kanouse *et al.*, *INFORMING PATIENTS ABOUT DRUGS: SUMMARY REPORT ON ALTERNATIVE DESIGNS FOR PRESCRIPTION DRUG LEAFLETS*, Rand Corporation, Santa Monica, Calif. (1981).

²⁴ Institute of Medicine, *EVALUATING PATIENT PACKAGE INSERTS*, National Academy of Sciences, Washington, D.C. (1979).

²⁵ Kanouse, *supra* note 23.



distribution to their patients. "Patient medication instructions" are also being developed for additional common drugs.²⁶

Opening Medical Libraries to the Public. Lay witnesses at Commission hearings complained about the limited access to health information outside the medical setting and advocated opening more medical libraries to patients as a means of supplementing information provided by health care professionals.²⁷ While the codes of such groups as the American Library Association do not deal specifically with the issue of access to medical materials, the Library Bill of Rights states that "libraries should provide materials and information presenting all points of view on current and historical issues. Materials

²⁶ The AMA decision was approved by the House of Delegates during the annual meeting in June 1982.

²⁷ Testimony of Martha Weinman Lear, transcript of 11th meeting of the President's Commission (July 10, 1981) at 209-70; testimony of Minna Nathanson, transcript of 17th meeting of the President's Commission (Feb. 12, 1982) at 114-91; testimony of Herbert Paris, representing the American Hospital Association, transcript of 7th meeting of the President's Commission (March 14, 1981) at 392-93.

should not be proscribed or removed because of partisan or doctrinal disapproval."²⁸ Librarians have argued that these statements should be applied not only in the literary and political spheres, but to medical information as well.²⁹

Librarians have recognized a burgeoning demand for medical library services from patients.³⁰ Some have identified this as an outgrowth of the consumer movement of the 1960s. They have linked this trend to phenomena such as the demystification of the professions generally, to the impact of the Freedom of Information Act, and to a desire by consumers to take greater responsibility for their own health through self-care.³¹ (Analogous have arisen for the legal profession with the advent of do-it-yourself divorce kits, small claims courts, and other legal self-help mechanisms.) Those at the forefront of the movement for patient access to medical records note that "[a] sophisticated patient might want to research the diagnosis himself and learn more about it while monitoring the physician."³²

The professional responsibilities of librarians, as they have identified them, include providing access to materials, helping patients find the proper references, and putting these references "in context." They have recognized their duties to specify that some materials may be out of date, to note that there are a number of leading texts in a certain field, and to refrain from injecting personal biases or engaging in the "unauthorized practice of medicine" by giving armchair medical advice or making clinical referrals.³³

Librarians have described a number of particularly problematic encounters with patients—the emotionally upset patient who wants the Physician's Desk Reference to identify a

²⁸ *Library Bill of Rights*, American Library Association, Chicago (1980). The bill was originally adopted in 1948 and was amended in 1961, 1967, and 1980. The American Hospital Association's Patients' Bill of Rights also includes the right to obtain information and speaks of health education as an integral part of health care, although it says nothing about access to libraries.

²⁹ *Library Bill of Rights*, *supra* note 28.

³⁰ See, e.g., Lynn Foster and Phyllis C. Self, *Legal and Medical Reference: A Dilemma for Public Libraries*, 60 ILL. LIBRARY 243 (1978); *Ethical and Legal Issues in the Dissemination of Health Information to the Health Care Consumer*, audio tapes from the Medical Library Association's 78th Annual Meeting, Chicago, Ill. (June 1978).

³¹ See, e.g., Norman Charney, *Ethical and Legal Questions in Providing Health Information*, 39 CALIF. LIBRARIAN 25 (1978); note 30 *supra*.

³² Budd N. Shenkin and David C. Warner, *Giving the Patient His Medical Record: A Proposal to Improve the System*, 289 NEW ENG. J. MED. 689 (1973).

³³ Foster and Self, *supra* note 30; Charney, *supra* note 31; telephone conversation with Arthur A. Levin, Director, Center for Medical Consumers and Health Care Information, New York.

handful of pills, the patient wanting to confirm or deny a diagnosis of terminal illness, the client seeking information about a sensitive or embarrassing condition. Medical librarians have urged that professional standards or codes of ethics be developed to guide actions in such situations.³⁴

Neither the American Hospital Association nor the Joint Commission on the Accreditation of Hospitals has a policy on access to hospital libraries, although they do have policies that deal with questions of patient information generally. Many medical libraries receive support from the Federal government under the Medical Library Assistance Act of 1965,³⁵ which was intended to make medical information available regardless of geographical location. Under this statute a number of regional libraries have been established so that "qualified persons and organizations shall be entitled to free loan services." While this issue has not been tested in court, "any individual who can read and who has a desire to research a particular medical question is a 'qualified' user under the act" and ought to have access and loan privileges to at least these federally established regional libraries.³⁶ In the Commission's view, institutional arrangements should be made so that individuals can generally have access to whatever medical information is desired, and libraries should facilitate those information needs whenever possible within the constraints of resources.

Although the literature reveals a growing desire on the part of patients to use medical books, articles, and reference materials to improve their understanding of medical conditions and treatments, comprehensive information is not available to describe how this need is being met. The Commission has found that some hospitals and clinics have information centers designed specifically for patients. Furthermore, the library profession has established networks linking some medical school and professional libraries with local public libraries, and at least a few medical libraries for laypeople have been established.

One example is the Center for Medical Consumers in New York City, a reading library open to the public that contains scientific and medical texts and journals and a clipping file from professional and lay sources.³⁷ The library is funded

³⁴ Foster and Self, *supra* note 30, at 246, discuss the need for such standards or codes for legal and medical libraries. They note, for example, that the American Association of Law Libraries' proposed code of ethics states that law librarians ought not engage in the practice of law or "create an attorney-client relationship," but that it neglects to define these terms.

³⁵ 79 Stat. 1059, 42 U.S.C. § 28b.

³⁶ George J. Annas, *THE RIGHTS OF HOSPITAL PATIENTS*, Avon, New York (1975) at 230-31.

³⁷ See note 33 *supra*.

through small foundation grants and subscriptions to a monthly newsletter that discusses issues and controversies surrounding specific diagnoses, prognoses, and treatments. The 10,000 subscribers include some physicians and institutions, but most are laypeople. Although staff at the Center will assist people in finding information and will make referrals to other sources of information, they are prohibited from providing clinical referrals even though they are sometimes pressured to do so. Establishing and maintaining separate libraries of this sort nationwide would be too expensive; in any case, such a service might be more efficiently performed by public libraries or, in some instances, by hospital libraries.

Involvement of Family in the Process

Another way to enhance patient-provider communications that was discussed by many of the Commission's witnesses is to involve a patient's family members more directly and deliberately in the information process.³⁸ For example, one of the intended side effects of having patients go home to write their own "consent forms" is that it gives others in the family a chance to help the patient understand the situation.³⁹ This issue has been extensively addressed at the Maternity Center Association in New York, whose director testified before the Commission on the importance of family involvement to promote understanding and support of a pregnant patient's preferences regarding childbirth. At the Center, involvement is coupled with detailed and candid informational materials.⁴⁰

Several lay and professional witnesses indicated that when families are not included in the disclosure process they feel left out and helpless.⁴¹ A pilot study conducted at the NIH Clinical Center, described to the Commission, has begun to document the important effects of including families.⁴² Being involved in the process of discussion and decision allowed family members to feel they could be helpful and more actively

³⁸ "Family" may be defined broadly to include closest relatives and intimate friends, since under some circumstances, particularly when immediate kin are absent, those with most concern for the patient may not be actual relatives.

³⁹ See p. 118 *supra*.

⁴⁰ Testimonies of Ruth Watson Lubic, transcript of 15th meeting of the President's Commission (Dec. 11, 1981) at 7-11.

⁴¹ Testimony of Maxwell Boverman, transcript of 15th meeting of the President's Commission (Dec. 11, 1981) at 15-20; testimonies of Minna Nathanson and Edwin Forman in panel discussion on the role of the family in biomedical decisions, transcript of 17th meeting of the President's Commission (Feb. 12, 1982) at 114-91.

⁴² Testimony of Boverman, *supra* note 41, and preliminary report of the study by John C. Fletcher and Maxwell Boverman, *Involving the Patient's Family in Informed Consent*, presented at American Psychological Association 88th Annual Convention, Montreal (Sept. 2, 1980).

involved with the patients. It also appeared to facilitate communication within the family generally by establishing a practice of talking openly even about matters that were unpleasant. Family involvement often gave physicians and other health care providers important information about the patient that they might otherwise not have received. Finally, family involvement seemed to help correct errors and omissions in communications, not only because family members remember things the patient has forgotten, but also because they ask for information the professional has neglected to discuss.

Beyond making the family feel more useful and aiding professional-patient communication, family involvement seems to be therapeutically desirable for two reasons. First, family members have an enormous influence on one another in terms of when and whether an individual actually gets sick,⁴³ recognizing that someone is ill and deciding whether or not to seek care initially,⁴⁴ facilitating or hindering adherence to medical regimens,⁴⁵ and ultimately, at least in some instances, influencing treatment outcomes.⁴⁶ Second, the interdependence of family members makes any particular individual's illness a family problem.⁴⁷ In some ways, therefore, the family may be viewed as the unit of care, which means it needs to be involved in medical decisionmaking because the effects of decisions about any one member will affect the entire family.

The value of full and active involvement of patients' families, like other strategies for improving patient-professional relations and communications, deserves further study. The Commission notes the importance of great care in this area,

⁴³ See, e.g., D. Katz, A. Katz, and L. Culpepper, *Family Life Cycle Stages: New Use of Family Characteristics Predicting Illness*, presented at Fifth Annual North American Primary Care Research Group Meeting, Williamsburg, Va. (March 24, 1977); and Theodore J. Litman, *The Family as a Basic Unit in Health and Medical Care: A Social Behavioral Overview*, 8 SOC. SCI. AND MED. 495 (1974).

⁴⁴ Ronald A. Anderson, A BEHAVIORAL MODEL OF FAMILIES' USE OF HEALTH SERVICES, Center for Health Administration Studies, Chicago (1968).

⁴⁵ See, e.g., Samuel Bloom, *THE DOCTOR AND HIS PATIENT*, Russell Sage Foundation, New York (1963) and Osterweis, Bush, and Zuckerman, *supra* note 20.

⁴⁶ To the extent that family members influence one another to comply with medical regimens they may indirectly influence health outcomes.

⁴⁷ It has long been recognized that the family is a social system whose overall functioning reflects the functioning of the individual members. Thus any member's illness has an impact on the whole family, though the nature of the impact will depend on the particular roles played by the ill member. See, e.g., Talcott Parsons and Renée Fox, *Illness, Therapy, and the Modern Urban American Family*, 8 J. OF SOC. ISSUES 31 (1952); and Janis Lee Gogan *et al.*, *Impact of Childhood Cancer on Siblings*, 1 HEALTH AND SOCIAL WORK 41 (1977).

however. Families are not always cooperative units. They may interfere, pressure, misinterpret, and misinform. What is in the patient's best interest may not be congruent with the interests of all other family members. And, most important, any involvement of outsiders in the therapeutic relationship—even family members—depends upon the patient's agreement. Even if the family has been involved, health professionals ought to make clear to the patient that he or she can insist upon privacy at any time and on any subject.

Professional Outlook and Behavior

6

The general acceptance by health care professionals of the obligations inherent in a process of mutual participation and shared decisionmaking is intimately tied to their attitudes toward their patients and colleagues. Such attitudes are formed over many years and are more subject to gradual evolution than to rapid change of the sort that can follow a scientific breakthrough. Individual attitudes are shaped by role models, prevailing social currents and attitudes, professional education, socialization, practice styles, and the other life experiences of the individual.

The "professional dominance" view of the physician-patient relationship¹ is deeply rooted in the history of the medical profession and is continued by the process of medical education and socialization into the professional role. Other health care professionals, as a group, have different attitudes than physicians on certain points, although all health care professionals have certain attitudes in common.²

If the objectives of increased communication and shared decisionmaking are to take root in health care, some reorientation of attitudes will be required. Accordingly, two possible means of influencing professional attitudes are discussed in this part of the Report: decisions about which individuals are admitted into the health care professions, and the content (both explicit and implicit) of professional training. The importance of both selection criteria and content of training has long been recognized. Indeed, the changes in medical education following the famous Flexner report in 1910 included not only the increased orientation toward empirical science,

¹ See, e.g., Eliot Freidson, *PROFESSIONAL DOMINANCE: THE SOCIAL STRUCTURE OF MEDICAL CARE*, Aldine Pub. Co., Chicago (1970) at 127-66.

² *Id.* at 20-22.

complex technology, and a biochemical and physical explanation of human life, but also the selection of students adept in these fields. Yet Flexner recognized that such developments were but a necessary stage, not the end point, when he said:

The reconstruction of our medical education...is not going to end matters once and for all. It leaves untouched certain outlying problems that will all the more surely come into focus when the professional training of the physician is once securely established on a scientific basis. At that moment the social role of the physician will generally expand, and to support such expansion, he will crave a more liberal disinterested educational experience.³

Thus, one direction for policy is to encourage the recruitment and selection into professional schools of individuals committed to, and likely to be skilled deliverers of, humane care, with respect for patients and their values. A second path would involve reinforcing those elements of professional education and socialization that are conducive to the development of the desired attitudes and to modify other elements that may be destructive.

The Commission is convinced that neither path is sufficient in itself. Efforts to recruit caring and humane individuals into professional schools are unlikely to be fully successful if the educational regimen is not conducive to these values. Collaterally, given the current realities of professional training, it is unlikely that any reform efforts that might be adopted would be able to transform the attitudes or reshape the behaviors of existing professionals. Thus, although the obstacles present on each path are recognized, the Commission is inclined to recommend movement along both.

Selection Criteria for Medical School

Some observers have argued that the quickest and most effective way to turn out doctors of broadly humane sympathies who are both committed to and skilled in communicating with patients is to admit to medical school more people likely to have such characteristics.⁴ While this strategy is appealing in theory, there is little evidence that such individuals can be readily identified, much less that the characteristics of people

³ Abraham Flexner, *MEDICAL EDUCATION IN THE UNITED STATES AND CANADA: A REPORT TO THE CARNEGIE FOUNDATION FOR THE ADVANCEMENT OF TEACHING*, Bulletin No. 4, Carnegie Foundation, New York (1910).

⁴ For a review of this argument and relevant data, see Caroline L. Kaufmann, *Medical Education and Physician-Patient Communication*, Appendix I, in Volume Three of this Report.

admitted to medical school are translated into their traits when they become physicians relating to patients.

Current Standards. Admission to medical school is a highly competitive process designed to select students who are academically gifted and strongly committed to a career in medicine. Yet a number of critics of medical education have suggested that the selection process encourages applicants who are *least* likely to espouse a humanitarian view of the medical enterprise—individuals who are tough, competitive, single-minded, and narrowly focused in the “hard” biological sciences.⁵

Although most medical schools require premedical training in such fields as biology and chemistry, few require humanities or social and behavioral science courses.⁶ Less than 8% of those who entered medical school in 1979-80 majored in these fields as undergraduates.⁷ Thus it may be that the undergraduate experiences of most successful applicants are deficient in the exposure to the social sciences and humanities that could help sensitize them to the concepts and skills essential to becoming effective and responsive communicators.⁸ Moreover, it appears that nonscience majors are ultimately less likely than science majors to choose careers in primary care in which continuing communication with patients is most necessary.⁹

Other medical educators have challenged the contention that medical students lack sufficient undergraduate training in the humanities and social sciences,¹⁰ and have argued that the

⁵ See, e.g., Samuel Gorovitz, *DOCTORS' DILEMMAS: MORAL CONFLICT AND MEDICAL CARE*, Macmillan Publishing Co., New York (1982) at 206-07; Edward D. Pellegrino, *Pruning an Old Root: Premedical Science and Medical School*, 243 J.A.M.A. 2518 (1980).

⁶ For the 1982-83 entering classes at the 126 medical schools in the United States, 14 (11%) required undergraduate courses in the humanities, 11 (9%) required behavioral science, and 10 (8%) required social science. See *Medical School Admission Requirements 1982-3*, 32nd ed., Assoc. of Amer. Med. Colleges, Washington, D.C. (1981) at 8.

⁷ Although relatively few people from these fields applied, they were accepted in similar proportions to those from the biological sciences. Therefore, it is not clear whether such applicants are discouraged from applying in the first place or whether college students who plan to apply to medical schools dare not pursue “irrelevant” majors. *Id.* at 9.

⁸ P. Prioreshi, *Medical Education, Irrelevancy and the Humanities*, 6 *MED. HYPOTHESIS* 509 (1980).

⁹ Testimony of Richard Moy, transcript of 19th meeting of the President's Commission (April 3, 1982) at 195-207.

¹⁰ R.G. Niemi and J.E. Phillips, *On Nonscience Premedical Education: Surprising Evidence and a Call for Clarification*, 55 *J. OF MED. EDUC.* 194 (1980).

almost exclusive focus on the sciences is needed for good performance in medical school.¹¹ There is some evidence, however, that students with undergraduate majors in the humanities and social sciences actually score higher than science majors in some basic science courses in medical school and on the Behavioral Science subtest of the National Board Medical Examination.¹²

Changes in Criteria and Process. In spite of this controversy over suitable characteristics of people admitted to medical school, a number of suggestions for changes in selection criteria have been made. One approach is to discount somewhat the current emphasis on undergraduate success in the hard sciences in favor of applicants with broader exposure to the humanities and social sciences or with personal experience in "helping" capacities.¹³ A second approach favors individual assessments, either through interviews or psychological tests, of an applicant's predisposition toward humane service.¹⁴

¹¹ See, e.g., Travis L. Gordon and Davis G. Johnson, *Study of U.S. Medical School Applicants, 1976-77*, 53 J. OF MED. EDUC. 873 (1978) and Travis L. Gordon, *Study of U.S. Medical School Applicants, 1977-78*, 54 J. OF MED. EDUC. 677 (1979).

¹² R.L. Dickman *et al.*, *Medical Students from Natural Science and Nonscience Undergraduate Backgrounds*, 243 J.A.M.A. 2506 (1980).

