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TO : Officers Responsible for Institutional Implementation of DHEW Policy on Protection of Human Subjects

FROM : Chief, Institutional Relations Branch, Division of Research Grants, NIH, DHEW

SUBJECT: Considerations in the Review of Projects (5)

Informed Consent: Legal Review

Attached are parts of the decision of the Supreme Court of California in the case of Cobbs v. Grant, 502 P.2d 1, constituting an extensive review by that court of the question of informed consent. Though the discussion is heavily weighted with California cases, citations are also given for significant cases in twelve other states and in Federal courts.

The review raises several interesting issues. Note for instance in paragraph (5) the basis for the arguement that the negligence theory of failure to obtain informed consent carries with it more than academic interest, the denial of the applicability of community standards in consent in paragraph (7), the arguements against the discretionary right of physicians to withhold information, developed in paragraphs (8)-(10). The "community standard" approach comes under attack again in paragraph (11) with respect to reasonableness of disclosure. Fortunately, the court concludes in paragraph (13) that "a lengthy polysyllabic. . .mini-course in medicine is not required."

This material is forwarded for your consideration. It does not necessarily reflect DHEW policy, and does not mandate any decisions by your institution's review committees. It may, however, constitute the basis for an interesting and valuable discussion with your legal counsel, particularly as it relates to the legal climate in your own jurisdiction.

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Enclosure

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(1) Since the question of informed consent is likely to arise on retrial, we address ourselves to that issue. In giving its instruction the trial court relied upon Berkey v. Anderson (1969 1 Cal.App.3d 790, 803, 82 Cal.Rptr. 67, a case in which it was held that if the defendant failed to make a sufficient disclosure of the risks inherent in the operation, he was guilty of a "technical battery" also see Pedesky v. Bleiberg (1967) 251 Cal.App.2d 119, 123, 59 Cal.Rptr. 294; Hundley v. St. Francis Hospital (1958) 161 Cal.App.2d 800,802, 327 P.2d 131). While a battery instruction may have been warranted under the facts alleged in Berkey, in the case before us the instruction should have been framed in terms of negligence.

(2) Where a doctor obtains consent of the patient to perform one type of treatment and subsequently performs a substantially different treatment for which consent was not obtained, there is a clear case of battery. (Berkey v. Anderson (1969) supra, 1 Cal.App.3d 790, 82 Cal.Rptr. 67 (allegation of consent to permit doctor to perform a procedure no more complicated than the electromyograms plaintiff had previously undergone, when the actual procedure was a myelogram involving a spinal puncture); Bang v. Charles T. Miller Hospital (1958) 251 Minn. 427, 88 N.W.2d 186 (plaintiff consented to a prostate resection when uninformed that this procedure involved tying off his sperm ducts); Corn v. French (1955) 71 Nev. 280, 289 P.2d 173 (patient consented to exploratory surgery; doctor performed a mastectomy); Zoterell v. Repp (1915) 187 Mich. 319, 153 N.W. 692 (consent given for a hernia operation during which doctor also removed both ovaries).

(3) However, when an undisclosed potential complication results, the occurrence of which was not an integral part of the treatment procedure but merely a known risk, the courts are divided on the issue of whether this should be deemed to be a battery or negligence. (Gray v. Grunnagle (1966) 423 Pa. 144, 223 A.2d 663 (failure to warn a patient a spinal operation involved an inherent risk of permanent paralysis; battery): Belcher v. Carter (1967) 13 Ohio App.2d 113, 234 N.E.2d 311 (failure to warn of danger of radiation burns; battery); Nolan v. Kechijian (1949) 75 RM. 165, 64 A.2d 866 (operation to strengthen ligaments of spleen when spleen was removed; trespass to the body and negligence): Natanson v. Kline (1960) 186 Kan. 393, 350 P.2d 1093 (radiation treatment produced a severe burn; semble battery or negligence); Natanson v. Kline (1960) 187 Kan. 186, 354 P.2d 670 (rehearing of previous case; negligence); Mitchell v. Robinson (Mo.1960) 334 S.W. 2d 11 (vertebrae broken during insulin shock treatment; negligence.) California authorities have favored a negligence theory. (Carmichael v.

