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#### **BOOK REVIEW**

Informed Consent: A Study of Decisionmaking in Psychiatry by Charles W. Lidz, Alan Meisel, Eviatar Zerubavel, Mary Carter, Regina M. Sestak, Loren H. Roth, The Guilford Press, New York, London, 1984, 365 pp., \$30.00

## REVIEWED BY MAUREEN D. MUDRON\*

Traditionally, the law protected a patient from unauthorized medical treatment by a physician and from treatment which failed to meet the standards of the medical profession. Treatment without consent gave rise to an action for battery, and treatment which failed to meet the standards of the profession gave rise to an action for malpractice. The doctrine of informed consent added a new dimension to the physician-patient relationship and created an additional element of protection for the patient. Informed consent imposes upon a physician a duty to make certain disclosures to a patient regarding a proposed treatment or procedure. If adequate disclosure is viewed as a necessary element of consent, the patient's lack of knowledge of the risks and consequences of a proposed treatment or procedure vitiates the consent. If viewed as a standard

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<sup>1.</sup> See, e.g., Mink v. University of Chicago, 460 F. Supp. 713 (N.D. Ill. 1978) (battery); Pratt v. Davis, 224 Ill. 300 (1906) (battery); Holtzman v. Hay, 118 Ill. 534 (1886) (malpractice).

See, e.g., Salgo v. Leland Stanford Jr. Univ., 154 Cal. App. 2d 560, 317
P.2d 170 (1957); Green v. Hussey, 127 Ill. App. 2d 174, 262 N.E.2d 156 (1970);
Natanson v. Kline, 186 Kan. 393, 350 P.2d 1093, modified, 187 Kan. 186, 354 P.2d 670 (1960).

In Salgo, the case which is regarded as the first in which the term informed consent was used, the plaintiff had initiated a malpractice action which was based, in part, on a claim that the physicians had not made adequate disclosure to the patient. The trial court's instruction requiring that the physician disclose "all the facts which mutually affect his rights and interests and of the surgical risk, hazard and danger, if any . . ." was considered by the reviewing court to be too broad. In holding that the instruction had to be modified to allow a physician some discretion in determining whether to explain every risk no matter how remote, to a patient, the court stated "the instruction should be modified to inform the jury that the physician has such discretion consistent, of course, with the full disclosure of facts necessary to an informed consent." Salgo, 154 Cal. App. 2d at 572, 317 P.2d at 181.

of professional practice, failure to make disclosure which results in harm to the patient is malpractice. The difference between applying the doctrine as an expansion of the definition of consent or as a standard of professional practice is significant. Under the theory of battery, action by the physician without informed consent warrants liability; in a malpractice claim, action of the physician without informed consent warrants liability only if it is the cause of some harm to the patient.

The states vary concerning whether the failure to obtain informed consent gives rise to a claim for battery or negligence; whether the standard for determining what must be disclosed is based on what the professional community would disclose or what the patient would consider significant; if the standard is what the patient would consider significant, whether it is the specific patient or the reasonable person in the patient's situation; and what, if any, discretion the physician has in limiting disclosure in the patient's interest.<sup>3</sup> The law of consent and informed consent is a creature of the traditions and beliefs of each state, and the values they represent in combination with the legislative and judicial precedents which interpret and give effect to those values through the law.

Whether and to what extent the doctrines of consent and informed consent apply in psychiatric settings is also a question of the law of each state. By definition, consent requires that the patient be competent to make decisions. The historical treatment of the mentally disabled by law, as well as by society, presents a mixed picture of whether they are excepted from the operation of the doctrine.

Authority over the mentally disabled is exercised by the legislatures of the states. This authority has its antecedents in the authority the King of England exercised over the persons and property of the insane.<sup>4</sup> Through legislative enactments, regulation of the mentally disabled and provision for their care and custody was effected. Institutionalization was the states' primary method of meeting their responsibility for the mentally disabled.<sup>5</sup> Power was delegated to the care provider to make decisions necessary to carry out the assigned responsibilities. Consent of the mentally disabled person was not an issue. Over the years, however, as treatment interventions and resources for the mentally disabled and attitudes

<sup>3.</sup> See generally Waltz & Scheuneman, Informed Consent to Therapy, 64 Nw. U.L. REV. 628 (1970) (presenting the differing views, as expressed by commentators and various courts, on the standards to be used in judging the legal sufficiency of disclosure and assent in individual cases).