¹³ See, e.g., Gorovitz, *supra* note 5, at 205-07.

¹⁴ Assessment of personal qualities of medical school applicants is done through letters of reference, interviews, and increasingly by various other "noncognitive" tests. Letters of reference generally do not discriminate well among applicants. See, e.g., Arthur S. Elstein and Howard S. Teitelbaum, *A Systematic Evaluation of an Admissions Process*, PROCEEDINGS OF THE CONFERENCE ON RESEARCH IN MEDICAL EDUCATION, Assoc. of Amer. Med. Colleges, Washington, D.C. (1974) at 207. Interviews are too costly to be used with every applicant and are considered by some to be too subjective and perhaps deceptive. See, e.g., John B. Molidor *et al.*, *Assessment of Problem-Solving Skills as a Screen for Medical School Admissions*, PROCEEDINGS OF THE CONFERENCE ON RESEARCH IN MEDICAL EDUCATION, Assoc. of Amer. Med. Colleges, Washington, D.C. (1978) at 119. Numerous measures of personality, attitudes, anxiety, depression, etc. have been used as adjuncts to the MCAT and undergraduate grade point average to assist in selecting medical students. As of 1972, almost half the medical schools in the U.S. and Canada were using at least one noncognitive test in their admissions process. A. D'Costa and A. Schafer, *Results of a Survey of Non-Cognitive Tests Used in Medical Schools*, Assoc. of Amer. Med. Colleges, Washington, D.C. (1972). The authors of an extensive review of such measures concluded: "1) that personality traits, as measured by structured tests, are of at least equal importance with cognitive qualities in predicting medical school performance; and 2) that structured personality tests are less time consuming and costly than most other techniques for measuring personality traits and are therefore more feasible for the admissions process." J.M. Cuca, L.A. Sakakeeny, and D.G. Johnson, *The Medical School Admissions Process: A Review of the Literature*,

Although neither approach is likely to revolutionize patterns of communication and decisionmaking in patient-provider relationships, further research and experience would be needed to determine what role they might together play in fostering changes in these directions when combined with changes in the style and content of medical education.

Even if changes in selection criteria were likely to produce the desired results, it is unclear whether such changes could be implemented. In response to criticism of the Medical College Admission Test (MCAT) for its exclusive emphasis on cognitive skills,¹⁵ the Association of American Medical Colleges (AAMC) expended considerable effort between 1971 and 1976 trying to devise measures of noncognitive qualities thought to be important to applicants' overall sensitivity as physicians. Compassion, coping capability, decisionmaking ability, inter-professional relations, realistic self-appraisal, sensitivity in personal relations, and "staying power" were thought to be the most important qualities to assess. Ultimately, the AAMC decided it was not possible to devise valid measures of these qualities in a multiple-choice format for a national admissions test and concluded instead that such assessments are best made by admissions interviewers (and later by clinical instructors). The Commission commends the subsequent efforts of the AAMC to help the professors in 500 departments in the medical schools improve methods to assess the personal qualities of students.¹⁶

A third suggestion for changes in admission criteria is that a "quick fix" might be achieved by admitting larger numbers of applicants belonging to groups traditionally associated with nurturing or caring roles (notably women) or with characteristics thought likely to improve sensitivity toward the concerns of minority groups and with the ability to communicate with patients "in their own language" (blacks, Hispanics, and members of other minority groups).¹⁷ The basis of such an

1955-76, Assoc. of Amer. Med. Colleges, Washington, D.C. (1976). It should be noted that in most cases the utility of these measures is being examined in relation to school performance, not in relation to the nontechnical aspects of patient care.

¹⁵ The MCAT is designed to assess students' abilities in four major areas: science knowledge, problem-solving, reading skills, and quantitative analysis.

¹⁶ Testimony of August Swanson, transcript of the 19th meeting of the President's Commission (April 3, 1982) at 114-18.

¹⁷ Recent analyses of application and enrollment in U.S. medical schools over roughly ten years have shown that women and ethnic minorities, historically underrepresented in the medical profession, have been admitted to medical school in increasing numbers in an effort to increase equity of access. Application and enrollment figures show a 27% increase in total female enrollment from 1974 to 1980. Women made up 27.8% of the 1979-80 first-year medical school class.

approach is the idea that social class, gender, and ethnic background are stronger determinants of attitudes and behavior among medical students than the training and professional socialization they receive in their formal academic careers.

Although some differences do occur in the admissions tests of women, racial/ethnic minorities, and the middle-class white males who are the predominant group of applicants, there is little evidence of persistent differences in attitudes or orientations in medical school. In fact, there seems to be a convergence of attitudes and orientations as students progress through medical school, thereby resulting in relative homogeneity. In terms of ultimate career patterns and responsiveness to patients, there is also increasing evidence of convergence between males and females.¹⁸

Combined Degrees and Early Admission. As discussed above, competition for admission to medical school often has the unfortunate consequence of narrowing the range of courses students feel free to take at the undergraduate level, thereby limiting exposure to disciplines other than science and leading to intense competition during college. Some limited attempts have been made to overcome these shortcomings at the premedical level by admitting students to medical school earlier. The Commonwealth Fund's "Interface Program" in seven schools is the most noteworthy example. Although the program varies somewhat, typically college and medical school are completed in six or seven years rather than eight. Students are accepted into the program after their sophomore year of college, thereby alleviating much of the pressure typifying the premedical experience and enabling more students to pursue serious studies in the liberal arts rather than in a narrow "premed" curriculum. In addition, such programs allow for better integration of the undergraduate and medical school curricula. In some schools this reduces the redundancy of science courses (covered both in undergraduate education and in first-year medical school), permitting students in their first year of medical school to select courses in clinical medicine and the social and behavioral sciences. Although there is some concern that, once admitted to such a program, students may stop studying and may ultimately fail in medical school, two evaluations concluded that these programs alleviated competition and stress at both the undergraduate and medical school

Enrollment by racial and ethnic minorities (including blacks, American Indians, Mexican Americans, and mainland Puerto Ricans but excluding Asian Americans) constitutes 8% of the total medical school enrollment (up from 2.8% in 1970, but short of the 12% goal recommended by the AAMC). In short, the gender, racial, and ethnic characteristics of medical students are becoming slightly less dominated by white, middle-class males. See Assoc. of Amer. Med. Colleges, *supra* note 6, at 21-24.

¹⁸ This evidence is reviewed in Kaufmann, *supra* note 4.

levels, eased the transition between the two, and encouraged students to pursue a broader array of courses.¹⁹

Innovations in Medical Education

The Commission recognizes that the first priority in training physicians must be to impart skills needed to use the ever-expanding body of biomedical knowledge and techniques. In addition, it is aware that medicine is a diverse profession with primary care practitioners, specialists, subspecialists, and researchers, and that the relative need of these professionals for technical and interpersonal skills will vary. Consequently, the educational goals at different institutions and in different programs will differ.

Nevertheless, medicine is a "helping profession," the primary purpose of which is to serve the needs of patients. Few would suppose that people who pursue careers in medicine are uninterested in its human elements. And yet the education process often discourages the development of caring attitudes by focusing so much attention on technical competence and by failing to nurture (or, in some cases, even denigrating) the development of the compassion and caring necessary to the practice of good medicine.²⁰ If physicians have an obligation to provide patients with a basis for effective communication and decisionmaking, they must learn to value this goal and acquire skills relevant to it.

Training students to practice as humane and caring physicians with an interest in serving rather than dominating patients is both an explicit and implicit process. Explicitly, students may be taught concepts and skills in the classroom or at the bedside. Implicitly, attitudes and values are learned from role models and reward systems. If certain practices and precepts are preached in formal course work, but subsequently students neither observe them in their role models nor are specifically rewarded for practicing them, they will quickly learn that such concepts and behaviors are in fact not highly valued.²¹ Therefore, in assessing medical education it is

¹⁹ Alfred Gellhorn, *An Evaluative Report of the Interface Programs Supported by the Commonwealth Fund*, mimeo. (1980); Janet T. Pozen, Allen R. Meyers, and Kathleen Scharf, *Boston University MMEDIC Program Phase I Final Evaluation Report*, mimeo (1980).

²⁰ See, e.g., Harold I. Lief and Renée C. Fox, *Training for Detached Concern in Medical Students*, in H. Lief, V. Lief, and N. Lief, eds., *THE PSYCHOLOGICAL BASIS OF MEDICAL PRACTICE*, Harper and Row, New York (1963) at 12.

²¹ Indeed there is reason to believe that the values underlying informed consent are not deeply rooted in medical practice or tradition. In his perceptive study of the training of young surgeons, sociologist Charles Bosk notes regretfully that he had to "bracket" the issue of informed consent in his field research in order to enter the everyday world of surgeons. As Bosk explains:

important to look beyond formal course requirements to the broader structure and climate in which students learn.

Frequently Cited Problems. Medical educators, students, and the public have become increasingly critical of medical education. Professional and popular journals abound with articles pointing out the defects in medical education and suggesting ways to correct them.

The traditional medical school curriculum is divided into two years of preclinical course work followed by two years of clinical rotations through various medical and surgical specialties. This division has often been criticized for being unnecessarily sharp and counterproductive.²² The basic sciences may seem irrelevant when presented outside the patient care context. The transition from preclinical to clinical work is abrupt and stressful, and once in clinical rotations there may be little opportunity to digress into nonclinical areas or to apply behavioral science concepts to the clinical aspects of patient care.

In addition, several other factors are commonly cited as contributing to a general climate that hinders the development of attitudes necessary for the humane practice of medicine. First, the explosion in medical technology has resulted in a massive and rapidly expanding body of facts that must be assimilated by students. Although an individual cannot know

I suspended judgment and bracketed the question because I was interested in surgeons' understandings of their social control responsibilities and in their definitions of error and failure. Whether the demands of "informed consent" were met or not was not a matter that surgeons considered a matter for social control. The quality of the consent obtained is not an issue that excites surgeons or affects their evaluations of each other.

Charles L. Bosk, *FORGIVE AND REMEMBER: MANAGING MEDICAL FAILURE*, Univ. of Chicago Press, Chicago (1979) at 218 n.5. Bosk characterizes that as "a sad commentary." *Id.*

The reasons for this phenomenon are explored and documented in the writings of Jay Katz; see, e.g., *Disclosure and Consent: In Search of Their Roots*, in Aubrey Milunsky and George J. Annas, eds., *GENETICS AND THE LAW II*, Plenum Press, New York (1980); *Disclosure and Consent in Psychiatric Practice: Mission Impossible?*, in Charles K. Hofling, ed., *LAW AND ETHICS IN THE PRACTICE OF PSYCHIATRY*, Brunner/Mazel, Inc., New York (1980); *Informed Consent—A Fairy Tale?: Law's Vision*, 39 U. PITT. L. REV. 137 (1977). If Katz and Bosk are correct, the task of creating role models and transforming medical education in a fashion conducive to fostering the Commission's vision of informed consent is daunting in scope and likely to be slow in execution.

²² For a detailed discussion of this topic, see Ruth Oratz, *Achieving Aesthetic Distance: Education for an Effective Doctor-Patient Relationship*, Appendix J, in Volume Three of this Report.

everything there is to know about medicine, medical schools typically place tremendous emphasis on the memorization of facts. Although there is clearly a need to know a great deal of factual information, many critics contend that students spend too much time memorizing and not enough time learning problem-solving and observation skills.²³ Especially during the first two years of medical school, intellectual thought may be stifled because the expectation (as reflected in examinations) is that students should simply memorize and regurgitate facts rather than learn to apply information and concepts to solving problems.²⁴

Second, many physicians and medical educators have noted that students spend relatively little time learning medicine at the bedside with "wise old doctors." Instead, their role models typically are students and house officers with not much more experience than the students have. The subtle influences that senior, experienced role models can have in conveying attitudes toward patients is illustrated in this account of a third-year medical student's first exposure to patient care during his surgical "clerkship" at University Hospital in New York. One afternoon Aaron Kenigsberg and several of his classmates had ward rounds with Dr. Frank C. Spencer, chair of the department of surgery, "an Olympian figure to students and residents," according to the writer, who observed Aaron's training over a number of weeks.

When Dr. Spencer finally arrived, he turned out to be an amiable, soft-spoken man with a great economy of gesture. He was not at all distant with the students, but he was a gentleman in the old sense of the word and so

²³ There are numerous articles in professional journals such as *J.A.M.A.*, the *New England Journal of Medicine*, and the *Journal of Medical Education* and in the general press on this subject and numerous proposals to streamline and make more rational the factual information that must be learned. Since the Flexner report to the Carnegie Foundation several other national commissions and committees have looked broadly at medical education and have recommended reforms. Dr. Carleton Chapman recently proposed that another national commission be established to reform medical education because it "is intellectually deficient, wasteful of money and time, and in urgent need of overhaul" (quoted in Lawrence K. Altman, *The Doctor's World: Med Schools Under Attack*, NEW YORK TIMES C4 (June 22, 1982). The Institute of Medicine and the Association of American Medical Colleges are in the planning stages of major studies of reforms in medical education. Dr. Daniel Tosteson, Dean of Howard Medical School, has called for major changes in medical education and has proposed experimental initiation of a radically new program as early as 1983.

²⁴ See, e.g., Oliver Cope, *The Endicott House Conference on Medical Education* in John H. Knowles, ed., *VIEWS OF MEDICAL EDUCATION AND MEDICAL CARE*, Harvard Univ. Press, Cambridge, Mass. (1968) at 157-58.

expected a certain civility of discourse, which students and residents apparently mistook for remoteness....

He saw his patients whole, rather than as collections of symptoms, and tried to help them see their illnesses in perspective, not as the one thing that should dominate their lives.

Perhaps most significantly, he translated the jargon of his profession into simple English. One patient, as a result of an infection, had developed a sheath of scar tissue around the heart. Dr. Spencer explained that the sheath had to be peeled away, as one would peel an orange, so the heart could expand and contract freely. The most striking thing Dr. Spencer did during rounds was kneel next to the bed of one patient who was in very bad shape, so that he could talk to him with their heads on the same level. The man would not have to stare up, as though gazing into the heavens. This may have been the single most generous act Aaron had seen—and would see—during his clerkships; and one that went unremarked.²⁵

Moreover, due to the large number of medical students, limited faculty, and the need for clinical training to occur in small groups, medical schools typically draw a substantial proportion of their clinical teachers from the surrounding community.²⁶ Control over what such part-time faculty teach, how it is taught, and the coherence and consistency of the material may be limited. It is particularly difficult to monitor or control the attitudes and implicit values projected by this diverse, numerous, adjunct faculty to ensure that they foster the desired attitudinal changes.

A third problem derives from the fact that typically each health profession carries out its own educational program in isolation from the others. Thus although doctors and nurses eventually practice together, they are rarely trained explicitly to collaborate.²⁷ As the role of nurses has expanded to include substantial portions of what was traditionally the exclusive domain of medicine, there is an increased need to clarify and coordinate the roles of the two professions.²⁸ Nowhere is this need greater than in communications with patients to ensure

²⁵ David Black, *The Making of a Doctor*, NEW YORK TIMES MAGAZINE 20, 59 (May 23, 1982).

²⁶ Leighton E. Cluff, *Medical Schools, Clinical Faculty, and Community Physicians*, 247 J.A.M.A. 200, 202 (1982).

²⁷ See, e.g., Marian Osterweis et al., *HMO Development for Primary Care Team Teaching of Medical and Nursing Students*, 55 J. OF MED. EDUC. 743 (1980).

²⁸ See, e.g., D.C. Baldwin and M.A. Baldwin, *Interdisciplinary Education and Health Team Training*, in Andrew D. Hunt and Lewis E. Weeks, eds., *MEDICAL EDUCATION SINCE 1960*, Mich. St. Univ. Found., Lansing, Mich. (1979) at 175.

they receive the information they need to make health care decisions.

Finally, concern has been voiced about a disproportionate amount of physicians' training taking place in university hospitals.²⁹ The principal criticism is that these highly specialized, sophisticated, technological centers prepare doctors poorly for the day-to-day practice of medicine elsewhere. Of particular concern to the issues in this Report are the relative lack of opportunity to have patients participate in their own care and the lack of opportunity and responsibility for long-term follow-up care.



These are but some of the concrete criticisms of medical education. Each has important implications for the particular elements of physician training that are of greatest concern here, namely the structuring of underlying values and attitudes conducive to the goals of effective patient participation in health care decisionmaking.

Curricular Innovations. Numerous innovations and experiments in medical education have been designed to address these issues. These include course offerings in the behavioral sciences and humanities, increased exposure to outpatient medical care, faculty development, alterations in grading systems designed to reduce competition (for example, the pass-fail grading now used by most schools), the restructuring and reordering of curricula to integrate the basic sciences with

²⁹ See, e.g., Cluff, *supra* note 26.

patient care, and some limited efforts at combined training of medical and nursing students. Innovations such as these have been introduced in traditional medical schools, in combined six- or seven-year college and medical school programs, and in the new community-based medical schools, where the entire curriculum has often been designed to foster a changed outlook on health care.³⁰

The teaching of social and behavioral sciences in medical schools began in the mid-1950s in an attempt to educate physicians about a variety of influences on patient behavior and to train them to assess patient needs.³¹ The social sciences tended to be taught in classrooms during the preclinical years; hence, students often found it difficult to appreciate their relevance to medical care. Moreover, the material taught by social scientists was typically not reinforced during clinical training and suffered from a lack of integration with the rest of the curriculum.³² By the 1970s the programs were beginning to decline, having never overcome some people's initial "romantic overenthusiasm" or others' "skeptical noninvolvement."³³

About this time, a new movement began in medical education—teaching humanities with a focus on the human values underlying the physician-patient relationship and medical practice. With this came courses in medical ethics, aimed initially at value questions that were being highlighted by rapid technological developments, by shifts in medical care delivery, and by the renewed interest of moral philosophers and lawyers in issues such as those examined in this Report.³⁴ Unlike the earlier social science movement, this human values movement has been aware since its inception of the need to collaborate with other departments, to educate faculty as well as students, and to integrate its teaching with students' clinical assignments.³⁵

³⁰ See, e.g., Hunt and Weeks, *supra* note 28; Gellhorn, *supra* note 19.

