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MAKING HEALTH CARE DECISIONS: A REPORT ON THE ETHICAL AND LEGAL IMPLICATIONS OF INFORMED CONSENT IN THE PATIENT-PRACTITIONER RELATIONSHIP, VOLUME 1. By *President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research*. U.S. Government Printing Office. 1982. Pp. 196.

Since it was developed over twenty-five years ago,¹ the doctrine of informed consent has been a hotly contested issue in both the legal and medical professions.² The controversy continues as American society becomes more rights-conscious and consumer-oriented and the health care system becomes increasingly complex.³ In response to these concerns, the President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research (the Commission)⁴ was asked to study and report on "the ethical and legal implications of the requirements for informed consent to . . . undergo medical procedures."⁵ In its study of this subject, the Commission obtained input from a variety of sources, including health care professionals, consumers and scholars, the existing literature, and three empirical studies contracted for by the Commission (pp. 6-7). While the Commission's report examines the law's role in the development of the doctrine of informed consent (pp. 18-31), it focuses on the ethical and practical elements of the doctrine in the broader context of relations between patients and health care professionals (pp. 31-35).

The central theme of the Commission's report is that ethically valid informed consent should consist of a process of shared decisionmaking based on mutual respect and the participation of both the patient and the health care professional. The Commission views this process as the most effective means of promoting the values underlying the doctrine of informed consent: patient well-being and respect for the individual's right to self-determination (pp. 36-39). The Commission recognizes, however, that realization of its ideal model of shared decisionmaking will not be a simple task (pp. 6, 39).

After reviewing the legal origins and ethical values⁶ underlying

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

2. The medical and legal literature on this subject is legion. For a partial listing, see Meisel, *The "Exceptions" to the Informed Consent Doctrine: Striking a Balance Between Competing Values in Medical Decisionmaking*, 1979 WIS. L. REV. 413, 413 nn.2-3, as well as the Commission's report and the literature that it cites.

3. See pp. 32-35; cf. Gillespie, *Unconventional Health Care: A Positive Alternative?*, FAM. & COMMUNITY HEALTH, Nov. 1979, at 40, 41 ("Dissatisfaction with medical treatment and practitioners, general distrust of the 'big business' image of American medicine, the grass-roots movement toward self-care and self-sufficiency, and a striving for freedom of choice and individual responsibility have recently led to an upsurge of interest in unconventional health care.").

4. The Commission is composed of eleven members appointed pursuant to 42 U.S.C. § 300v (Supp. V 1981).

5. 42 U.S.C. § 300v-1(a)(1)(A) (Supp. V 1981).

6. The central values underlying informed consent in the provider-patient relationship are "promotion of a patient's well-being and respect for a patient's self-determination." P. 41. Ascertainment of the course of action that will best promote a patient's well-being is complicated by a frequent lack of "objective medical criteria," p. 42, and the "reasonable subjective preferences" of the particular patient. P. 43. Self-determination has both intrinsic value to the individual, pp. 45-47, and practical limitations. Pp. 47-50. What is perhaps lacking in the

informed consent, the Commission examines the goals and realities of effective patient participation in health care decisionmaking. The report fills in the contours of the shared decisionmaking model: the roles and characteristics of patient and practitioner, the content and extent of information to be exchanged, the method of presentation, and other aspects of the ideal communication process.⁷ These ideals are then compared with the realities reflected in the Commission's empirical studies. These studies included observational research in clinics and hospitals, as well as telephone surveys of the public and of physicians regarding their perception, attitudes, and experiences concerning informed consent and the patient-physician relationship (pp. 70-111). The comparison of the goals with these views of reality and the comparison of these different views of reality with each other (e.g., public versus physicians and observational studies versus survey results) provide an interesting perspective and aid in delineating targets for change.⁸

The next section of the report discusses means for bringing the vision of shared decisionmaking closer to reality. The Commission suggests that a number of practical innovations deserve further study. These include increasing patient access to alternative sources of information such as pharmacists, pamphlets and medical libraries (pp. 115-26), and increasing the involvement of the patient's family in the decisionmaking process (pp. 126-28). The Commission also suggests that the third-party payment system needs to be adjusted in order to reimburse physicians for time spent in shared decisionmaking (p. 120). The Commission further recommends substantial changes in medical education in order to achieve a needed reorientation in professional attitudes.⁹ Possible areas of change include selec-

Commission's analysis is acknowledgment of an explicit as well as functional link between well-being and self-determination. Physicians have traditionally ignored or disparaged the insight that a patient's intuitions about his or her own condition may offer for diagnosis and treatment. See, e.g., Arms, *Why Women Must Be in Control of Childbirth and Feminine Health Services*, in 1 21ST CENTURY OBSTETRICS NOW 73, 82-83 (2d ed. 1978); Gillespie, *supra* note 3, at 44-47; cf. pp. 58-62 (capacity to participate in decisionmaking evaluated on basis of patient's ability to understand medical explanations and to make rational choices of medical options).

7. The Commission defines "three foundations" for "[e]ffective patient participation in health care decisionmaking": decisionmaking capacity, voluntariness, and information. P. 55. Capacity depends upon "(1) possession of a set of values and goals; (2) the ability to communicate and to understand information; and (3) the ability to reason and to deliberate about one's choices." P. 57 (footnote omitted). Voluntariness may be compromised by coerced treatment, pp. 63-66, or more subtly by manipulation. Pp. 66-68. Communication of information promotes two major objectives: the therapeutic function of promoting health by reducing anxiety and the enhancement of patients' ability "to better advance their own life plans." Pp. 69-70.

8. For instance, the percentage of doctors who reported that they always or usually explained treatment alternatives was higher than the proportion of the public reporting that their doctors actually did so. Observational studies in hospital settings indicated that in general patients received little or no information about alternative or recommended treatments. Pp. 78-85.

9. "The 'professional dominance' view of the physician-patient relationship is deeply

tion criteria, content of training, and continuing education (pp. 129-49). In general, the Commission urges that the federal government invest in research regarding the human as well as the scientific component of health care (p. 114).

The Commission does not view the law as playing a major role in the achievement of its vision. The primary reason for this position lies in the practical difficulties inherent in translating the Commission's goal into a workable legal standard. The goal is a process, subjective in nature, that varies with the needs of the particular patient. The law is better suited to dealing with more objective standards. The Commission does recognize, however, that the law plays an important symbolic and functional role in setting minimum standards for disclosure and thus reminding society of its commitment to self-determination (pp. 151-55).

The Commission report concludes with a discussion of issues related to decisionmaking incapacity. The Commission suggests that attention should be directed to legal reforms that would facilitate the recognition of directives made in advance by patients who anticipated their incapacity, so that incapacitated patients would have some input in decisionmaking regarding their own care (pp. 155-66). The Commission discourages routine advance judicial review of surrogate decisionmaking and instead recommends that institutions experiment with various forms of private informal review such as ethics committees (pp. 184-87).

This report contains a wealth of information from a variety of sources. In particular, the results of the Commission's empirical studies are a significant contribution to the literature on informed consent. Informed consent is a frequently misunderstood concept in both the legal and medical communities, as well as among the general public.¹⁰ The Commission's effort represents a worthwhile attempt to clarify some of these misconceptions. It succeeds in many ways; most importantly, it provides a promising view of what informed consent could be. While the report is occasionally redundant, it effectively establishes that shared decisionmaking can make an important contribution to better health care. The ideas and goals in this report deserve further attention from both the legal and health care communities.

rooted in the history of the medical profession and is continued by the process of medical education and socialization into the professional role." P. 129 (footnote omitted).

10. See the survey results reported on pp. 17-18.