<sup>4.</sup> See, e.g., Dodge, Conservator v. Cole, 97 Ill. 338 (1881) (reviewing the law and tradition of England regarding authority over the mentally disabled, and discussing its application under the structure of state government).

<sup>5.</sup> See Winslade, Ethics and Ethos in Psychiatry: Historical Patterns and Conceptual Changes, in LAW AND ETHICS IN THE PRACTICE OF PSYCHIATRY 23 (C. Hofling ed. 1981).

about them have changed, the law changed regarding care and custody of the mentally disabled.<sup>6</sup>

The litigation of the last 20 years has challenged the legal status of the mentally disabled and their treatment under the law. The early efforts concentrated on assuring that professional standards were enforced and met in the institutions and on securing alternatives more normalized than institutions.7 The more recent focus in institutional cases has been the challenge to forced treatment. In the few cases which have been decided by the federal appellate courts, much of the analysis focused on the role of the parens patriae and police powers in the relationship between the state and the mentally disabled.8 Two principles, the autonomy of the individual and the authority of the state to protect the health, safety, and welfare of the society, formed the guidelines for deciding the facts of each case. The doctrine of informed consent was not a principle relied on or discussed by the courts in resolving the issues of these cases. The practices and laws of the states at issue in these cases evidence the reluctance of states to embrace completely the doctrine of informed consent for the mentally disabled.

The authors of Informed Consent: A Study Of Decisionmaking In Psychiatry begin their work from the point of view that informed consent is a legal doctrine and an ethical doctrine, and that informed consent applies in psychiatric settings. In the introduc-

<sup>6.</sup> Early Illinois law provided that a person found by a court to be an "idiot, lunatic, or distracted person" would be placed under the authority and responsibility of another. ILL. REV. STAT. ch. 50,  $\S$  1 (1833).

If the person had an estate, a conservator was appointed who had "entire care" of the estate, real and personal. Id. at § 3. If the individual was poor, "the overseer of the poor" of the county would "take charge of the body" and had the power to confine him or her. Id. at § 6.

Later, Illinois law provided that both voluntary and involuntary patients were subject to "such standard treatment including surgery as may be necessary for the welfare of the patient or of the public." ILL. REV. STAT. ch. 91 ½, §§ 4-8, 5-18 (1951).

The present Illinois Code distinguishes between "generally accepted" and other types of mental health and developmental disability services. ILL. REV. STAT. ch. 91 ½, § 2-107 (1983). For generally accepted services a recipient is given the authority to refuse them, unless they are "necessary to prevent the recipient from causing serious harm to himself or others." *Id.* Informed consent is required in order to provide "electro-convulsive therapy, unusual, hazardous, or experimental services or psychosurgery." *Id.* at § 2-110.

<sup>7.</sup> See, e.g., Romeo v. Youngberg, 457 U.S. 307 (1982) (right to safe conditions, freedom from bodily restraints, right to habilitation); Lake v. Cameron, 364 F.2d 657 (D.C. Cir. 1966) (right to least restrictive alternative); Wyatt v. Stickney, 325 F. Supp. 781 (M.D. Ala. 1971) (right to treatment declared in order granting preliminary injunction), aff'd sub nom. Wyatt v. Aderholt, 503 F.2d 1305 (5th Cir. 1974) (affirming trial court's declaration of constitutional right to treatment).

<sup>8.</sup> See, e.g., Rennie v. Klein, 653 F.2d 836 (3d Cir. 1981), vacated, 102 S. Ct. 3506 (1982); Rogers v. Okin, 634 F.2d 650 (1st Cir. 1980), vacated sub nom. Mills v. Rogers, 457 U.S. 291 (1982).

tory chapters of their book, they give a summary history of the development of the legal doctrine of informed consent, highlight the competing interests in formulating the ethical doctrine, and provide background information about a project they undertook to study informed consent. The bulk of the book is devoted to reporting their study. Their concluding chapter provides a summary of their findings, the implications of those findings, and recommendations for improving the implementation of informed consent.