³¹ See, e.g., Patricia L. Kendall and George G. Reader, *Contributions of Sociology to Medicine*, in Howard E. Freeman, Sol Levine, and Leo G. Reeder, eds., *HANDBOOK OF MEDICAL SOCIOLOGY*, 3rd ed. (1979) at 1-22.

³² See, e.g., Evan G. Pattishall, *The Relevance of Behavioral Science for the Training of Physicians*, Presented at Third International Conference on Social Science and Medicine, Elsinore, Denmark (August 14, 1972).

³³ Edmund Pellegrino, "Foreword," in William R. Rogers and David Barnard, eds., *NOURISHING THE HUMANISTIC IN MEDICINE: INTERACTIONS WITH THE SOCIAL SCIENCES*, Univ. of Pittsburgh Press (1979) at xii.

³⁴ Programs on human values increased from 11 in 1972 to 65 in 1981. Thus approximately half the medical schools in the United States have such programs, which vary tremendously in size, scope, and structure. Some are separate departments, while others may have a single professor located in a traditional medical school department; some offer only a required lecture or two while others offer entire courses that may be required or electives.

³⁵ See, e.g., Rogers and Barnard, *supra* note 33.

Despite impressive modifications of the curricula, most courses in the behavioral sciences and humanities are offered primarily as electives (see Table 4). The students who take them are therefore self-selected and already aware of the importance of the subject.

Table 4:

**Selected Elective Courses Offered in Medical Schools,
1977-78 and 1981-82**

Elective	1977-78	1981-82
	(N=119)	(N=126)
Biomedical Engineering	42 (35.3%)	46 (36.5%)
Community Medicine	93 (78.2%)	113 (89.7%)
Cost Containment	*	12 (9.5%)
Death and Dying	*	23 (18.2%)
Ethical Problems in Medicine	71 (59.7%)	88 (69.8%)
Health Care Delivery	80 (67.2%)	83 (65.8%)
Medical Jurisprudence	49 (41.2%)	54 (42.9%)
Patient Education	15 (12.6%)	20 (15.9%)

* Not asked in 1977-78.

Source: AAMC: 1981-82 Curriculum Directory.

Half the physicians in the Commission's survey had received "some formal training" in medical ethics while in medical school; 36%, some training in medical law; and 54%, some formal training in physician-patient communications. The exact meaning of "some formal training" is unclear in light of the Medical Student Graduation Questionnaire Survey conducted by the AAMC in 1981, in which only 5% of the 10,795 students questioned reported having taken actual courses in ethical problems in medicine, and less than 3% reported courses in medical jurisprudence and in the behavioral and social sciences.³⁶ When graduates were asked to assess the adequacy of the time spent in such areas as patient-interviewing skills, management of patients' socioeconomic, educational, and emotional problems, and teamwork with other health professionals, sizable proportions of them felt that too little time had been devoted to each of these topics (see Table 5). Thus it appears that relatively few recent medical graduates have been exposed to these curricular innovations and that many find their training inadequate in a number of areas relevant to informed consent.

³⁶ Results of 1981 Medical Student Graduation Questionnaire Survey, Assoc. of Amer. Med. Colleges, Washington, D.C.

Table 5:

Graduates' Reports on Adequacy of Time Devoted to Instruction in Selected Topics During Medical School

Topic	Adequacy of Time (in percent)		
	Excessive	Adequate	Inadequate
Behavioral Sciences	14%	64%	22%
Patient-Interviewing Skills	6%	79%	15%
Management of Patients' Socioeconomic, Educational, and Emotional Problems	4%	49%	47%
Teamwork with Health Professionals	4%	75%	21%

Source: Derived from AAMC 1981 Medical Student Graduation Questionnaire Survey.

Unfortunately, very little is known about the effects of these courses upon the attitudes and behaviors of even the self-selected fraction of medical students who take them. Standard examinations and evaluations by students of their professors and courses only indicate what has been learned and liked, not whether attitudes and behaviors towards patient care have been affected. Unlike clinical techniques, which can be directly observed and assessed, the ultimate effects of these teachings in the behavioral sciences have eluded direct study.³⁷ Ideally such effects would be assessed over time, but such an evaluation would be compromised by uncontrolled and perhaps unidentifiable intervening variables. Compensating for the self-selection in such courses initially would involve undesirable interventions (that is, by artificially controlling admission to certain courses in the behavioral sciences and the humanities). Finally, development of valid and reliable mea-

³⁷ In the Commission's survey some significant differences were found between physicians who had some formal training in ethics, law, and doctor-patient communication and those who had not. Physicians with such training (especially in communication) were significantly more likely than those without it to view patient participation in decisionmaking positively. They were also more likely to report that they obtained consent from patients before proceeding with a variety of treatments. However, in terms of information disclosure, physicians with formal training in ethics, law, and communication were somewhat less likely to report that they routinely disclosed most items of information. Although this seems to contradict the other findings, these physicians were possibly reflecting more carefully on the disclosure questions because of their training and were giving more honest answers.

tures of the empathic qualities that the courses would be seeking to affect would be extremely difficult.

Although the impact of particular courses should be assessed, physicians' attitudes and behaviors are ultimately determined by the totality of the educational experience and not by any single course. Therefore support for the values and skills that students are exposed to in such courses must come from the entire structure of medical education if these courses are to have the desired effect.³⁸

The Commission does not believe that any one approach to physicians' basic medical education should be adopted while all others are dismissed. Given the diversity in patient care needs and in the medical care delivery system—to say nothing of the absence of firm proof that any particular educational approach can achieve predictable ends in the full range of educational settings—diversity in the goals and techniques of medical education is reasonable. However, since the Commission believes that physicians are responsible for ensuring that patients can participate as far as possible in decisions about their care, medical educators ought to train students to carry out this obligation. Such education and training should not only equip students with necessary communication skills but also lead them to value the patient as a full participant in medical decisionmaking.

This goal is more easily stated than accomplished. Indeed, there are certain irreducible problems inherent in medical education and in being a physician. As a leading philosopher of medical ethics has commented: “[N]o amount of change in medical education or public education will solve the moral problems in medicine; at best it can merely increase the quality of thought that is brought to bear on them.”³⁹ While recognizing that education will not resolve all the problems, the Commission agrees with Eric Cassell, a prominent physician-educator that:

A doctor who listens skillfully and who is as careful with words as with drugs has the basic tools for the recognition and relief of suffering. Therefore, training in

³⁸ There is extensive literature on the professional socialization of medical students that analyzes the effect of the overall structure on the development of attitudes and behaviors. One of the most difficult dilemmas facing students involves learning to maintain some emotional distance from patients while being compassionate. See, e.g., Robert K. Merton, George G. Reader, and Patricia L. Kendall, *THE STUDENT PHYSICIAN*, Harvard Univ. Press, Cambridge, Mass. (1957); H.S. Becker *et al.*, *BOYS IN WHITE*, Univ. of Chicago Press, Chicago (1961); Leif and Fox, *supra* note 20; Eileen C. Shapiro and Leah M. Lowenstein, eds., *BECOMING A PHYSICIAN: DEVELOPMENT OF VALUES AND ATTITUDES IN MEDICINE*, Ballinger Pub. Co., Cambridge, Mass. (1979); and Oratz, *supra* note 22.

³⁹ Gorovitz, *supra* note 5, at 208.

communication must enter the medical-school curriculum. Physicians must also (and can) be taught how to weigh and evaluate subjective and value-laden information in equal partnership with objective data and scientific thinking. Otherwise, responding well to sick patients (rather than merely to their diseases) will remain the property of an intuitive few.⁴⁰

Therefore, the Commission commends continued and expanded efforts to devise innovative training programs and urges that they be accompanied by evaluation efforts to discover which changes in medical education produce "better doctors" in terms of the issues discussed here.

Postgraduate Training. Residency level training provides an opportunity to reinforce and synthesize the skills and values learned in medical school; indeed, some believe that such training may be an ideal time to teach the humanities and ethical analysis and to refine interpersonal skills. The testimony heard by the Commission suggests that physician roles in patient communication are shaped very differently depending on the specialty. Residency training in some specialties, most notably family practice, recognizes the primacy of the patient and explicitly trains physicians to encourage participation by patients in decisions, while many of the hospital-based specialties devote almost no training time to such issues.⁴¹ Even in situations where patient contact is limited and time is short, communication is important; in fact, there is still more reason to train such physicians well in interpersonal skills in order to make optimal use of the time they have with patients.

The education of physicians does not end with medical school, residency training, or specialty fellowship programs. Recent developments in biomedical knowledge and techniques are so great that to remain competent a physician must be continually engaged in education and retraining.⁴² Such a process—whether conducted at large conferences, through intensive seminars, or by means of written and recorded materials—ought to include attention to new thinking about bioethics, such as the findings and recommendations of this Report, as well as to new laboratory and clinical findings.

Examinations. The Commission recommends that the issues discussed here be incorporated not only in examinations in medical school but also in national medical board and specialty board examinations. Teaching medical ethics and the humanities principally as electives and enhancing communica-

⁴⁰ Eric J. Cassell, *To the Editor*, 307 NEW ENG. J. MED. 759 (1982).

⁴¹ Testimonies of Drs. Eugene Hildreth, Lynn P. Carmichael, and John Steinhaus, transcript of 19th meeting of the President's Commission (April 3, 1982) at 153-89.

⁴² Most states now require physicians to have a certain number of hours of continuing education credits in order to renew their licenses.

tion skills on an ad hoc basis makes it too easy to dismiss these issues as unimportant or tangential to medical practice. But if students and faculty know that these topics are on national examinations they are likely to view them as essential elements in the education of future physicians.

The central difficulty, of course, lies in designing appropriate exams, since what is ultimately of greatest importance is not knowledge per se but attitudes and behaviors. Careful consideration should be given to testing students in this regard.⁴³ The efforts of the American Board of Internal Medicine to incorporate these issues into its residency training programs and into its certification examination should provide valuable experience for leaders in other areas of medicine who are trying to respond to this important issue.⁴⁴

In all of these areas of medical education, from selection criteria to examination, the American Medical Association and other professional bodies at the state and local levels exert considerable influence.⁴⁵ Therefore, the Commission hopes that these groups will give careful consideration to the recommendations in this Report in order to effect some needed changes in medical education.

Innovations in Nursing Education

Like medical education, nursing education is undergoing major changes. Ironically, while medical education is responding to social pressures to become "more humane," nursing education is under pressure (from the health care delivery system and from within the profession) to become more "scientific" and more technologically sophisticated. Many of the changes suggested in medical education are already an integral part of professional nursing education, which traditionally has placed great emphasis on respect for patients' values, the therapeutic importance of patient participation in health care decisionmaking, and the teaching of good communication skills.⁴⁶ For nursing, the more urgent changes would

⁴³ Although multiple-choice questions have been used in the context of case studies to examine the process of clinical reasoning, they are probably not appropriate to measure compassion and the humane practice of medicine. Instead, efforts must be made to devise revealing case studies, develop essay questions, or even incorporate the issues into oral examinations for specialty boards. The potential subjectivity of the last two methods will have to be weighted against their ability to produce valid assessments of physicians' attitudes and problem-solving abilities.

⁴⁴ American Board of Internal Medicine, *Report of Task Force II*, Newsletter, Philadelphia (January 1981) and Testimony of Hildreth, *supra* note 40.

⁴⁵ David Mechanic, *MEDICAL SOCIOLOGY*, Free Press, New York, 2nd ed. (1970) at 400-04.

⁴⁶ The President's Commission brought together a group of nursing

seem to be in the practice context, for it is in patient care that nurses often face a divergence between what they have been taught to do (and believe is right) and the actual role they are permitted to play due to ambiguities in the law, in practice, and in the profession itself.⁴⁷

Full discussion of the sources and resolution of this problem would go well beyond the scope of this Report. This question is currently being studied in depth by the National Commission on Nursing, an independent commission that was established with funds primarily from the American Hospital Association, and that includes representatives from medicine, nursing, hospital administration, and other groups.⁴⁸ In this section of the Report the Commission focuses on several changes in nursing education and practice that could have major consequences for the involvement of nurses in the informed consent process as well as for the nature of the relationship between care-givers in medicine and nursing.

Changes in Skills and Responsibilities. Nursing practice has changed dramatically in the last 40 years. Increased technology coupled with shifts in disease patterns have led to a major restructuring of the health care delivery system. Recently, perhaps partly as a reflection of the women's movement, the nursing profession has become more assertive and concerned about being recognized in its own right rather than as a mere handmaiden to medicine.⁴⁹ These changes in practice and orientation have been accompanied by significant changes in nursing education. Two- and three-year diploma schools are being superceded by baccalaureate programs whose graduates are in turn increasingly going on for advanced degrees.⁵⁰

Traditionally, nurses were educated primarily to carry out physicians' orders regarding medications and treatments and to provide comfort and support to patients. Nurses today are prepared in the direct application of complex technologies to patient care. Students of nursing learn to develop nursing care plans for patients that require skills in history-taking, physical

experts from all over the country in March 1981, see Addendum, p. 191 *infra*, to discuss the issues addressed in this Report generally and this section specifically. See also Claire Fagin, Margaret McClure, and Rozella Schlotfeldt, *Can We Bring Order Out of the Chaos of Nursing Education?*, 76 AMER. J. NURSING 98 (1976).

⁴⁷ See, e.g., Linda H. Aiken, ed., *NURSING IN THE 1980S: CRISIS, OPPORTUNITIES, CHALLENGES*, J.B. Lippincott, Philadelphia (1982).

⁴⁸ Although this Commission has not completed its work, in September 1981 it issued an *Initial Report and Preliminary Recommendations*.

⁴⁹ Aiken, *supra* note 47.

⁵⁰ See, e.g., J.C. Vaughn, *Educational Preparation for Nursing-1979, 1 NURSING AND HEALTH CARE 6* (1980).

examinations (which may include diagnostic procedures), and the independent generation of nursing care procedures.⁵¹ In addition, their traditional training in communication skills has expanded. With the shift in disease patterns toward chronic illnesses, nursing education has increased its long-established emphasis on the skills needed for educating patients, especially about self-care techniques and the long-term management of disease. Consumer demands for information and the self-help and health promotion movements have also had their effects on nursing education. More than ever, nurses see themselves as patients' advocates—assisting patients to achieve better health and more-effective participation in their own health care.⁵²

One of the stated functions in nursing codes and state laws, often under the rubric of "patient education," is to prepare patients by providing information about their condition and treatment, alternatives, risks, and benefits.⁵³ This responsibility is often shared with the attending physician,



who may specifically delegate it to nurses, although it may be carried out independently by nurses in the course of treating patients. When this is a shared or delegated function, nurses are responsible for following orders knowledgeably and for bringing errors, omissions, and misunderstandings on the part of patients to the attention of physicians. Although ultimate legal responsibility varies according to the context in which care is delivered, the nature of the intervention, and the person treating the patient, nurses as a practical matter typically have a central role in the process of

⁵¹ Testimony of Patricia Balassone, transcript of 19th meeting of the President's Commission (April 3, 1982) at 208-18.

⁵² This is reflected in changes in the code of nursing ethics between 1950 and 1976 and in statements at nursing schools on the philosophy of nursing, which guide curricular development. See also Catherine Norris, *Self-Care*, in Barbara W. Spradley, ed., *READINGS IN COMMUNITY HEALTH NURSING*, 2nd ed. (1982) at 214-19.

⁵³ See, e.g., Anne J. Davis and Mila A. Aroskar, *ETHICAL DILEMMAS AND NURSING PRACTICE*, Appleton-Century Crofts, New York (1978) at 67-88.

providing patients with information.⁵⁴

Early graduate programs at the master's level established in the 1950s prepared nurses to be administrators and teachers. By the 1960s, however, mirroring the trend in medicine, the emphasis in nurses' graduate education shifted towards more clinical training and specialization in such areas as intensive care, pediatrics, cardiology, and orthopedics. With the nurse-practitioner movement came a new awareness by other health care providers and the public of the clinical capabilities of nurses.⁵⁵ Today nursing is moving to strengthen its role as a distinct profession, without trying to imitate medicine, and to specify more clearly the contributions of nursing to patient care. As a profession, nursing is demanding more responsibility as well as more legal, moral, and practical accountability.⁵⁶

Relationship to Medicine. With all these changes, professional nursing and medicine have become both more independent and more interdependent. On the one hand, nurses with graduate training and nurse-practitioners (including midwives) are increasingly caring for patients on their own. Especially in ambulatory settings and in nursing homes, nurses may sometimes do checkups, chronic disease follow-up, and some management of acute disease; they may order tests and initiate therapeutic interventions, sometimes with a physician's cosignature and other times independent of physicians.⁵⁷ In these cases nurses have full responsibility for informing patients about their conditions, treatments, and tests, for ensuring that the patient has understood the information, and for securing consent.

In some areas, on the other hand, greater interdependence exists among health care professions, most notably in hospitals.⁵⁸ As the roles and functions of physicians and nurses overlap more, there is an even greater need to coordinate patient care activities. Such coordination requires that both professions understand each other's capabilities and work together to foster patients' well-being.

In recognition of the need for coordinated team practice, the American Medical Association and the American Nurses' Association established the Joint Practice Commission, which

⁵⁴ *Id.*; Teresa Stanley, *Nursing*, in Warren T. Reich, ed., *ENCYCLOPEDIA OF BIOETHICS*, Free Press, New York (1978) at 1138-45.

⁵⁵ See, e.g., Loretta C. Ford, *Nurse Practitioners: History of A New Idea and Predictions for the Future*, in Aiken, *supra* note 47, at 231-47.

⁵⁶ Aiken, *supra* note 47; Stanley, *supra* note 54.

⁵⁷ The requirements for nursing orders to be cosigned by physicians vary according to the nature of the medical intervention and to the requirements of state laws and third-party reimbursers (both federal and state).