Reitz (1971) 17 Cal.App.3d 958, 95 Cal.Rptr. 381 (pulmonary embolism caused by adverse reaction to drug; negligence); Dunlap v. Marine (1966) 242 Cal.App.2d 162, 51 Cal.Rptr. 158 (cardiac arrest allegedly caused by administration of anesthetic; negligence); Tangora v. Matanky (1964) 231 Cal.App.2d 468, 42 Cal.Rptr. 348 (anaphylactic shock as a result of intramuscular penicillin shot; negligence); Salgo v. Leland Stanford, etc., Bd. of Trustees (1957) 154 Cal.App.2d 560, 317 P.2d 170 paralysis of lower extremities after aortographic examination; negligence).

(4) Dean Prosser surveyed the decisions in this area and concluded, "The earliest cases treated this as a matter of vitiating the consent, so that there was liability for battery. Beginning with a decision in Kansas in 1960 (Natanson v. Kline (1960) supra, 187 Kan. 186 (354 P.2d 670)), it began to be recognized that this was really a matter of the standard of professional conduct... . .(T)he prevailing view now is that the action. . .is in reality one for negligence in failing to conform to the proper standard. . . ." (Fns. omitted; Prosser on Torts (4th ed. 1971) pp. 165-166).

(5) Although this is a close question, either prong of which is supportable by authority, the trend appears to be towards categorizing failure to obtain informed consent as negligence. That this result now appears with growing frequency is of more than academic interest; it reflects an appreciation of the several significant consequences of favoring negligence over a battery theory. As will be discussed infra, most jurisdictions have permitted a doctor in an informed consent action to interpose a defense that the disclosure he omitted to make was not required within his medical community. However, expert opinion as to community standard is not required in a battery count, in which the patient must merely prove failure to give informed consent and a mere touching absent consent. Moreover a doctor could be held liable for punitive damages under a battery count, and if held liable for the intentional tort of battery he might not be covered by his malpractice insurance. (Comment, Informed Consent in Medical Malpractice (1967) 55 Cal.L.Rev. 1396). Additionally, in some jurisdictions the patient has a longer statue of limitations if he sues in negligence.

(6) We agree with the majority trend. The battery theory should be reserved for those circumstances when a doctor performs an operation to which the patient has not consented. When the patient gives permission to perform one type of treatment and the doctor performs another, the requisite element of deliberate intent to deviate from the consent given is present. However, when the patient consents to certain treatment and the doctor performs the treatment but an undisclosed inherent complication with a low probability occurs, no intentional deviation from the consent given appears; rather, the doctor in obtaining consent may have failed to meet his due care duty to disclose pertinent information. In that situation the action should be pleaded in negligence.

(7) Since this is an appropriate case for the application of a negligence theory, it remains for us to determine if the standard of care described in the jury instruction on this subject properly delineates defendant's duty to inform plaintiff of the inherent risks of the surgery. In pertinent part, the court gave the following instruction: "A physician's duty to disclose is not governed by the standard practice in the community; rather it is a duty imposed by law. A physician violates his duty to his patient and subjects himself to liability if he withholds any facts which are necessary to form the basis of an intelligent consent by the patient to the proposed treatment."

(8) The thesis that medical doctors are invested with discretion to withhold information from their patients has been frequently ventilated in both legal and medical literature. (See; e.g., Salgo v. Leland Stanford, etc., Board of Trustees (1957) supra, 154 Cal.App.2d 560, 578, 317 P.2d 170; Mitchell v. Robinson (Mo.1960) supra, 334 S.W. 2d 11 (even though patient was upset, agitated, depressed, crying, had marital problems and had been drinking, the court found that since no emergency existed and he was legally competent he should have been advised of the risks of shock therapy); Mosely, Textbook of Surgery (3d ed. 1959) pp. 93-95; Laufman, Surgical Judgment in Christopher's Textbook of Surgery (Davis ed. 1968) pp. 1459, 1461; Louisell & Williams, Medical Malpractice (1970) § 22.02; McCoid, A Reappraisal of Liability for Unauthorized Medical Treatment (1957) 41 Minn.L.Rev. 381; Plante, An Analysis of "Informed Consent" (1968) 36 Fordham L.Rev. 639). Despite what defendant characterizes as the prevailing rule, it has never been unequivocally adopted by an authoritative source. Therefore we probe anew into the rationale which purportedly justifies, in accordance with medical rather than legal standards, the withholding of information from a patient.