The subject of their book and their study is informed consent. For the authors, informed consent represents "values fundamental to our society, to the community of societies of which we are a part, and to a long religious, ethical, and political tradition." As they point out in their initial chapters, informed consent is not uniformly accepted or appreciated. As an ethical doctrine, they describe two positions on which it can be grounded: deontological, which argues that it is a good in itself or consequential, which argues that it will provide benefit. The ethical doctrine, as the authors describe it, is oriented toward the promotion of "individual autonomy" and the "encouragement of rational decisionmaking." It is the consequentialist position which is deemed relevant by the authors for their work. To determine whether the doctrine accomplishes what its advocates expect or what its detractors fear was an implied goal of the study.

The authors sought to study informed consent as it had not been studied before. In reviewing the empirical literature which existed at the time, they found it both limited and in some instances unreliable. The focus of the studies was almost completely on the patients' understanding. Efforts to look at the disclosure process were based either on hypothetical studies or reviews of consent forms. Voluntariness and the decisionmaking process were hardly considered. The authors identified specific deficiencies in the studies, and ultimately questioned whether what had been reported as fact was correct. They found that in a high proportion of the studies, the conclusions were too sweeping given the reported findings.

In 1976, shortly after revision of the Pennsylvania Mental Health Procedures Act, the authors began their study in a university hospital in that state. The focus of the study was an in depth look at discreet segments of informed consent which, when present, would be evident in a manner capable of empirical study. They developed a model of informed consent, and on that basis determined what they would look for and observe in the hospital. The model developed described how they expected informed consent to oper-

C. Lidz, A. Meisel, E. Zerubavel, M. Carter, R. Sestak, L. Roth, Informed Consent: A Study of Decisionmaking in Psychiatry 330 (1984).
Id. at 4.

ate: "the doctor discloses information to a patient who is competent; the patient understands the information and voluntarily renders a decision." They chose participant observation as the method for conducting the study. They wanted to study a real life setting and observe what actually takes place between clinicians and patients regarding treatment decisions. Because they could not identify in advance how informed consent would look on the units, they decided to observe exchanges and contacts as they happened. They believed that to use a "naturalistic study" rather than a "rigorous experimental or interview design" would give them, better than any other, a "feel" for what was being studied. 12

Their concept of informed consent for the study encompassed a definition of the doctrine as well as specification of the circumstances under which it applied in the treatment setting. To determine which aspects of psychiatric care the doctrine applied to the authors claimed reliance on the Pennsylvania statute, Pennsylvania regulations, case law, common law, legal theory and ethical theory. In their judgment, informed consent applied in the following circumstances: the execution of a voluntary application for inpatient treatment, the formulation of a treatment plan, the use of electroconvulsive therapy, and the use of medications that have a potential of risk.

Three psychiatric settings were studied at the hospital: the evaluation center, an inpatient research unit, and an outpatient clinic. Two observers were used. One was assigned to observe events from the staff's perspective and the other was used to observe events from the patients' perspective. When it happened that both were present at the same event, one recorded all that was said and the other had responsibility to note other aspects of the encounter, such as the nonverbal features of the interactions. They focused on behavior and events related to the elements of their model of informed consent: disclosure of information, understanding of the patient about treatment, competency of the patient, how decisions were made, and the freedom with which patients made their decisions.

The authors identify two problems with their methodology. One is that the observers' presence may result in change in the behavior of those observed and the second is that the samples were not randomly chosen. The authors believe the influence of the observer has been exaggerated due to social scientists' tendency to "overemphasize their own significance for their research subjects." They cite their own findings as evidence that their research

<sup>11.</sup> Id. at 22.

<sup>12.</sup> Id. at 35-36.

<sup>13.</sup> Id. at 38.

subjects were not influenced by the presence of the observers.

The authors' response to the lack of randomness is to indicate that their concern is with universals, not particulars. Their sampling was primarily one of first come, first observed. They observed those patients who first presented themselves at the evaluation center and the outpatient clinic during each period of observation. And they observed in some way all of the patients on the research unit during the period of observation. In their view, the significant questions regarding bias in the sample were whether there was anything about the patients they observed, as patients, that made them different from other patients on the unit who were not seen, and whether there was anything about the settings studied that suggested what went on was significantly different than what would be observed at other mental health settings. To the first they answer, no; to the second, they propose the reader will answer no after reading the book.