⁵⁸ See, e.g., Ingeborg G. Mauksch, *Nurse-Physician Collaboration: A Changing Relationship*, 11 J. OF NURSING ADMIN. 35 (1981).

operated from 1971 to 1980. In its *Guidelines for Establishing Joint or Collaborative Practices in Hospitals*, the Commission recommended the formal institution of joint practice and outlined the necessary elements in the functional relationships between professionals involved in direct patient care and the administrative structure that supports those activities.⁵⁹ The President's Commission commends the work of the Joint Practice Commission and agrees that explicit attention should be paid to furthering the goals of coordinated team practice among professionals who have completed their formal education.

The Commission further encourages joint training programs for students in the two professions, since most nurses and physicians ultimately practice in teams. Only a few small experiments have tried to train medical and nursing students together. More frequently, students of one profession have been taught by faculty from the other or by teams of physicians and nurses. There are many logistical and attitudinal barriers to joint training, which seem to have curtailed the expansion of such programs. Typically, it is not until residency training that physicians begin to appreciate nurses' skills and the need to coordinate patient care activities. Although the Commission heard some testimony suggesting that residency was the optimal time to train physicians for team practice, others argue that earlier exposure of the two professions to one another is preferable.

In the Commission's view, coordination and understanding among the various professionals facilitate optimal patient care and the provision to patients of an effective basis for participation in health care decisionmaking. More study by the professions and by Federal officials with responsibility for health care and education is clearly needed. But enough is already known to recognize the value of the emphasis placed by professional nursing on the education and involvement of the patient, as well as the need for further efforts at joint training of nurses and physicians throughout their clinical preparation.

⁵⁹ *Guidelines for Establishing Joint or Collaborative Practices in Hospitals*, National Joint Practice Commission, Chicago (1981).

Legal Reforms and Their Limitations

7

The Law as a Means of Improvement

The law has an important function as a moral teacher, both for the professions and for the general public. Even though they do not always give full effect to the value of self-determination, legal rules and court decisions remind society of its commitment to this value.¹ Beyond this symbolic function, law establishes minimum, enforceable standards for disclosure that enable injured patients to receive compensation for injuries caused by health professionals' failure to meet these standards. Although the existence of this potential liability has generated anxiety among practitioners, it has also spurred valuable reassessment of ethical norms and professional practices and has made practitioners more sensitive to patients' needs and expectations.² The Commission firmly believes that the law can and should continue to perform these essential functions.

The Commission appreciates the practical difficulties of adopting its approach to patient-professional relationships as

¹ See Jay Katz, *Informed Consent—A Fairy Tale?: Law's Vision*, 39 U. PITT. L. REV. 137 (1977); Joseph Goldstein, *For Harold Lasswell: Some Reflections on Human Dignity, Entrapment, Informed Consent, and the Plea Bargain*, 84 YALE L.J. 693 (1975).

² From the Commission's survey it is apparent that several aspects of the legal doctrine of informed consent and its implementation (*i.e.*, increased disclosure, increased patient involvement in decisionmaking, and consent forms) have made physicians more sensitive to patients' needs and expectations. As discussed in Chapter Four, these aspects are generally viewed as beneficial to the doctor-patient relationship because they tend to provoke discussion, enhance understanding on the part of both doctor and patient, lead to better decisions, and aid compliance.

the normative legal expectation for informed consent. Transcending these practical difficulties is a more fundamental issue: the Commission is not convinced that its vision of the patient-professional relationship can be achieved primarily through reliance on the law.³ Having analyzed the relationship in a way that recognizes the complexities and variations of individual cases, the Commission is aware that the informed consent process may not be susceptible to detailed regulation by so blunt an instrument as the law of battery or of medical negligence. Indeed, the Commission is concerned that efforts to draw the law further into regulating the subtler aspects of relationships between patients and health care professionals may prove ineffective, burdensome, and ultimately counterproductive.⁴

³ One obstacle to the implementation of the Commission's vision through law is the difficulty of formulating an appropriate means of enforcement. When a health care professional does not engage in ethically proper discussion with a patient, and the failure to do so causes no bodily harm to the patient, the amount of damages to which the patient would be entitled are nominal, and thus few if any patients (and lawyers) would be willing to bring suit under such circumstances. Instead of relying on traditional litigation to implement the Commission's vision,

[t]his could be achieved by establishing a system of non-insurable tort-fines for violation of the duty to disclose and a compensation fund. The fines would be paid into the fund, which would be used to compensate those persons the legislature defines as injured by nondisclosure. Under this arrangement doctors are provided with guidance and are subject to specific deterrence. All physicians who violate a duty to disclose would be liable for fines that could be set in accordance with their deterrence objective. Only those patients suffering injury, as defined by the legislature, would be compensated.

Leonard L. Riskin, *Informed Consent: Looking for the Action*, 1975 U. ILL. L. F. 580, 606-07.

⁴ One unfortunate by-product of the legal regulation, through malpractice suits, of the doctor-patient relationship in an attempt to establish a minimum level of quality in the provision of medical services is practice of what is referred to as "defensive" medicine, which "consist[s] of medically unjustified care provided by the physician for the purpose of reducing the possibility of a malpractice suit..." Project, *The Medical Malpractice Threat: A Study of Defensive Medicine*, 1971 DUKE L.J. 939, 942. This study concludes that "[t]he threat of a malpractice suit does induce physicians to overutilize diagnostic tests and procedures in particular cases, but...the practice is not extensive and probably not a contributing factor to the rising costs of medical care." *Id.* at 964. *But see* Elliot Sagall, *Medical Malpractice: Are the Doctors Right?*, 10 TRIAL (July/Aug 1974) at 59, 60, suggesting that reports on the extent of the practice of defensive medicine are exaggerated.

Nevertheless, in this Report the Commission has set forth a vision of informed consent that could, if incorporated into state law as cases arise, bring the law closer to its ethical roots as well as to the realities and potentialities of day-to-day health care. Although the Commission does not regard changes in the law as the major way its conclusions about informed consent will be translated into practice, it does believe that it would be appropriate—even desirable—for the law on the subject to adjust its minimum expectations in the direction pointed to in this Report.

Most fundamentally, the law could emphasize the process of continuing communication and decisionmaking, rather than the pro forma disclosure of particular risks that now strikes many practitioners as a hollow charade.⁵ Such a shift in focus would make clear that a professional's obligation is not satisfied—and the professional is not insulated from legal liability—simply by obtaining the patient's signature on a consent form.⁶ Instead, courts could engage in a more qualitative evaluation of the entire process that would account for the professional's overall effort to elicit matters of particular concern to the patient and to respond to the patient's worries, insofar as reasonably possible, through disclosure and discussion. Instead of focusing, as is now the case, on whether the

In Texas, informed consent is legally governed by a set of detailed regulations describing what doctors are supposed to disclose for particular procedures. See 3 Tex. Reg. 4293-96, §§ 319.01.03.001-.003 (Dec. 12, 1978), issued pursuant to Tex. Rev. Civ. Stat. Ann. art. 4590i, § 6.03 (Vernon Cum. Supp. 1980). The limitations of law in regulation of the relationship between doctors and patients is well developed by Fox and Swazey in their discussion of the famous heart transplant case of *Karp v. Cooley*, 493 F.2d 408 (5th Cir. 1974). See Renée C. Fox and Judith P. Swazey, *THE COURAGE TO FAIL: A SOCIAL VIEW OF ORGAN TRANSPLANTS AND DIALYSIS*, Univ. of Chicago Press, Chicago (1974) at 201 *et seq.*

⁵ The requirement of informed consent has frequently been described by physicians as a myth or a fiction. See, e.g., Henry K. Beecher, *Consent in Clinical Experimentation—Myth and Reality*, 195 J.A.M.A. 34-35 (1966); Preston J. Burnham, *Medical Experimentation on Humans*, 152 SCIENCE 448 (1966); William P. Irvin, "Now, Mrs. Blare, About the Complications....," 40 MED. ECON. 102 (1963); Eugene G. Laforet, *The Fiction of Informed Consent*, 235 J.A.M.A. 1579 (1976); Edmund B. Middleton, *Informed Consent*, 233 J.A.M.A. 1049 (1975); Mark Ravitch, *Informed Consent—Descent to Absurdity*, 101 MED. TIMES No. 9, 164 (1973). The articles critical of informed consent appear to have diminished in frequency in the last few years.

⁶ See note 44, Chapter One *supra*. If informed consent is viewed as a process—as this Report envisions—rather than as an event, proposals to embody "informed consent" in a written or "electronic" document are ultimately unavailing. See, e.g., Note, 44 BROOKLYN L. REV. 241, 273-81 (1978).

practitioner warned the patient of risks, courts would inquire into whether or not the practitioner took sufficient steps to involve the patient in the decisionmaking process. The questions before the court could include, for example, whether the practitioner made reasonable efforts to impart information, to determine whether the patient understood it, to elicit the patient's values and preferences, to create a noncoercive atmosphere for the decision, and to encourage the patient to decide on the basis of the available information and the patient's own values.⁷

Efforts to translate the Commission's recommendations of ethical norms for the communication process directly into detailed legal rules may create evidentiary difficulties. To the extent that the issues to be examined in a lawsuit would be more subtle and subjective than they currently are if the Commission's recommendations were to form the ethical basis of law, proof of what occurred would be complicated. Of course, the direct testimony of both professional and patient could provide accounts of the decisionmaking process. Yet as discussed in Chapter One, the tendency of such testimony to be selective and self-serving is familiar and difficult to overcome.⁸ Documentary evidence could be introduced as well, but the production of a full documentary record reflecting not merely a formal written consent but the entire process of communication and decisionmaking over an extended time would impose substantial burdens. Of particular concern would be the time needed to generate and ensure the accuracy of such records from the viewpoints of all parties.

The implication to be drawn from these difficulties is not, however, that professionals should comply with the limited requirements of the law, and then go about their business as they see fit. The Commission rejects the attitude that divides obligations into two categories: those that are legally established and must be obeyed under pain of penalty, and those that are not so established and hence can be ignored. Throughout this Report the Commission has employed the

⁷ Several current dilemmas in informed consent law would remain problematic in this view. For example, what causal relationship needs to be established between the professional's failure to provide a basis for effective participation and the physical injury associated with treatment? When the professional's failure to provide such a basis did not result in physical injury to the patient, there would be no readily ascertainable monetary damages to serve as a basis for redress (or to encourage an attorney to take the case on a contingent-fee basis). A standard for money damages to redress dignitary injuries may be needed, or the governmental and voluntary organizations that regulate licensure and certification may need to investigate allegations of systematic violation of patients' rights, as a ground for professional discipline.

⁸ See pp. 25-26 *supra*.

terminology of "professional-patient relationships" rather than the language of the marketplace, which treats patients as "consumers," to underline the importance of recapturing a sense of professional norms and obligations. Such norms are more than gratuitous advice; they are to be taken seriously, both by individual professionals and by their organizations.⁹

In distinguishing between a strictly legal obligation to secure consent and a professional's broader obligation to provide patients with a basis for effective participation in decisionmaking, the Commission hopes to remind health care professionals that their obligations transcend legal requirements and incorporate objectives that the law cannot readily enforce. The roots of the broader obligation are ethical and reside with the mutual trust and expectations that are appropriate for parties to the relationship. The Commission believes that recognition and fulfillment of these professional obligations by health care practitioners will go a long way toward alleviating the sometimes adversary character that has encroached upon patient-professional relationships in recent years and will reinforce the mutual trust on which successful relationships are ultimately founded.

Enhancing Self-Determination of the Formerly Competent

In addition to any judicial modification in the law of consent to bring it into line with the Commission's conclusions, states should direct legislative attention to giving patients the means to have at least some say about treatment decisions in the event they become incapable of participating in decisions directly.¹⁰ More than one-third of the public in the Commission's survey have given instructions (though only one-quarter of those are in writing) to someone about how they would like to be treated if they become too sick to make decisions themselves. While this issue has gained prominence largely because of the attention recently accorded to so-called living wills for dying patients, people can and do set forth instructions to guide a wide variety of health care decisions.

As discussed in Chapter Two, such means would permit two of the goals of self-determination to be fulfilled: individualizing the meaning of well-being and showing respect for personal dignity. The third goal—that a patient be an active

⁹ Indeed, although the broad generalities of battery and malpractice law, which aim largely at redressing past misconduct, may not be helpful here, the rules spelled out by hospital boards, medical societies, and licensing bodies could provide more detailed prospective guidance and encouragement.

¹⁰ Standards and procedures for assessing which patients are incapable of participating in a health care decision are discussed in Chapter Eight *infra*.

agent in decisions about his or her own care—would be impossible to achieve at all in the case of an unconscious patient and impossible to achieve fully with patients who are less seriously incapacitated. Although this Report focuses on patients' direct decisions about their own care, no discussion of legal reforms would be complete without some attention to how a person's informed consent might carry forward to a time when he or she is no longer able to participate directly through the use of written directions (known as "advance directives") prepared in anticipation of some future incapacitating illness.

Without changes in the law, the problem facing a person who wants to direct the care he or she will receive if incompetent is that the authorization provided to a family member or physician ceases to be legally effective at just the time when it is needed, namely when the person becomes incompetent, because of the legal rule (which is quite sensible in other contexts) that an agent's authority is terminated by incompetence of the person who appointed that agent.¹¹ Thus, special provision must be made if a person's directions about medical care, set down while he or she is competent, are to be effective in determining, or even officially guiding, the decisions actually made if the person becomes incompetent.

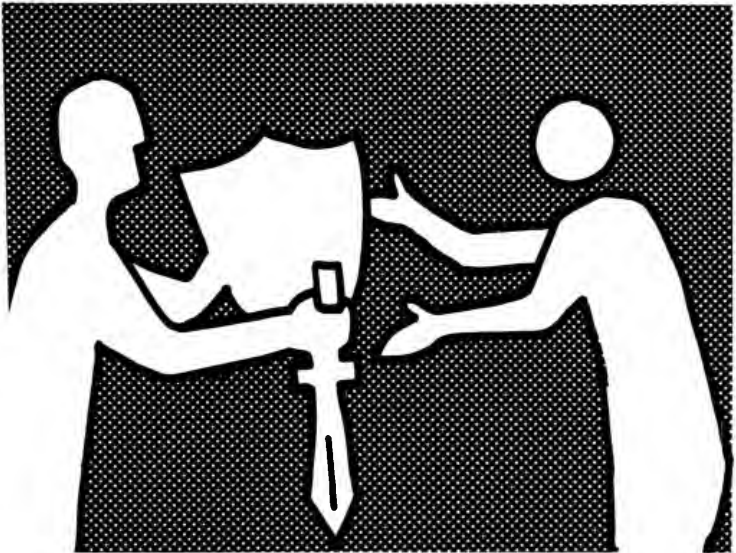
Instruction Directives. Two types of advance directives have already been recognized by some states: instruction directives and proxy decisionmaking directives. The best known examples of the first type are the "natural death" statutes that have been enacted in 14 states since the first was adopted in 1976 in California.¹² These specify certain circumstances under which a directive to a treating physician (the wording of which is usually set forth in the statute) will be effective in limiting the extent of life-sustaining treatment administered to a patient whose condition has been diagnosed as imminently fatal. Instruction directives are, in theory, limited neither to terminal illness nor to orders to desist from treatment. They could be employed by patients who have been told that they may soon become incapable of making decisions (for example, because of a brain tumor) or by those who simply

¹¹ See American Law Institute, *RESTATEMENT (SECOND) OF AGENCY*, American Law Institute Publishers, St. Paul, Minn. (1957) at § 122.

¹² See Ala. Code §§ 22-8A-1 to 22-8A-10 (Supp. 1981); Ark. Stat. Ann. §§ 82-3801-.3804 (Supp. 1981); Cal. Health and Safety Code §§ 7185-7195 (Deering Supp. 1982); D.C. Code §§ 6-2421 to 2430 (Supp. 1982); Del. Code Ann. tit. 16, §§ 2501-2509 (1982); Idaho Code §§ 39-4501 to 4508 (Supp. 1982); Kan. Stat. Ann. §§ 65-28,101 to 65-28,109 (Supp. 1981); Nev. Rev. Stat. §§ 449.540-.690 (1979); N.M. Stat. Ann. §§ 24-7-1 to 24-7-11 (1981); N.C. Gen. Stat. §§ 90-320 to 90-322 (1981); Or. Rev. Stat. §§ 97.050-.090 (1981); Tex. Rev. Civ. Stat. Ann. art. 4590h §§ 1-11 (Vernon 1982); 18 Vt. Stat. Ann. §§ 5251-5262 (1982); Wash. Rev. Code Ann. 70.122.010-70.122.905 (West 1982).

wish to have "standing orders" about some aspect of their care (such as no blood transfusions). Instructions could authorize the use of certain types of treatments, as in the case of people diagnosed as having progressive senile dementia of the Alzheimer's type who, before they become incompetent, give their permission for research procedures of more than minimal risk. And rather than specifying that under particular circumstances an individual does or does not authorize a particular type of medical intervention, instructions could describe a person's attitude toward a particular state of affairs.¹³

Whether the instructions are quite precise or very general, for several reasons an advance directive of this type is of limited use in providing effective self-determination. First, it would be extremely difficult to draft a directive that did not leave considerable range for interpretation; both the existence of the circumstances making the directive effective and the steps to be taken under it will often require discretion by health care professionals and family. Second, if the terms of the document were made more precise in order to leave the choices more with the patient and less with the treating professionals, the range of circumstances to which the document would apply would have to be narrowed or its length and complexity would have to be increased.



¹³ An example of such a directive would be one stating: "I feel that I would rather not live than remain in an unconscious state from which I have no likelihood of recovering." This might provide a clearer sense of a person's feelings and wishes than a directive that merely specifies the treatment a person does or does not want under certain circumstances.

Third, and perhaps most important in light of the analysis of informed consent contained in this Report, instruction directives are likely to address only a limited range of medical situations that occur frequently enough to be of general concern to people. Beyond these, a directive would itself be an example of knowing and voluntary self-determination only if it emerged from a patient-professional relationship in which the patient had been counseled about the future risk of a particular disability and about the courses of treatment that would probably then be available. Even then, decisionmaking under an instruction has a truncated quality since the patient will have dictated specific decisions before all the particulars of the situation were clear and before the process of mutual participation and shared decisionmaking had fully ripened. Consequently, such directives are likely to be more useful in excluding certain procedures that are totally unacceptable to a patient than in fine-tuning decisionmaking about a full range of possible health care choices.