Preliminarily we employ several postulates. The first is that patients are generally persons unlearned in the medical sciences and therefore, except in rare cases, courts may safely assume the knowledge of patient and physician are not in parity. The second is that a person of adult years and in sound mind has the right, in the exercise of control over his own body, to determine whether or not to submit to lawful medical treatment. The third is that the patient's consent to treatment, to be effective, must be an informed consent. And the fourth is that the patient, being unlearned in medical sciences, has an abject dependence upon and trust in his physician for the information upon which he relies during the decisional process, thus raising an obligation in the physician that transcends arms-length transactions.

(9) From the foregoing axiomatic ingredients emerges a necessity, and a resultant requirement, for divulgence by the physician to his patient of all information relevant to a meaningful decisional process. In many instances, to the physician, whose training and experience enable a self-satisfying evaluation, the particular treatment which should be

undertaken may seem evident, but it is the prerogative of the patient, not the physician, to determine for himself the direction in which he believes his interests lie. To enable the patient to chart his course knowledgeably, reasonable familiarity with the therapeutic alternatives and their hazards becomes essential.

(10) Therefore, we hold, as an integral part of the physician's overall obligation to the patient there is a duty of reasonable disclosure of the available choices with respect to proposed therapy and of the dangers inherently and potentially involved in each.

(11) A concomitant issue is the yardstick to be applied in determining reasonableness of disclosure. This defendant and the majority of courts have related the duty to the custom of physicians practicing in the community. (Aiken v. Clary (Mo.1965) 396 S.W.2d 668, 675; Roberts v. Young (1963) 369 Mich. 133, 119 N.W.2d 627, 630; Haggerty v. McCarthy (1962) 344 Mass. 136, 181 N.E.2d 562, 565; Di Filippo v. Preston (Del.1961) 3 Storey 539, 173 A.2d 333, 339). The majority rule is needlessly overbroad. Even if there can be said to be a medical community standard as to the disclosure requirement for any prescribed treatment, it appears so nebulous that doctors become, in effect, vested with virtual absolute discretion. (See Note, Physicians and Surgeons (1962) 75 Harv.L.Rev. 1445; Waltz and Scheuneman, Informed Consent to Therapy (1970) 64 Nw.U.L.Rev. 628.) The court in Canterbury v. Spence, supra, 464 F.2d 772, 784, bluntly observed; "Nor can we ignore the fact that to bind the disclosure obligation to medical usage is to arrogate the decision on revelation to the physician alone. Respect for the patient's right of self-determination on particular therapy demands a standard set by law for physicians rather than one which physicians may or may not impose upon themselves." Unlimited discretion in the physician is irreconcilable with the basic right of the patient to make the ultimate informed decision regarding the course of treatment to which he knowledgeably consents to be subjected.

(12) A medical doctor, being the expert, appreciates the risks inherent in the procedure he is prescribing, the risks of a decision not to undergo the treatment, and the probability of a successful outcome of the treatment. But once this information has been disclosed, that aspect of the doctor's expert function has been performed. The weighing of these risks against the individual subjective fears and hopes of the patient is not an expert skill. Such evaluation and decision is a nonmedical judgment reserved to the patient alone. A patient should be denied the opportunity to weigh the risks only where it is evident he cannot evaluate the data, as for example, where there is an emergency or the patient is a child or incompetent. For this reason the law provides that in an emergency consent is implied (Wheeler v. Barker (1949) 92 Cal.App.2d 776, 785, 208 P.2d 68;