The authors devote 12 of 17 chapters to reporting their study. For each of the three settings the same pattern is followed in presenting their work. Four chapters are given to each setting. The first describes the setting, its organization and how it operates; the second and third report on observations about information, understanding and decisionmaking; the fourth is a summary of their findings. They present their work on the units primarily by quoting excerpts from conversations. Contacts between staff, between patients, between staff and patients, between observer and patient, and observer and staff are described in this way and serve as a starting point for the presentation of their findings. Although there are some statistics mentioned, they are incidental to the presentation. In this book, the "data" is the narrative.

The benefit of this type of presentation is that the reader is afforded what the authors hoped to experience in conducting their study through participant observation: an opportunity to develop a "feel" for what was happening at the setting. What it does not provide, however, is an opportunity for the reader, relying on the authors' fieldwork, to make an independent judgment about the authors' findings. The reader must look to a source outside the book to judge the authors' findings. For the reader familiar with the mental health system of care, the descriptions will most likely seem believable, with some difference of opinion on how close to or far from the norm the particular hospital appears. Ultimately, the authors rely on feedback from their colleagues to validate their findings. Although the authors are cautious in discussing the applicability of their observations and findings to other psychiatric settings, they are confident enough in their findings to use them as the basis for making recommendations to others.

Although each of the settings was unique, the authors identified certain findings which were common to all the settings. Their findings paint a picture of how both staff and patients typically approached decisions about treatment. The staff was viewed as having a commitment to a specific outcome in the decisionmaking process based on its view of what was the best treatment it could provide for the patient. The patient was seen as deferring to the physician to make the treatment decision. Disclosure, when made, was made by staff other than the doctor and what was disclosed was influenced by the staff's impression of the patient's competency. Information when disclosed was limited, the disclosure was brief, and it occurred after the decision had been made. The patient's understanding, when it came, occurred over time, not immediately, and was incomplete and technically limited.

The book is an impressive collection of information about informed consent. It is not, however, a book about how the legal doctrine of informed consent is implemented. The authors' "primary finding about informed consent is that it did not often exist." In setting the stage for the presentation of their study, the authors create an expectation that their study will produce a body of knowledge about the effects of informed consent, which will contribute to an assessment of the actual benefits or detriments of the legal doctrine. Without directly acknowledging it, what began as a study of the effects of implementation of informed consent, ended as a study of what was observed in the absence of informed consent. Instead of reporting findings about the effects of implementation of informed consent, the authors reported findings about the elements and patterns of decisionmaking they observed.

For many who will read this book, the term informed consent is commonly understood as a principle or mandate of the law. Throughout the book the authors use the term without always clearly identifying when it is the legal doctrine or the ethical doctrine to which they refer. The authors make clear in their introductory chapters that except for the core of the legal doctrine, which is disclosure, informed consent is in a state of constant flux as the courts extend or contract its coverage. They regard the ethical doctrine as more expansive, having as its goal the reordering of the doctor-patient relationship. In the presentation of their study, the distinction between the two doctrines is blurred. This is especially significant when the authors define the term and identify the treatment situations in which it applies. Taken literally, the authors' primary finding could be read to suggest that the physicians observed in the study and others in similar factual circumstances may be subject to actions for battery or malpractice.

The authors real interest is not in the legal doctrine, except to the extent that it is the force of law which imposes on the physician the obligation to make disclosure. Their interest is in what the doctrine represents. It is an instrument through which to advocate change in the status of the patient as an individual in the health care system. Their definition of informed consent and their application of it reach beyond Pennsylvania law and the legal doctrine. They are partisans in the controversy surrounding the duty to disclose and they articulate their position and rationale well. This book will not serve as a resource for the lawyer interested in learning the requirements or application of the legal doctrine of informed consent in his/her state. It does, however, serve as a useful resource for learning about and understanding the dynamics of various psychiatric settings in which treatment decisions are made, and how in one setting specific types of decisions are made.