Proxy Directives.¹⁴ An alternative type of directive, which would avoid the difficulties both of anticipating all possible treatment choices and of leaving full discretion to health care professionals, would designate a person as authorized to make treatment decisions on a patient's behalf under specified circumstances.¹⁵ Both the range of circumstances in which the proxy may act and the range of choices he or she is authorized to make could be broad or narrow. For example, a person who wanted vigorous treatment could authorize a proxy to make all necessary decisions, subject only to the requirement that all therapies be aggressively pursued if they offered any possibility of benefit.

Although a proxy's decisions are not directly acts of the patient, proxy directives meet the objective of allowing patients to limit what happens to them if they appoint proxies with whom they have discussed their views and who are willing to insist on treatment decisions that are consistent with those views. The proxy can participate in the process of shared decisionmaking in the patient's stead, so that that process is

¹⁴ The term "surrogate" is used in this report (*see* Chapter Eight *infra*) to designate an agent authorized to make a health care decision on behalf of a patient who lacks the capacity to do so personally. Within this category, a "proxy" is a surrogate appointed by a patient.

¹⁵ In the context of the present discussion, the triggering event under a directive designating a proxy would be (at the least) that the signer had become incapable of participating in decisions about his or her own care. Directives could, in theory, designate a proxy to step into the decisionmaking shoes of a person who remained capable of making his or her own choices but who chose not to.

not artificially truncated. The degree to which this proxy process actually substitutes for a patient's direct participation depends upon how extensively the patient had previously talked over the relevant issues with health professionals.

By combining a proxy directive with specific instructions, an individual could control both the content and the process of decisionmaking about care in case of incapacity. The use of instructions would help overcome the open-ended nature of designating a proxy by increasing the likelihood that in the process of deciding on instructions a person would have discussed relevant considerations with both the potential proxy and the health care professionals—in other words, that the person would go through a process of prospective informed consent.

The possibility of appointing a proxy for health care decisionmaking already exists in the laws of 37 states that have adopted statutes authorizing what is usually termed a durable power of attorney.¹⁶ Although these were fashioned over the past 30 years primarily to provide a less expensive means than court-ordered guardianship or conservatorship for dealing with small property interests, there is nothing in the acts that would explicitly preclude the use of durable powers of attorney to designate or instruct a proxy to make health care decisions. Commentators have suggested such use and there is

¹⁶ See Alaska Stat. §§ 13.26.325, .330 (1979); Ariz. Rev. Stat. §§ 14-5501 to 5502 (1975); Ark. Stat. Ann. §§ 58-501 to 511 (1971); Colo. Rev. Stat. §§ 15-14-501 to 502 (Supp. 1979); Conn. Gen. Stat. § 45-690 (1979); Del. Code tit. 25, §§ 175-180 (Supp. 1978); Fla. Stat. Ann. § 709.08 (West 1980); Ga. Code Ann. § 4-214.1 (1975); Haw. Rev. Stat. §§ 560:5-501 to 502 (Supp. 1979); Idaho Code §§ 15-5-501 to 502 (1979); Ind. Code Ann. §§ 30-2-1.5-1 to 2 (Burns Supp. 1979-1981); Iowa Code Ann. §§ 633.705-.706 (West Supp. 1980-1981); Ky. Rev. Stat. § 386.093 (Supp. 1978); Me. Rev. Stat. tit. 18-A, §§ 5-501 to 502 (1979); Md. Est. & Trusts Code Ann. §§ 13-601 to 602 (1974); Mass. Ann. Laws, ch. 201, § 50 (Michie Supp. 1980); Mich. Comp. Laws Ann. §§ 700.495-.499 (Supp. 1980-1981); Minn. Stat. Ann §§ 524.5-501 to 502 (West 1975); Miss. Code Ann. § 87-3-15 (1973); Mont. Code Ann. §§ 72-5-501 to 502 (1979); Neb. Rev. Stat. §§ 30-2662 to 2663 (1975); N.J. Stat. Ann. §§ 46:2B-8 to 9 (West Supp. 1979-1980); N.M. Stat. Ann. §§ 45-5-501 to 502 (1978); N.Y. Gen. Oblig. Law § 5-1601 (McKinney 1978); N.C. Gen. Stat. § 47-115.1 (1976 & Supp. 1979); N.D. Cent. Code §§ 30.1-30-01 to 02 (1976); Ohio Rev. Code Ann. §§ 1337.09-.091 (Page 1979); Okla. Stat. Ann. tit. 58, §§ 1051-1062 (West Supp. 1979-1980); Or. Rev. Stat. §§ 126.407, .413 (1979); Pa. Stat. Ann. tit. 20, §§ 5601-5602 (Purdon 1975); S.C. Code § 32-13-10 (Supp. 1979); Tex. Prob. Code Ann. tit. 17A, § 36A (Vernon Supp. 1980); Utah Code Ann. §§ 75-5-501 to 502 (1978); Vt. Stat. Ann. tit. 14, §§ 3-51-3052 (Supp. 1979); Va. Code §§ 11-9.1 to .2 (1978); Wash. Rev. Code Ann. §§ 11.94.010-.020 (Supp. 1980-1981); Wyo. Stat. §§ 34-9-101 to 110 (1977). See also Uniform Durable Power of Attorney Act, 8 U.L.A. 74-80 (1981).

anecdotal evidence that it has occurred, but this use has not been the subject of any reported judicial decisions.¹⁷

Statutory Developments. In addition to the existing statutes that provide a means for patients to create one type of advance directive or another, several model statutes have been proposed specifically to allow such directives in health care.¹⁸ In evaluating existing or proposed means or in devising new ones, several factors need to be taken into account. Four groupings of such considerations are presented here to suggest the range of issues the Commission believes should be addressed in evaluating statutory alternatives.

Requisites for a valid directive. Special attention needs to be given to the basic requisites for a valid directive, particularly since some of the statutes that might be employed—such as the durable power of attorney acts—were not designed specifically for the appointment of proxy health care decisionmakers.

Decisionmaking capacity of principal: There should be some way to establish that a person filling out a directive (the principal) was legally competent to do so at the time. The emphasis of this Report (as discussed in Chapters Three and Eight) is on patients possessing decisional capacity rather than on legal competence. Should a statute insist that when a directive is executed the person has the capacity to understand the choice embodied in the directive? To certify a signatory's capacity, statutes often require one or two witnesses to a document. It would seem advisable for a statute to be clear on whether the witnesses must attest to the principal's capacity or merely serve as safeguards against fraudulent signatures. Since such witnesses are likely to be laypeople, the standard of decisionmaking capacity they apply will rest on common sense, not psychological expertise.

Due regard for the step being taken: The related concern that everyone involved in the execution of a directive, particularly the principal and the prospective proxy, recognize the seriousness of the step is something that would be more difficult to guarantee by statute. It is, however, a consideration that arises in evaluating the wisdom of using existing durable-power statutes, which were intended to address only property matters. One way to increase the likelihood that due regard is given to the subject matter would be to provide that before a

¹⁷ *Legal Problems of the Aged and Infirm—The Durable Power of Attorney—Planned Protective Services and the Living Will*, 13 REAL PROPERTY, PROBATE AND TRUST JOURNAL 1, 2-4, 35-36, 41 (Spring 1978).

¹⁸ Yale Law School Legislative Services Project, MEDICAL TREATMENT DECISION ACT, Society for the Right to Die, New York (1981) at § 3; UNIFORM HEALTH CARE CONSENT ACT, National Conference of Commissioners on Uniform State Laws, New York (1982) at § 6; UNIFORM RIGHT TO REFUSE TREATMENT ACT, Concern for Dying, Chicago (Draft, May 1982) at §§ 3-5.

directive is executed, the principal (and proxy, where one is involved) must have had a discussion with a health care professional of the patient's objectives and of the directive's potential consequences. This would also help ensure that any instructions reflect a process of active self-determination on the part of the patient-to-be.

Legal effect of directives. Several questions arise about the effects that a directive should have in the law and about how these effects might be achieved.

Registration: Certain documents are officially registered, so that they will not be ignored and so there can be no doubt that all concerned parties are aware of their existence. The process of registration also provides an opportunity to ensure that all the basic documentary requisites have been met; for example, an official who is charged with registering directives could be trained to determine the competence of signers. On the other hand, the additional formality of required registration might seriously discourage the use of directives, and it is doubtful whether in this context—unlike in a commercial or real estate setting—there is really much need for a directive to be on file in a governmental office in order for it to have its desired effect at the time it would be needed.

Legal immunity: A statute should make clear that people acting pursuant to a directive are not subject to civil or criminal liability for any action they take that they would not be liable for were they acting on the direct consent of a competent patient. Yet since directives—particularly those including instructions—may contain unavoidable ambiguities, some leeway must be offered if this legal immunization is to provide adequate reassurance for health care professionals. Some of the existing statutes speak of protection for actions taken in "good faith."¹⁹ Language of this sort provides sensible protection for subsidiary health personnel who follow the orders of the physician in charge of the patient, provided they believe the physician's orders are in line with the directive or have been authorized by a proxy. Some standard of reasonable interpretation of the directive may need to be imposed, however, on an attending physician's reading of the document, lest "good faith" offer too wide a scope for discretion. Such a standard might best be developed in case law and scholarly commentary rather than in the statute itself.

Penalties for noncompliance: In order to make directives legally binding, several states have included penalties in their

¹⁹ See Ala. Code § 22-8A-7 (Supp. 1981); Del. Code Ann. tit. 16 § 2505 (1982); Kan. Stat. Ann. § 65-28,106 (Supp. 1981); N.M. Stat. Ann. § 24-7-7 (1981); Or. Rev. Stat. § 97.065 (1981); Wash. Rev. Code Ann. § 70.122.050 [West 1982]. See also MEDICAL TREATMENT DECISION ACT, *supra* note 18, at § 9; UNIFORM RIGHT TO REFUSE TREATMENT ACT, *supra* note 18, at § 12.

statutes (fines, for example, or suspension or revocation of professional licenses) for failing to follow an advance directive.²⁰ The wisdom or necessity of such penalty clauses depends upon the problem a statute is attempting to remedy. If health care providers are unwilling to share responsibility with patients and, in particular, tend to overtreat patients whose physical or mental condition leaves them unable to resist, then—unless they are made legally binding—advance directives are unlikely to protect effectively patients who want to limit their treatment. On the other hand, if health care professionals are simply unsure of what patients want, or if they are anxious to share decisionmaking responsibility but are apprehensive about their legal liability if they follow the instructions of a person whose decisionmaking capacity is in doubt, then the threat of penalties would be unnecessary. Indeed, it could even be counterproductive if it fostered an adversarial relationship between patient and provider.

Proxy's characteristics and authority. Several special questions arise in the context of health care concerning who may act as a proxy and what the proxy may do.

Competency of the proxy: The basic consideration about a proxy is that he or she should have the capacity to make a particular health care decision when needed. The means for assuring this capacity are not so simply stated, however. Basically, they would seem to be the same ones that are applied to patients themselves, as discussed in Chapter Eight.²¹

Disqualifications: Another issue, which could also be treated as a prerequisite for appointing a proxy, concerns whether limitations should be placed on who may serve. The main consideration is to avoid the appointment of anyone with interests that are adverse to a patient's. In some "natural death" statutes, this has led to explicit exclusion of anyone financially involved (as debtor, creditor, or heir) with the patient.²² Special concern may also be warranted for patients in nursing homes.²³ Unfortunately, in the absence of a special

²⁰ Cal. Health and Safety Code § 7191(b) (Deering Supp. 1982); Kan. Stat. Ann. § 65-28, 107(a) (Supp. 1981); Tex. Rev. Civ. Stat. Ann. art. 4590h § 7(b) (Vernon 1982). See also MEDICAL TREATMENT DECISION ACT, *supra* note 18, at § 9; UNIFORM RIGHT TO REFUSE TREATMENT ACT, *supra* note 18, at § 12.

²¹ See pp. 172-73 *infra*.

²² See Ala. Code § 22-8A-4 (Supp. 1981); Cal. Health and Safety Code § 7188 (Deering Supp. 1982); Del. Code Ann. tit. 16, § 2503(b) (1982); Idaho Code § 39-4505 (Supp. 1982); Kan. Stat. Ann. § 65-28,103(a) (Supp. 1981); Nev. Rev. Stat. § 449.600 (1979); N.C. Gen. Stat. § 90-321(c) (1981); Or. Rev. Stat. § 97.055 (1981); Tex. Rev. Civ. Stat. Ann. art. 4590h § 3 (Vernon 1982); 18 Vt. Stat. Ann. § 5254 (1982); Wash. Rev. Code Ann. § 70.122.030 (West 1982).

²³ See, e.g., Cal. Health and Safety Code § 7188.5 (Deering Supp. 1982): "A directive shall have no force or effect if the declarant is a patient in

group of people who serve as proxies for patients there, the people most readily available—the nursing staff and institutional officers—are typically not disinterested.

Redelegation: In certain circumstances a proxy may be temporarily or permanently unable or unwilling to serve as a substitute decisionmaker. When that occurs, should alternate proxies be limited to people who were named by the principal in an original or amended directive, or, in the absence of such alternates, should a proxy be allowed to delegate his or her authority to another person of the proxy's choosing?²⁴ This issue might be affected by whether either the original or a substitute proxy was a close relative of the patient, as opposed to a stranger.

Access to information: Since the proxy stands in the shoes of the patient and is expected to engage in a comparable decisionmaking process, logically the proxy should have access to the patient's medical record. Yet it may be advisable to limit the proxy's access only to that information needed for the health care decision at hand, in order to respect the patient's interest in privacy.

Bases of decision: In the case of a proxy directive, a proxy would be expected to decide about health care in a way calculated to serve the patient's best interests. Although that concept is an elastic one, the law of each state gives it some meaning, and it has received extensive attention in legal and philosophical commentary.²⁵ Ought the concept of best inter-

a skilled nursing facility...at the time the directive is executed unless one of the two witnesses to the directive is a patient advocate or ombudsman as may be designated by the State Department of Aging for this purpose...." The explanation given by the legislature for enacting this provision is "that some patients in skilled nursing facilities may be so insulated from a voluntary decisionmaking role, by virtue of the custodial nature of their care, as to require special assurance that they are capable of willfully and voluntarily executing a directive."

²⁴ The UNIFORM HEALTH CARE CONSENT ACT addresses this issue in several sections. Section 5 provides for a limited delegation of power by some individuals authorized to consent to health care for another under § 4(a)(2), (b)(2), and (b)(3). According to § 5, the only individuals authorized to consent for another who may delegate their decisional authority are *family members*. Nonfamily health care representatives, who may be appointed according to the terms of § 6, are not authorized to delegate their decisional authority. All delegations must be in writing, and unless the writing so specifies, no further delegation of decisional authority is permitted. Any delegated authority terminates six months after the effective date of the writing.

²⁵ See Joel Feinberg, *RIGHTS, JUSTICE, AND THE BOUNDS OF LIBERTY*, Princeton Univ. Press, Princeton, N.J. (1980); Ruth Macklin, *Return to the Best Interests of the Child*, in Willard Gaylin and Ruth Macklin, eds., *WHO SPEAKS FOR THE CHILD*, Plenum Press, New York (1982); A. M. Capron, *The Authority of Others to Decide About Biomedical*

ests be uniform, or should it vary, within certain outer limits, if the surrogate is the next-of-kin rather than a stranger? An instruction directive, whether by itself or joined with a proxy directive, creates the potential for decisions based upon the particular (and perhaps idiosyncratic) wishes of the patient. The interpretation of such a directive would seem to lie with the surrogate decisionmaker, particularly in the case of a proxy designated by the patient, at least in the first instance. Provision may have to be made, of course, for an administrative mechanism to decide situations in which a health care professional challenges the decision of a proxy on the ground that it is not based on the patient's best interests or on a reasonable interpretation of the patient's instructions.

Administrative aspects. Several procedural concerns probably need to be addressed in any statute for advanced health care directives.

Triggering event: A statute needs to specify how a directive becomes effective. Two sets of concerns are involved. The first, already mentioned, relates to the necessary guarantee that the directive reflects the wishes of the patient. Some of the "natural death" acts, for example, require that a directive must be executed after the patient has been informed of a diagnosis, so that the patient's instructions are arrived at in the context of the actual, not hypothetical, choices to be made.²⁶ Statutes also typically provide that the designation of a surrogate or the content of specific instructions be renewed every few years so that the signatory can reconsider the instructions or designation in light of changed circumstances or opinions.²⁷ Once it is determined that a directive is valid, a separate issue needs to be addressed: what makes it operative? A statute may leave that question to the document itself, to be specified by the person executing the directive. Or it may provide that a particular event or condition brings the document into play. In either case, the triggering event will require both a standard for action and a specification of who will make the determination. For example, a directive may become operative when a physician makes a particular prognosis ("terminal illness") or determines that a patient lacks decisional capacity regarding a particular health care choice.

Intervention with Incompetents, in Gaylin and Macklin, *id.*; Joseph Goldstein, Anna Freud, and Albert J. Solnit, *BEYOND THE BEST INTERESTS OF THE CHILD*. Free Press, New York (1979).

²⁶ See Cal. Health and Safety Code § 7188 (Deering Supp. 1982); Idaho Code § 39-4504 (Supp. 1982); Or. Rev. Stat. § 97.055 (1981); Tex. Rev. Civ. Stat. Ann. art. 4590h § 3 (Vernon 1982).

²⁷ See Cal. Health and Safety Code § 7188 (Deering Supp. 1982); Del. Code Ann. tit. 16, § 2506(c) (1982); Idaho Code § 39-4504 (Supp. 1982); Or. Rev. Stat. § 97.055 (1981).