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Preston v. Hubbell (1948) 87 Cal.App.2d 53, 57-58, 196 P.2d 113), and if the patient is a minor or incompetent, the authority to consent is transferred to the patient's legal guardian or closest available relative (Callard v. Anderson (1971) 4 Cal.3d 873, 883, 95 Cal.Rptr. 1, 484 P.2d 1345; Doyle v. Giuliucci (1965) 62 Cal.2d 606, 43 Cal.Rptr. 697, 401 P.2d 1; Bonner v. Moran (1941) 75 U.S.App.D.C. 156, 126 F.2d 121). In all cases other than the foregoing, the decision whether or not to undertake treatment is vested in the party most directly affected; the patient.

(13) The scope of the disclosure required of physicians defies simple definition. Some courts have spoken of "full disclosure" (e.g., Berkey v. Anderson, supra, 1 Cal.App.3d 790, 804, 82 Cal.Rptr. 67; Salgo v. Leland Stanford, etc. Bd. of Trustees, supra, 154 Cal.App.2d 560, 578, 370 P.2d 170) and others refer to "full and complete" disclosure (Stafford v. Shultz (1954) 42 Cal.2d 767, 777, 270 P.2d 1; Pashley v. Pacific Elec. Ry. Co. (1944) 25 Cal.2d 226, 235, 153 P.2d 325), but such facile expressions obscure common practicalities. Two qualifications to a requirement of "full disclosure" need little explication. First, the patient's interest in information does not extend to a lengthy polysyllabic discourse on all possible complications. A mini-course in medical science is not required; the patient is concerned with the risk of death or bodily harm, and problems of recuperation. Second, there is no physician's duty to discuss the relatively minor risks inherent in common procedures, when it is common knowledge that such risks inherent in the procedure are of very low incidence. When there is a common procedure a doctor must, of course, make such inquiries as are required to determine if for the particular patient the treatment under consideration is contraindicated--for example, to determine if the patient has had adverse reactions to antibiotics; but no warning beyond such inquiries is required as to the remote possibility of death or serious bodily harm.

(14) However, when there is a more complicated procedure, as the surgery in the case before us, the jury should be instructed that when a given procedure inherently involves a known risk of death or serious body harm, a medical doctor has a duty to disclose to his patient the potential of death or serious harm, and to explain in lay terms the complications that might possibly occur. Beyond the foregoing minimal disclosure, a doctor must also reveal to his patient such additional information as a skilled practitioner or good standing would provide under similar circumstances.

(15) In sum, the patient's right of self-decision is the measure of the physician's duty to reveal. That right can be effectively exercised only if the patient possesses adequate information to enable an intelligent choice. The scope of the physician's communications to the patient, then, must be measured by the patient's need, and that need is whatever information is material to the decision. Thus

the test for determining whether a potential peril must be divulged is its materiality to the patient's decision. (Canterbury v. Spence, supra, 464 F.2d 772, 786).

(16) Whenever appropriate, the court should instruct the jury on the defenses available to a doctor who has failed to make the disclosure required by law. Thus, a medical doctor need not make disclosure of risks when the patient requests that he not be so informed. (See discussion of waiver; Hagman, The Medical Patient's Right to Know, supra, 17 U.C.L.A.L.Rev. 758, 785). Such a disclosure need not be made if the procedure is simple and the danger remote and commonly appreciated to be remote. A disclosure need not be made beyond that required within the medical community when a doctor can prove by a preponderance of the evidence he relied upon facts which would demonstrate to a reasonable man the disclosure would have so seriously upset the patient that the patient would not have been able to dispassionately weigh the risks of refusing to undergo the recommended treatment. (E.g., see discussion of informing the dying patient; Hagman, The Medical Patient's Right to Know, supra, 17 U.C.L.A.L.Rev. 758, 778). Any defense, of course, must be consistent with what has been termed the "fiducial qualities" of the physician-patient relationship. (Emmett v. Eastern Dispensary & Cas. Hosp. (1967) 130 U.S.App.D.C. 50, 396 F.2d 931, 935).

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