Revocation: Provision must be made for the process and standard by which a document can be revoked. The theory of self-determination suggests that as long as the principal remains competent, he or she should unquestionably have the power to revoke a directive. But what about an incompetent (incapacitated) person? The "natural death" acts have uniformly provided that *any* revocation by a principal negates a directive.²⁸ In the context of termination of life-sustaining treatment, that result may be sensible, since it would generally seem wrong to cease such treatment based upon a proxy's orders when a patient, no matter how confused, asks that treatment be continued. In other circumstances, however, allowing revocations by an incompetent patient could wreak havoc on a course of treatment authorized by the proxy. Perhaps when a proxy does not believe he or she should be guided by a principal's contemporaneous instructions, on the grounds that the principal is incompetent and is contradicting earlier competent instructions and/or acting against the principal's own best interests, the question of whether to follow the proxy or the principal ought to be subject to independent review.

Review and safeguards: When disputes arise, either about the choice made by a proxy or about an attempted revocation by an apparently incapacitated principal, some means of review will be necessary to safeguard the patient's interests. In some circumstances the review mechanism need only judge the process by which a decision has been reached. In other circumstances it may seem advisable to review the health care decision itself, which in turn may involve either a subjective or an objective approach to the patient's well-being. In the absence of a special provision in the statute, questions of this sort would lead to review by institutional bodies and, eventually, to judicial proceedings.

In sum, serious issues need to be addressed, either in the applicability to health care of existing statutes created to resolve other problems, such as the durable power of attorney acts, or in the drafting or revision of statutes specifically to permit advance directives for health care. Many people are concerned that, as they become old or ill or especially if they are hospitalized, decisions about their health care will pass out of their hands and into those of health care professionals, who may be strangers to them. This widespread concern justifies

²⁸ See Ala. Code § 22-8A-5 (Supp. 1981); Cal. Health and Safety Code § 7189 (Deering Supp. 1982); Del. Code Ann. tit. 16, § 2504 (1982); Idaho Code § 39-4505 (Supp. 1982); Kan. Stat. Ann. § 65-28,104 (Supp. 1981); Nev. Rev. Stat. § 449.620 (1979); N.M. Stat. Ann. § 24-7-6 (1981); N.C. Gen. Stat. § 90-321(e) (1981); Or. Rev. Stat. § 97.055 (1981); Tex. Rev. Civ. Stat. Ann. art. 4590h § 4(a) (Vernon 1982); Wash. Rev. Code Ann. § 70.122.040 (West 1982).

continued attempts to find a simple way to extend at least basic self-determination into a period of decisional incapacity. Although the issue has received particular public attention in the context of terminal illness,²⁹ it is not limited to that setting, and there are good reasons to treat the entire subject of advance directives within a single statute. Without endorsing any particular statute, the Commission does endorse the development of advance directives and encourages patients and professionals to use them as appropriate whether or not there is a specific statute that regulates and enforces their use.

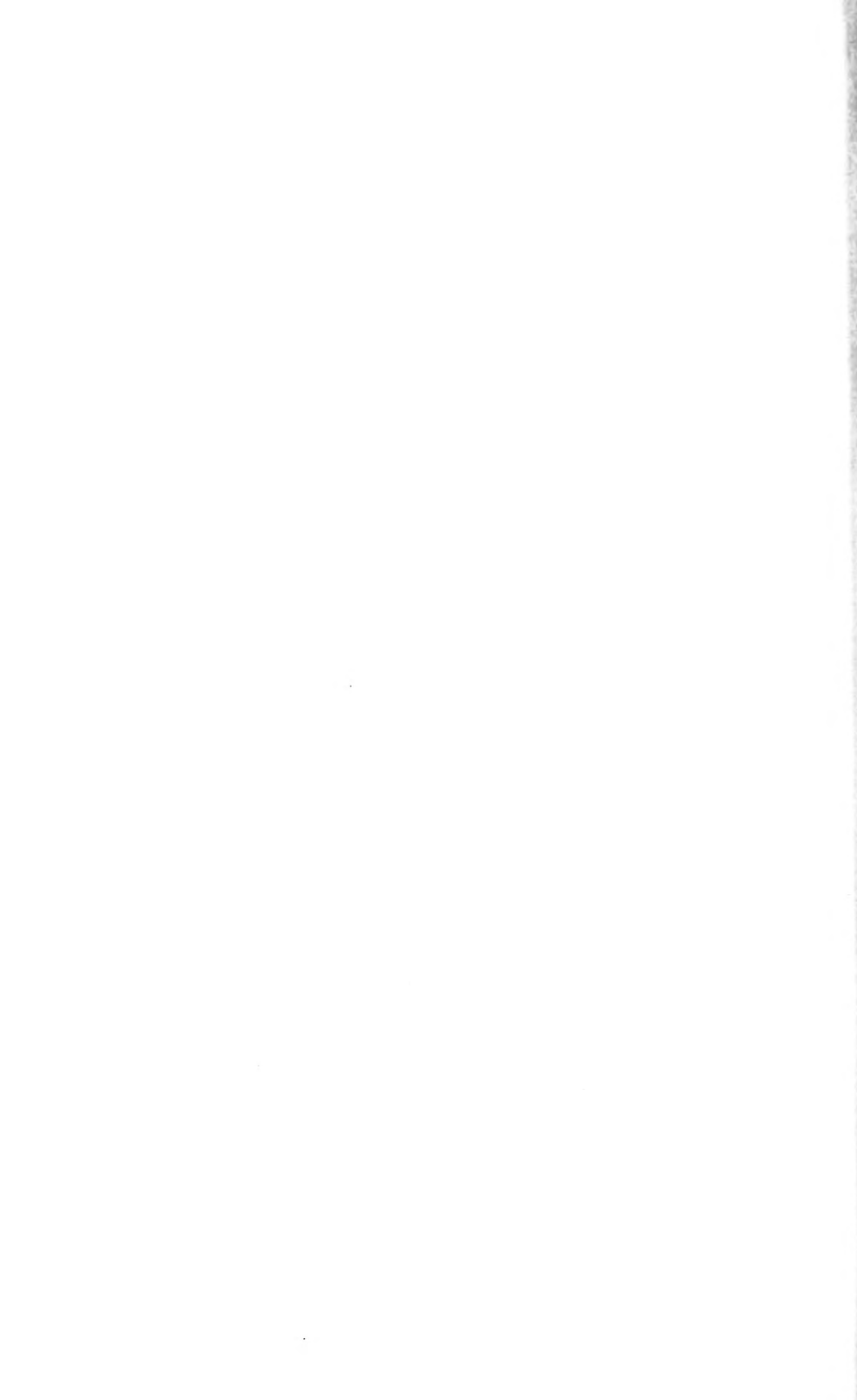
²⁹ Indeed, the subject receives further attention from the Commission in its forthcoming report on deciding about life-sustaining therapy.

Decisionmaking Incapacity

IV

This Report deals primarily with decisionmaking about health care when patients possess the capacity to make their own decisions. Since adults typically are able to decide among most medical alternatives most of the time—a fact reflected in the legal presumption of competence—treatment decisions are usually made with little if any attention to whether or not a patient is incapacitated. When the patient is not incapacitated, there are no signals to raise the issue, which is as it should be. Although data do not exist about the prevalence of decisional incapacity, there is reason to believe that the problem is quite small. Yet when the issue does arise it can greatly complicate decisionmaking, especially when the consequences of a decision are significant.

In the final Part of this Report, the Commission turns briefly to a number of important issues raised by the problem of decisional incapacity: Who is incapacitated? What principles should govern decisionmaking for incapacitated patients? Who should make decisions for incapacitated patients? And what review of such decisions is necessary and appropriate?



Who Is Incapacitated and How Is It To Be Determined?

One of the conditions for health care decisionmaking is the capacity to make such decisions, as described in Chapter Three. The components of decisional capacity were delineated there as possession of a set of values and goals, the ability to communicate and understand information, and the ability to reason and deliberate. This Chapter goes beyond that conceptual framework to discuss more fully three aspects of incapacity: the identification of those who are incapacitated,¹ the means for making such assessments, and the relationship between professionals, institutions, and the state in this process.

Identification of Incapacity

In light of the presumption that most patients have the capacity to make health care decisions, on what grounds might a person be found to lack such a capacity? Three general criteria have been followed: the outcome of the decision, the status or category of the patient, and the patient's functional ability as a decisionmaker.

¹ The terms "incapacity" and "incapacitated" as used in this Report are shorthand labels for patients who lack the capacity to make a particular health care decision, as described in Chapter Three. These terms are not synonymous with either mental or physical incapacity. Though decisional incapacity ordinarily results from mental or physical infirmity, all persons with such infirmities are not *ipso facto* "incapacitated" as that term is used here.

The outcome approach—which the Commission expressly rejects²—bases a determination of incapacity primarily on the content of a patient's decision. Under this standard, a patient who makes a health care decision that reflects values not widely held or that rejects conventional wisdom about proper health care is found to be incapacitated.

Using the status approach, certain categories of patients have traditionally been deemed incapable of making treatment decisions without regard to their actual capabilities.³ Some of these categories of patients—such as the unconscious—correspond closely with actual incapacity. But other patients who are presumed to be incapacitated on the basis of their status may actually be capable of making particular health care decisions. Many older children, for example, can make at least some health care decisions,⁴ mildly or moderately retarded individuals hold understandable preferences about health care, and the same may be true in varying degrees among psychotic persons.

The third approach to the determination of incapacity focuses on an individual's actual functioning in decisionmaking situations rather than on the individual's status. This approach is particularly germane for children above a certain age (variously described as from seven to mid-teens).⁵ For example, rather than considering children under the age of majority incompetent to decide unless they come within one of the exceptions created by the statutory and common law, these patients could be regarded as competent unless shown to lack decisionmaking capacity.⁶ Similarly, a senile person may have

² See p. 61 *supra*.

³ See Loren H. Roth, Alan Meisel, and Charles W. Lidz, *Tests of Competency to Consent to Treatment*, 134 AM. J. PSYCHIATRY 279 (1977).

⁴ See Lois A. Weithorn and Susan B. Campbell, *The Competency of Children and Adolescents to Make Informed Treatment Decisions*, 53 CHILD DEVELOPMENT (in press); Sanford L. Leiken, *Minors' Assent or Dissent to Medical Treatment* (1982), Appendix K, in Volume Three of this Report; Barbara Mishkin, *The Report and Recommendations of the National Commission for the Protection of Human Subjects: Research Involving Children*, 1 ADVANCES IN LAW & CHILD DEVELOPMENT 63, 76 (1982).

⁵ Weithorn and Campbell, *supra* note 4. See also Thomas Grisso, *JUVENILES' WAIVER OF RIGHTS—LEGAL AND PSYCHOLOGICAL COMPETENCE*, Plenum Press, New York (1981).

⁶ Law has traditionally viewed people under a specified age—long set at 21 years and more recently at 18—as precluded from making decisions about any contractual matters, including their own health care. In effect, there has been a presumption of *incompetency*, contrary to the usual presumption of competency accorded adults. Some exceptions of a loosely functional nature have been created for “emancipated” or “mature” minors, in recognition that some children under some circumstances in fact have the capacity to make health

been declared incompetent by a court and a guardian may have been appointed to manage the person's financial affairs, but the functional standard would not foreclose the need to determine whether the senility also negated the individual's capacity to make health care decisions. What is relevant is whether someone is in fact capable of making a particular decision as judged by the consistency between the person's choice and that individual's underlying values and by the extent to which the choice promotes the individual's well-being as he or she sees it.

The Commission recommends that determinations of incapacity be guided largely by the functional approach, that individuals not in certain basic categories (such as under the age of 14, grossly retarded, or comatose) should be assumed to possess decisionmaking capacity until they demonstrate otherwise, and that incapacity should be found to exist only when people lack the ability to make decisions that promote their well-being in conformity with their own previously expressed values and preferences.⁷ The fact that a patient belongs to a category of people who are often unable to make general

care decisions and that for reasons of social policy such decisions ought to be sufficient. This system, based on a general rule of incompetence with an ever-expanding number of statutory exceptions, has meant that children are more often presumed competent to make health care decisions, or has at least brought about an implicit lowering of the age of presumed incompetence. See A. M. Capron, *The Competence of Children as Self-Deciders in Biomedical Interventions*, in Willard Gaylin and Ruth Macklin, eds., *WHO SPEAKS FOR THE CHILD*, Plenum Press, New York (1982) at 57-114.

The Commission endorses this general trend, recognizing that there is an age, below about 14 years old, at which the traditional presumption of incompetence still ought to govern. The presumption, however, is merely a starting point for inquiry. Even when children lack the capacity to make decisions, their involvement in the decisionmaking process not only acknowledges their individual status but also may enhance their cooperation in and compliance with therapeutic procedures. The variations in children's capabilities could appropriately be recognized by providing that for certain interventions, a practitioner should obtain both the *consent* of a child's legal guardian and the *assent* of the child. The latter would be insufficient by itself to authorize the intervention, but the intervention could not go ahead without it. Cf. National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, *REPORT AND RECOMMENDATIONS: RESEARCH INVOLVING CHILDREN*, Government Printing Office, Washington (1977) at 5-19.

⁷ When efforts to communicate with a patient and learn his or her preferences would jeopardize the patient's well-being because of an urgent need for treatment, it is appropriate for health care providers to treat the patient as incapacitated and to turn to a surrogate decision-maker or, when none is available, to care for the patient without consent, as permitted by the "emergency" exception. See generally

decisions for their own well-being or that an individual makes a highly idiosyncratic decision should alert health care professionals to the greater possibility of decisional incapacity. But it does not conclusively resolve the matter.

Rarely—again, the unconscious patient is the main exception—will incapacity be absolute. Even people with impaired capacity usually still possess some ability to comprehend, to communicate, and to form and express a preference. In such cases, even when ultimate decisional authority is not left with a patient, reasonable efforts should be made to give the person relevant information about the situation and the available options and to solicit and accommodate his or her preferences.

Assessments of Incapacity

The objective of any assessment of decisional incapacity is to diminish errors of mistakenly preventing competent persons from directing the course of their own treatment or of failing to protect the incapacitated from the harmful effects of their decisions. Health care professionals will probably play a substantial role, if not the entire one, in the initial assessment and the finding may never be reviewed by outside authorities. Nonetheless, since assessment of an individual's capacity is largely a matter of common sense, there is no inherent reason why a health care professional must play this role.

"Decisionmaking incapacity" is not a medical or a psychiatric diagnostic category; it rests on a judgment of the type that an informed layperson might make—that a patient lacks the ability to understand a situation and to make a choice in light of that understanding. Indeed, if a dispute arises or a legal determination of a patient's competence is required, the judge empowered to make the determination will consider the situation not as a medical expert but as a layperson. On the basis of the testimony of health care personnel and others who know the individual well, and possibly from personal observation of the patient, the judge must decide whether the patient is capable of making informed decisions that adequately protect his or her own interests.

Health care professionals are called upon to make these assessments because the question of incapacity to make health care decisions usually arises while a person is under their care. Particularly within institutions such as hospitals, a treating physician often involves colleagues from psychiatry, psychology, and neurology who have ways to accumulate, organize, and analyze information relevant to such assessments.⁸ These

Alan Meisel, *The "Exceptions" to the Informed Consent Doctrine: Striking a Balance Between Competing Values in Medical Decision-making*, 1979 Wis. L. Rev. 413, 436, 476.

⁸ The "mental status examination" is perhaps the best example of how

examinations can yield considerable information about the patient's capabilities. The sources of useful information to be collected include discussions of the situation with relatives and other care-givers, particularly those in close contact with the patient, such as nurses. Ultimately, whether a patient's capabilities are sufficiently limited and the inadequacies sufficiently extensive for the person to be considered incapacitated is a matter for careful judgment in light of the demands of the situation. If the patient improves (or worsens) or if the decision to be made has different consequences, a reassessment of the individual's capacity may be required.

Finally, in any assessment of capacity due care should be paid to the reasons for a particular patient's impaired capacity, not because the reasons play any role in determining whether the patient's judgment is to be honored but because identification of the causes of incapacity may assist in their remedy or removal.⁹ The Commission urges that those responsible for assessing capacity not be content with providing an answer to the question of whether or not a particular patient is incapacitated. Rather, in conjunction with the patient's health care team (of which the assessor may be a member), they should to the extent feasible attempt to remove barriers to decisional capacity.

Policies and Procedures

It is important for the sake of consistency and accuracy—and even more so for the protection of the right to self-determination in the pursuit of well-being—that health care professionals and institutions develop clear policies to assess incompetency. Such policies should acknowledge who within an institution has initial and ultimate responsibility for making such determinations and should, at least in a general way, instruct those who assess capacity about the kinds of inquiries to make, data to collect, and records to keep.

professional expertise can be enlisted in making assessments of incapacity. Such an evaluation is intended, among other things, to elicit the patient's orientation to person, place, time, and situation, the patient's mood and affect, and the content of thought and perception, with an eye to any delusions and hallucinations; to assess intellectual capacity, that is, the patient's ability to comprehend abstract ideas and to make a reasoned judgment based on that ability; to review past history for evidence of any psychiatric disturbance that might affect the patient's current judgment; and to test the patient's recent and remote memory and logical sequencing.

⁹ See Paul S. Appelbaum and Loren H. Roth, *Clinical Issues in the Assessment of Competency*, 138 AM. J. PSYCHIATRY 1462 (1981); Loren H. Roth et al., *The Dilemma of Denial in the Assessment of Competency to Refuse Treatment*, 139 AM. J. PSYCHIATRY 910 (1982).

Patient capacity for decisionmaking will usually be called into question first by attending health care personnel or possibly (though less likely) by the family. Although formal legal procedures exist for determining incompetency, usually such determinations are made extrajudicially; only occasionally are they subsequently subjected to judicial review.¹⁰ The status of nonjudicial determinations of incapacity is therefore uncertain, though there is a growing trend toward requiring formal, judicial proceedings in certain nonroutine situations, such as the termination of life-sustaining treatment¹¹ or the administration of irreversible procedures (for example, sterilization).¹²

¹⁰ The problem of who is to make health care decisions when patients are incapacitated is one that has been the subject of only scant judicial analysis. Evidently this has been recognized for quite some time. At the turn of the century, one legal treatise writer noted that "where an operation is to be performed upon...[a] person *non compos mentis*, who is to give consent is not decided." Edgar Benton Kinkead, COMMENTARIES ON THE LAW OF TORTS: A PHILOSOPHIC DISCUSSION OF THE GENERAL PRINCIPLES UNDERLYING CIVIL WRONGS EX DELICTO, Bancroft Whitney Co., San Francisco (1903) § 376 at 789. One of the leading informed consent cases gives the subject very short shrift: "Where the complaint in suit is unauthorized treatment of a patient legally or factually incapable of giving consent, the established rule is that, absent an emergency, the physician must obtain the necessary authority from a relative." *Canterbury v. Spence*, 464 F.2d 772, 789 n.92 (D.C.Cir. 1972).

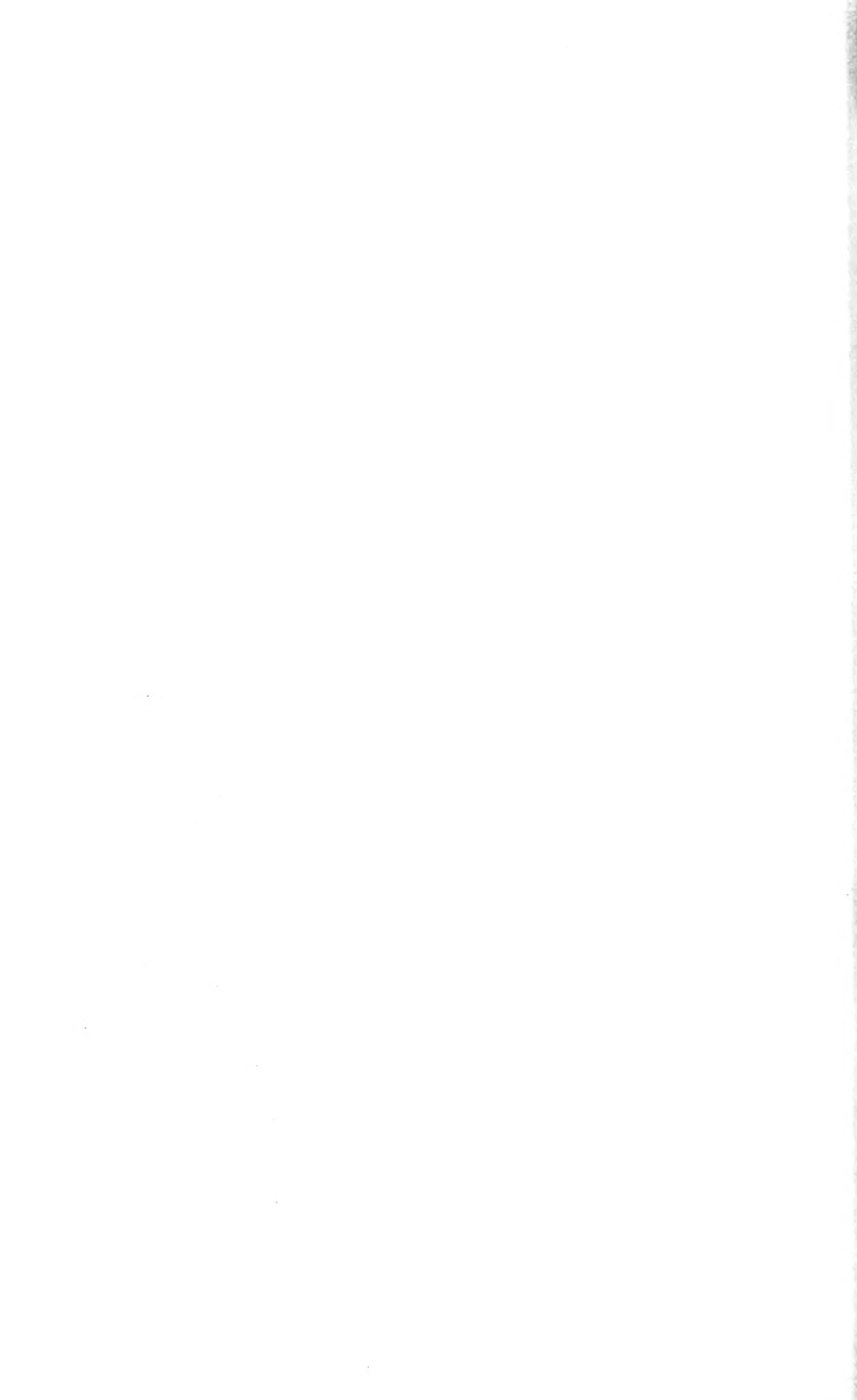
The procedure to be followed in making treatment decisions for incapacitated patients has been appropriately characterized as "haphazard." See Charles P. Kindregan, *The Court as Forum for Life and Death Decisions: Reflections on Procedures for Substituted Consent*, 11 SUFFOLK U. L. REV. 919, 924 (1977). Rather than comprehensive judicial analysis, there is a conflicting collection of platitudes that fails to address many of the issues that are involved. See, e.g., *Lester v. Aetna Cas. & Sur. Co.*, 240 F.2d 676 (5th Cir. 1957); *Karp v. Cooley*, 493 F.2d 408 (5th Cir. 1974). About the only generalization that can be made is found in the treatises suggesting that the proper practice when the patient cannot give consent is for a close family member to do so if one is available. See, e.g., 2 HOSPITAL LAW MANUAL, *Consents* (1975) paragraph 4-12, at 58; Joseph H. King Jr., THE LAW OF MEDICAL MALPRACTICE IN A NUTSHELL, West Publishing Co., St. Paul, Minn. (1977) at 140; Note, 14 CIN. L. REV. 161, 170-72 (1940). The practice of obtaining consent from family members "is so well known in society at large that any individual who finds the prospect particularly odious has ample warning to make other arrangements better suited to protecting his own ends or interests." A. M. Capron, *Informed Consent to Catastrophic Disease Treatment and Research*, 123 U. PA. L. REV. 340, 424-25 (1974).

¹¹ See the Commission's forthcoming Report on decisions about life-sustaining treatment.

¹² 44 TENN. L. REV. 879 (1977); 17 NEW ENG. L. REV. 527 (1981-82).

The Commission believes that determinations of incapacity are best made without routine recourse to the courts. Although there is a loose parallel between the criteria for judicial determinations of incompetence and the determination of decisional incapacity, the judicial processes leading to the appointment of a guardian or conservator ordinarily address an individual's incapacity to manage property and financial matters. As a result, guardians are often, though not always, financial institutions or institutional employees such as bankers, who are either ill-suited to or uninterested in the task of managing an individual's personal affairs.

Furthermore, resorting to the courts to adjudicate incompetency—that is, to confirm the patient's lack of decisional capacity—is often so burdensome to both providers and patients or to their families that there is a tremendous reluctance to undertake it. Even when an adjudication of incompetency is sought, the proceedings are in many cases so perfunctory and/or deferential to the professional expertise of providers that the role of the courts amounts to little more than pro forma ratification of what was readily apparent to health professionals. Thus the Commission recommends that, except where state law clearly requires judicial intervention, determinations of decisional incapacity be made at the institutional level and that lawmakers be encouraged to recognize the validity of such determinations. This recognition will require institutions to adopt procedures that merit such deference; in turn, it should reinforce for all participants in the process the importance of reaching a sound decision.



Substantive and Procedural Principles of Decisionmaking for Incapacitated Patients

Substantive Principles

As described in Chapter Two, there are two values that guide decisionmaking for competent patients: promoting patient welfare and respecting patient self-determination. They should also guide decisionmaking for incapacitated patients, though of necessity their implementation must differ. They are reflected, roughly speaking, in the two different standards that have traditionally guided decisionmaking for the incapacitated: "substituted judgment" and "best interests." Although these standards are now used in health care situations, they have their origins in a different context—namely, the resolution of family disputes and decisions about the control of the property of legal incompetents. When people become seriously disabled and unable to manage their property, they may be judged incompetent and a guardian appointed to make financial and property decisions. These doctrines were developed to instruct guardians about the boundaries of their powers without issuing detailed and specific guidelines and to provide a standard for guidance of courts that must review decisions proposed by a guardian.¹

Simply stated, under the substituted judgment standard, the decisions made for an incapacitated person should attempt to arrive at the same choice the person would make if

¹ See generally Lawrence A. Frolik, *Plenary Guardianship: An Analysis, a Critique, and a Proposal for Reform*, 23 ARIZ. L. REV. 599 (1981).

competent to do so (but within boundaries of "reasonableness" intended to protect the incompetent).² Under the best interests standard, decisions are acceptable if they would promote the welfare of the hypothetical "average person" in the position of the incompetent, which may not be the same choice the individual would make (but which may still have some aspects of subjectivity to it).³

Despite the long legal history of both these standards, they provide only hazy guidance for decisionmaking even in their original contexts, not to mention in the often far more complex, urgent, and personal setting of health care. Although a number of recent cases involving decisions about health care for incapacitated patients have given courts the opportunity to clarify these often vague guidelines, increased confusion may have accompanied some of the attempts to add precision to these doctrines.

Substituted Judgment. The substituted judgment standard requires that the surrogate attempt to replicate faithfully the decision that the incapacitated person would make if he or she were able to make a choice. In so doing, the patient's interest in achieving well-being as he or she defines it in accordance with personal values and goals, as well as the individual's interest in self-determination, are both honored to the maximum extent possible, given the fundamental reality that the patient literally cannot make a contemporaneous choice. The surrogate's decision is limited, however, by two general external constraints. First, the surrogate is circumscribed by the same limitations that society legitimately imposes on patients who are capable of deciding for themselves,⁴ such as not compromising public health (e.g., by refusing a mandatory vaccination) or not taking steps contrary to the criminal law (e.g., intentional maiming). Second, there are certain decisions that a patient might be permitted to make but that are outside the discretion of substitute decisionmaking and must therefore be decided by the standards of "reasonableness." This is

² For example, the substituted judgment doctrine permits a surrogate to make a gift of some of an incompetent's assets to a relative to whom the incompetent person had previously made gifts. The court will approve such a gift to the extent that it does not endanger funds needed for the incompetent's support—even if the incompetent person would have been willing to be more generous.

³ The best interests doctrine has received most attention in law in cases involving questions of the custody and care of children, *see generally* 2 C.J.S. *Adoption of Persons* §§ 90-91 (1972), and in cases involving the expenditure of trust funds, *see generally* 76 AM. JUR. 2d, *Trusts* § 288 (1975), neither of which are entirely accurate guides to understanding how the standard ought to operate in instances of surrogate health care decisionmaking for adults who lack decision-making capacity.

⁴ *See* Chapter Two *supra*.

especially true for cases in which the decision risks imposing substantial harm on patients or depriving them of substantial benefit; people may volunteer for risky research with no direct therapeutic benefits to themselves but guardians may not enroll people in such research merely because it is known that, when they were competent, they believed that such research was very important. Thus even the essentially subjective substituted judgment standard is constrained by external limitations—that is, limitations not arising from the patient's own views.

For the substituted judgment standard to be employed there must be evidence of the patient's views, which could be derived from various sources. The surrogate may be guided in decisionmaking by prior directives expressly made by that patient governing the precise matter at issue. A person might, for instance, have clearly stated that he or she wished to avoid a potentially beneficial treatment that poses a risk of crippled mental faculties if there were another treatment available that, although promising more limited benefits, also poses substantially smaller risks of damaging the mind.

The substituted judgment standard is markedly simpler to use—and contains greater assurance of being faithfully implemented—when a competent individual has given clear directives regarding medical care in the event of incapacity, although such a directive does not necessarily resolve all problems.⁵ When directives are written rather than oral, it is more likely that the surrogate (or a third party who may report the incapacitated patient's putative directions to the surrogate) will not forget or misunderstand the patient's advance directives.

In the absence of advance directives, surrogates may be guided by the known values, goals, and desires of an incapacitated patient. It can reasonably be presumed, for example, that a person who is known to have had a particular aversion to painful medical interventions would wish to continue avoiding them if possible.

Best Interests. Decisionmaking guided by the best interests standard requires a surrogate to do what, from an objective standpoint, appears to promote a patient's good without reference to the patient's actual or supposed preferences. This does not mean the surrogate must choose the means the practitioner thinks is "best" for promoting the patient's well-being, but only a means reasonably likely to achieve that goal. Where, for example, there is more than one therapy available, a decision in favor of any one of those considered appropriate by health care professionals will be acceptable under the best

⁵ See pp. 155-66 *supra*.

interests standard. However, the best interests standard would preclude the surrogate from choosing a therapy that is totally unacceptable by professional standards, even if the surrogate might choose that treatment for him- or herself. Fundamentally, the standard of "reasonableness" is inherently cautious.

In assessing whether a procedure or course of treatment would be in a patient's best interests, the surrogate must take into account such factors as the relief of suffering, the preservation or restoration of functioning, and the quality as well as the extent of life sustained.⁶ An accurate assessment will encompass consideration of the satisfaction of present desires, the opportunities for future satisfactions, and the possibility of developing or regaining the capacity for self-determination.

The impact of a decision on an incapacitated patient's loved ones may be taken into account in determining someone's best interests, for most people do have an important interest in the well-being of their families or close associates. To avoid abuse, however, especially stringent standards of evidence should be required to support a claim that reasonable people would disregard their exclusively self-regarding interests (for example, in prolonging or avoiding suffering) in favor of their interest in avoiding psychological or financial burdens on the people to whom they were attached.

The Standard for Surrogate Decisionmaking. The Commission believes that decisionmaking for incapacitated patients ought, when possible, to be guided by the principle of substituted judgment, since it promotes the underlying values of self-determination and well-being better than the best interests standard does. However, the principle of substituted judgment cannot be employed universally; what some patients would want if competent cannot always be ascertained because of insufficient evidence about a patient's values and preferences or because the patient's cognitive abilities have always been so limited that he or she was never capable of developing or expressing preferences about the decision in question.⁷ When a patient's likely decision is not known, the best interests standard presumes that the individual would

⁶ The phrase "quality of life" has been used in differing ways; sometimes it refers to the value that the continuation of life has for the patient, and other times to the value that others find in the continuation of the patient's life, perhaps in terms of their estimates of the patient's actual or potential productivity or social contribution. In applying the best interest principle, the Commission is concerned with the value of the patient's life for the patient.

⁷ Allen E. Buchanan, *The Limits of Proxy Decision Making for Incompetents*, 29 UCLA L. REV. 393 (1981); John A. Robertson, *Legal Criteria for Orders Not to Resuscitate: A Response to Justice Liacos*, in A. Edward Doudera and J. Douglas Peters, eds., *LEGAL AND ETHICAL*

prefer what most reasonable people would want in similar circumstances. On certain points, of course, no consensus may exist about what "most reasonable people" would prefer. Furthermore, whenever a range of choices exists, even a best interests determination will display an element of subjectivity on the part of the surrogate in defining and weighing the patient's interests.

To the extent feasible, efforts should be made with patients who are incapacitated though able to engage in communication to take into account their expressions of their own values and goals.⁸ Doing so will both promote their welfare as they understand and conceive of it and honor self-determination, though of an attenuated kind. When recovery of the capacity to make decisions is a reasonable possibility, enhancing its prospect should be another goal.

Procedures for Surrogate Decisionmaking

Regardless of the substantive principle used to guide decisionmaking for patients lacking decisional capacity, policies and procedures are needed for the selection and guidance of surrogate decisionmakers. Furthermore, there is a need to specify the circumstances under which review of the surrogate's decision should be permitted or required and who should undertake such a review. The Commission recommends that however these problems are actually to be resolved, health care institutions should have clear policies about who has the authority and responsibility to determine incapacity, to speak for the patient, and to review determinations and decisions.

The Selection of a Surrogate. A sound policy for decisionmaking for incapacitated patients should take into account the urgency of the need to make a decision and the existence of suitable substitutes such as interested family members or a legal guardian.

ASPECTS OF TREATING CRITICALLY AND TERMINALLY ILL PATIENTS, AUPHA Press, Washington, D.C. (1982) at 159-63.

⁸ The only necessary implication of a determination of incapacity to decide about health care is that the patient's decision, if any, may be overruled. Even if patients' decisionmaking capacities are sufficiently impaired that it would be inappropriate to take their preferences as binding, patients may still be able to appreciate many aspects of the decision and may feel they have been treated more respectfully if those vested with the power to make decisions about them recognize the extent to which they are sentient beings with values and preferences of their own. Encouraging participation in the decisionmaking process may in fact facilitate recovery of capacity under some circumstances. These patients would be well served if their surrogates were to let them make such decisions for themselves, although the surrogate's permission may also be required.

Emergencies. When a decision must be made immediately, in order to avoid seriously jeopardizing a patient's life or well-being, health care professionals are the proper decision-makers.⁹ Since such emergency care is so often provided in institutional settings involving many practitioners, one aspect of a sound policy is having the means to assign decisionmaking authority to a particular member of the treatment team. This person should usually be the available professional who is most qualified to make the decision, according to the provider's estimate of the patient's best interests.

The line between emergency and nonemergency decisions will sometimes be hard to draw and will depend in part upon the type of facility and the ready availability of additional personnel for quick consultation. Institutional policy should minimize any tendency to overextend the exceptionally broad decisionmaking authority that genuine emergencies confer on practitioners. As soon as possible, without compromising the patient's well-being, other surrogates (such as family members) should be located, informed about the choices to be made, and involved in the decisionmaking.¹⁰

Nonemergency situations. In nonemergency situations, the proper presumption is that the family, defined to include closest relatives and intimate friends,¹¹ should make health care decisions for an incapacitated patient. There are several grounds for this stance:

- (1) The family is generally most concerned about the good of the patient.

⁹ Allen Buchanan, *Medical Paternalism or Legal Imperialism: Not the Only Alternatives for Handling Saikewicz-type Cases*, 5 LAW & MED. 97, 105-06 (1979); Alan Meisel, *The "Exceptions" to the Informed Consent Doctrine: Striking a Balance Between Competing Values in Medical Decisionmaking*, 1979 WIS. L. REV. 413, 476.

¹⁰ Meisel, *supra* note 9, at 476.

¹¹ The Commission's broad use of the term "family" reflects a recognition of the fact that many of those with most knowledge and concern for the patient may not be his or her actual relatives. The fact that more than one person may fall within this category points to the need to designate one person as the principal decisionmaker for the incapacitated patient. One possibility is to define a presumptive priority, e.g., that a person living with his or her spouse will speak for that spouse, that adult children will speak for elderly widowed parents, etc. In some cases such presumptions may be helpful. Nevertheless, the Commission believes that it is the responsibility of the practitioner to determine who acts as the patient's "surrogate." No neat formulas or serial orderings will suffice to capture the complexities involved in determining who among the individuals presenting themselves as friends and relatives of the patient knows the patient best and has his or her best interests in view. The responsibility is therefore on the practitioner either to determine who this spokesperson is or to go to court to have a guardian appointed.

- (2) The family will also usually be most knowledgeable about the patient's goals, preferences, and values.
- (3) The family deserves recognition as an important social unit that ought to be treated, within limits, as a single decisionmaker in matters that intimately affect its members.

Especially in a society in which many other traditional forms of community have been eroded, participation in a family is often an important dimension of personal fulfillment. Since a protected sphere of privacy and autonomy is required for the flourishing of this interpersonal union, institutions and the state should be reluctant to intrude, particularly regarding matters that are personal and on which there is a wide range of opinion in society.



The presumption that the family is the principal decisionmaker may be challenged for any of a number of reasons: decisional incapacity of family members, unresolvable disagreement among competent adult members of the family about the correct decision, evidence of physical or psychological abuse or neglect of the patient by the family, evidence of bias against the patient's interest due to conflicting interests, or evidence that the family intends to disregard the patient's advance directive or the patient's undistorted, stable values and preferences.¹² Even if, for one or more of these reasons, the family is disqualified from being the principal decisionmaker, it will often be appropriate to include family members in the decisionmaking process.

¹² Buchanan, *supra* note 9, at 111.

Nonemergency situations in which an incapacitated patient has no family but does have a court-appointed guardian raise special issues that are sometimes overlooked. The considerations that support a strong presumption in favor of the family's being the principal decisionmaker are weaker in the case of a court-appointed guardian, unless the guardian had been nominated by the patient prior to his or her incapacitation (in which case the guardian would be included in the definition of family used here).¹³ In the absence of disqualifying reasons, a guardian should act as health care decisionmaker since the person was already making the patient's other, nonhealth-related decisions. Through involvement in past decisionmaking, the guardian may have acquired a knowledge of the patient's beliefs, concerns, and values. Finally, in addition to the ethical grounds there are legal ones: the guardian has the sanction of court authority, which should reduce the concerns of practitioners that following this particular surrogate's decisions will expose them to civil liability.

If no family or legal guardian is initially available, a suitable surrogate decisionmaker should be designated to ensure a clear assignment of authority for decisionmaking and of responsibility for the exercise of this authority. Unless a suitable surrogate decisionmaker is identified, treatment decisions may lack continuity or may rest on an unclear foundation, making it difficult if not impossible to ensure that the process by which decisions are made is ethically and legally sound.

Review Procedures. Many people have "natural guardians" whose authority is either recognized as a matter of law (for example, parents deciding for children) or as a matter of custom (for example, one spouse deciding for the other).¹⁴ The decisions made by such surrogates are not routinely subjected to formal review. Such review is more likely to occur when very significant medical interventions are being contemplated, when disagreement arises between health professionals and surrogate decisionmakers, or when decisions are made by a guardian appointed by the court.

Formal review appears to be occurring with greater frequency; at the least, it is being more widely reported in the press. Review may be more frequent because of practitioners' growing sensitivity to the need to protect the interests of patients or because of their increased fear of legal liability, from which an advance ruling by a court could insulate them.¹⁵

¹³ If an incapacitated patient has both a competent family and a legal guardian, they should function together as principal decisionmakers to the extent permitted by local law.

¹⁴ See note 10, Chapter Eight *supra*.

¹⁵ See generally Robert A. Burt, *TAKING CARE OF STRANGERS*, The Free Press, New York (1979).

Although state law may require judicial review of certain decisions by a surrogate, well-conceived and carefully executed institutional guidelines may eliminate recourse to the courts that is unnecessary for adequate protection of patients' interests. Certainly, formal court proceedings on each and every health care determination would be unduly intrusive, slow, and costly and would frame treatment decisions in misleadingly adversarial terms.¹⁶

Judicial review. The most important kind of formal review at the moment is judicial. The justifications for turning to the courts are: (1) the state has a proper role, as *parens patriae*, in protecting the helpless, such as patients lacking health care decisionmaking capacity; (2) the authority of the state is legitimately exercised by courts in life-and-death matters, as in other important situations requiring individual decision; and (3) courts can reach appropriate judgments because of their expertise and disinterested stance in the resolution of disputes.¹⁷

Greater reliance on advance judicial review has raised a number of concerns about the relative costs and benefits of relying on courts to pass on the decisions of surrogates for incapacitated patients. Judicial review in such cases is costly in terms of time and expense; it can disrupt the process of providing care for a patient, since medical decisionmaking is evolutionary rather than static; it can create unnecessary strains in the relationship between the surrogate decisionmaker and others, such as the health care providers, who may be forced into the role of formal adversaries in the litigation; and it exposes delicate matters that are usually regarded as private

¹⁶ Nevertheless, arrangements should be made to ensure that the appropriate cases do come before a formal tribunal, as when, for example, the patient expresses a desire for judicial review, or the patient's health needs will require continual decisionmaking on a broad range of issues. Further, it is incumbent upon health care providers to seek review when they believe that a surrogate's decision about treatment fails to reflect the patient's values and goals (to the extent that they are ascertainable) or the patient's best interests.

¹⁷ The argument for judicial review is well stated by Professor Baron. See Charles H. Baron, *Assuring "Detached But Passionate Investigation and Decision": The Role of Guardians Ad Litem in Saikewicz-Type Cases*, 4 AM. J. LAW & MED. 111 (1978); Charles H. Baron, *Medical Paternalism and the Rule of Law: A Reply to Dr. Relman*, 4 AM. J. LAW & MED. 337 (1979). See also *In re Roe*, 421, N.E.2d 40, 51-56 (Mass. 1981); *Superintendent of Belchertown State School v. Saikewicz*, 370 N.E.2d 417, 432-35 (1977). The view that judicial review is inappropriate is well stated by Dr. Relman, the editor of the NEW ENGLAND JOURNAL OF MEDICINE. See Arnold S. Relman, *The Saikewicz Decision: A Response to Allen Buchanan's Views on Decision Making for Terminally Ill Incompetents*, 5 AM. J. LAW & MED. 119 (1979).

to the scrutiny of the courtroom and sometimes even to the glare of the communications media.¹⁸

These costs may be justifiable if wiser decisions are made and if patients are provided with additional protection from harm. Frequently, however, it appears that the process of judicial review is merely a formality. Judges may not feel that they are able to add very much to the decisions already reached by those most intimately involved, particularly in cases that are brought simply to obtain judicial sanction for an agreed course of conduct.¹⁹ Rather than being an issue the courts are accustomed to addressing, such as whether the surrogates are appropriate decisionmakers or should be disqualified because they are incompetent or have a conflict of interest, the question typically addressed is whether the treatment chosen is the right one.²⁰ Since this judgment

¹⁸ Buchanan, *supra* note 9, at 105-06.

¹⁹ See, e.g., *In re Nemser*, 51 Misc.2d 616, 273 N.Y.S.2d 624, 629 (S.Ct. 1966), in which a trial court judge to whom a petition for the appointment of a guardian to consent to surgery on an elderly, somewhat incapacitated, but objecting woman, chided the woman's family, the hospital, and the doctors for seeking his imprimatur:

[I]t is apparent that this proceeding was necessitated only because of the current practice of members of the medical profession and their associated hospitals of shifting the burden of their responsibilities to the courts, to determine, in effect, whether doctors should proceed with certain medical procedures definitively found necessary or deemed advisable for the health, welfare, and perhaps even the life of a patient who is either unwilling or unable to consent thereto....

It seems incongruous in light of the physicians' oath that they even seek legal immunity prior to action necessary to sustain life. [H]ow legalistic minded our society has become, and what an ultra-legalistic maze we have created to the extent that society and the individual have become enmeshed and paralyzed by its unrealistic entanglements!

See also William J. Curran, *A Problem of Consent, Kidney Transplantation in Minors*, 34 N.Y.U. L. REV. 891 (1959)

²⁰ See, e.g., *In re Quinlan*, 70 N.J. 10, 355 A.2d 647, 664, *cert. denied*, 429 U.S. 922 (1976):

If a putative decision by Karen to permit this non-cognitive, vegetative existence to terminate by natural forces is regarded as a valuable incident of her right of privacy, as we believe it to be, then it should not be discarded solely on the basis that her condition prevents her conscious exercise of the choice. The only practical way to prevent destruction of the right is to permit the guardian and family of Karen to render their best judgment subject to the qualification hereinafter stated, as to whether she would exercise it in these circumstances. If their conclusion is in the affirmative this decision should be accepted by a society the overwhelming majority of whose members

requires substantial understanding of the patient's medical condition and options, the court may simply defer to the recommendation of the treating physicians. The courts' vaunted disinterest may be closer, in practical effect, to lack of interest.

Institutional review. To provide an alternative that is more responsive to the needs of all parties, "institutional ethics committees"²¹ are increasingly being used.²² Because they are closer to the treatment setting, because their deliberations are informal and typically private (and are usually regarded by the participants as falling within the general rules of medical confidentiality), and because they can reconvene easily or can delegate decisions to a separate subgroup of members, ethics committees may have some marked advantages over judicial review when it comes to decisionmaking that is rapid and sensitive to the issues at hand. Furthermore, testimony presented to the Commission indicated that these committees have had a valuable educational role for professionals.²³

Very little is known, however, about the actual effectiveness of institutional ethics committees, especially in comparison with private, informal mechanisms or with judicial decisionmaking for patients who lack decisionmaking capacity. The composition and functions of existing ethics committees vary substantially from one institution to another. Not enough experience has accumulated to date to know the appropriate and most effective functions and hence the suitable composition of such committees. If their role is to serve primarily as "prognosis committees" to pass on the accuracy of an attending physician's judgment, then committees composed largely of physicians would seem appropriate.²⁴ If the ethics committees are supposed to reach decisions that best reflect the individually defined well-being of patients or the ethicality of decisions, however, it seems doubtful that an exclusively medical group would be suitable. And if the appropriate role of such review

would, we think, in similar circumstances exercise such a choice in the same way for themselves or for those closest to them.

²¹ The Commission uses the term "institutional ethics committee" rather than "hospital ethics committee" because such committees could well function in other health care institutions such as nursing homes.

²² In the past decade, 5% of large hospitals (that is, those with more than 200 beds) have established such committees. Stuart Youngner, *Hospital Ethics Committees* (1982), Appendix to Commission's forthcoming Report on decisions about life-sustaining treatment.

²³ Testimony of Ronald Cranford, M.D., transcript of 21st meeting of the President's Commission (June 10, 1982) at 18, 39.

²⁴ Carole Levine, *Hospital Ethics Committees: A Guarded Prognosis*, 7(3) HASTINGS CTR. REP. 25, 27 (1977); Robert Veatch, *Hospital Ethics Committees: Is There a Role?*, 7(3) HASTINGS CTR. REP. 22, 24 (1977).

bodies should be to determine whether a surrogate decision-maker is qualified to make medical decisions on a patient's behalf (and to set only outer boundaries on the nature of the decision reached rather than second-guessing the choice), membership should be diverse.

Alternative institutional and private arrangements, formal and informal, deserve careful examination and evaluation. Furthermore, important details, such as means of case referral, range of functions, committee composition, protection of privacy, and legal status, have not been debated, much less resolved. From what little is already known, it seems that ethics committees may be able to take a leading role in formulating and disseminating policy on decisionmaking for incapacitated patients, assisting in the resolution of difficult situations, and protecting the interests of incapacitated patients. Although committees can be reasonably prompt, efficient, sensitive, and private, having many of the decisions about health care for the incapacitated made in an informal manner between surrogate and provider is plainly a desirable objective as well, just as routine decisions for competent patients should be made by patient and provider without any outside intervention. Furthermore, just as judicial review may sometimes be an unnecessarily onerous means of reviewing medical decisions, review by an ethics committee may also sometimes be inappropriate.

The Commission believes there should be various kinds of review mechanisms available. Thus, the Commission recommends that health care institutions not only develop appropriate mechanisms but also encourage and cooperate in comparative evaluations of such approaches.²⁵ The results of these studies will have particular importance for society because one presumed advantage of institutional mechanisms is that they avoid the undesirable aspects of having to turn to more formal means of review. Assurance that any new mechanisms have been well thought out and are appropriate to the task is needed before widespread official sanctions can be expected.

²⁵ To assist in this endeavor, the Commission's forthcoming report on decisions about life-sustaining treatment will provide a more detailed examination of the potentials, liabilities, and reported experience with institutional ethics committees and other mechanisms for ensuring that decisionmaking of high quality occurs.

Addendum

Commission Hearings

Informed Consent in Health Care and Research January 10, 1981

Dan W. Brock, Professor of Philosophy, Brown University

Dr. Eric J. Cassell, Clinical Professor of Public Health, Cornell Medical School

Ruth Faden, Professor of Health Services Administration, Johns Hopkins University

Charles W. Lidz, Professor of Sociology, Western Psychiatric Institute and Clinic, University of Pittsburgh

Alan Meisel, Professor of Law and Psychiatry, School of Law, and Law and Psychiatry Program, Western Psychiatric Institute and Clinic, University of Pittsburgh

Arnold J. Rosoff, Professor of Legal Studies, Wharton School, University of Pennsylvania

Dr. Loren Roth, Professor, Law and Psychiatry Program, Western Psychiatric Institute and Clinic, University of Pittsburgh

Informed Consent and the Patient-Provider Relationship July 9, 1981

Tom Beauchamp, Professor and Senior Research Scholar, Kennedy Institute for Bioethics, Georgetown University

Mrs. Martha Weinman Lear, author of Heartsounds

Dr. Edmund Pellegrino, President, Catholic University

Martin Pernick, Professor of History of Medicine, University of Michigan

Dr. Mark Siegler, Professor of Medicine, Pritzker School of Medicine, University of Chicago

Patient Participation in Health-Care Decisions December 11, 1981

Dr. Maxwell Boverman, Psychiatric Consultant to the Assistant for Bioethics to the Director of the Clinical Center, National Institutes of Health

Lawrence W. Green, Professor, Schools of

Government and Public Health, Harvard University

Ruth Watson Lubic, R.N., General Director, Maternity Center Association, New York

Dr. Gordon Ray, Radiotherapist, Palo Alto Medical Foundation

Dr. Arnold Roberts, Obstetrician-Gynecologist, Silver Spring, Maryland

Debra L. Roter, Professor of Health Education, School of Hygiene and Public Health, Johns Hopkins University

Norma Swenson, Boston Woman's Health Collective

Robert Veatch, Professor and Senior Research Scholar, Kennedy Institute for Bioethics, Georgetown University

Dr. Donald Vickery, President, The Center for Consumer Health Education, Vienna, Virginia

Decisionmaking in Health Care: Issues of Competence and the Roles of Families

February 12, 1982

Andrew Duncan, Assistant Administrator, George Washington University Hospital

Dr. Edwin Forman, Pediatric Oncologist, Rhode Island Hospital, Providence

Bernard H. Greene, Visiting Lecturer, Yale Law School

Thomas Grisso, Professor of Psychology, St. Louis University

Gerald P. Koocher, Acting Chief Psychologist, Children's Hospital Medical Center, Boston

Mrs. Minna Nathanson, Director of Policy, Planning and Publication, Candlelighters Foundation, Washington, DC

Dr. David Reiss, Professor and Director of Research, Center for Family Research, George Washington University

William Ruddick, Professor of Philosophy, New York University

Dr. James J. Strain, Professor and Director of Liaison Psychiatry, Mount Sinai School of Medicine, New York

The Education of Physicians and Nurses in Relation to Informed Consent

April 3, 1982

Patricia Balassone, R.N., Research Fellow, Primary Care Programs, University of Maryland

Samuel Bloom, Professor of Sociology and Community Medicine, Mount Sinai School of Medicine, New York

Dr. Lynn Carmichael, Chairman, Department of Family Medicine, University of Miami School of Medicine

Dr. Eugene Hildreth, Chairman of the Board of Internal Medicine and Chief of Medicine, Reading Hospital, Pennsylvania

Elaine Hubbard, R.N., Professor, Rochester University School of Nursing

- Dr. Richard Moy, Dean and Provost, Southern Illinois
School of Medicine, Springfield
- Dr. John Steinhaus, Chairman, Department of
Anesthesiology, Emory University School of
Medicine
- Dr. Louis Sullivan, President and Dean, Morehouse
School of Medicine, Atlanta
- Dr. August Swanson, Director, Department of
Academic Affairs, Association of American Medical
Colleges, Washington, DC

Nursing Consultants

National Nursing Panel

March 5, 1981

- Mila Aroskar, Associate Professor, School of Public
Health, University of Minnesota
- Carol Buder, Clinical Assistant Professor, School of
Nursing, Georgetown University
- Luther Christman, Dean, College of Nursing, Rush-
Presbyterian-St. Luke's Medical Center, Chicago
- Ann J. Davis, Professor, School of Nursing, University
of California, San Francisco
- Sister Rosemary Donley, Dean, School of Nursing,
Catholic University
- Rhetaugh Graves Dumas, Deputy Director, National
Institute of Mental Health
- Veronica Evaneshko, Associate Professor, College of
Nursing, Arizona State University
- Juanita W. Fleming, Professor and Assistant Dean for
Graduate Education, School of Nursing, University
of Kentucky
- Loretta C. Ford, Dean and Director of Nursing,
University of Rochester Medical Center
- Susan R. Gortner, Professor and Associate Dean for
Research, School of Nursing, University of
California, San Francisco
- Ruth Watson Lubic, General Director, Maternity
Center Association, New York
- Catherine Murphy, Assistant Professor, School of
Nursing, Boston University
- Dorothy Sheahan, Assistant Professor, School of
Nursing, University of Pennsylvania

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