Expansion of the Scope of Disclosure Required under the Informed Consent Doctrine: Moore v. The Regents of the University of California

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Expansion of the Scope of Disclosure Required under the Informed Consent Doctrine: Moore v. The Regents of The University of California

I. INTRODUCTION

The informed consent doctrine has traditionally required that a physician disclose to a patient the nature, risks and benefits of a proposed medical procedure.¹ The California courts¹ and legislature¹


2. See, Magan Medical Clinic v. California State Bd. of Medical Examiners, 249 Cal. App. 2d 124, 132, 57 Cal. Rptr. 256, 262 (1967) (recognizing that a patient deserves to be free of any suspicion that a physician's judgment has been affected by a profit motive).

3. See CAL. BUS. & PROF. CODE § 654.1 stating in its pertinent part:
   Persons licensed under Chapter 4 (commencing with Section 1600) of this division or licensed under Chapter 5 (commencing with Section 2000) of this division or licensed under any initiative act referred to in this division relating to osteopaths may not refer patients, clients, or customers to any clinical laboratory licensed under Section 1265 in which the licensee has any membership, proprietary interest, or co-ownership in any form, or has any profit-sharing arrangement, unless the licensee at the time of making such referral discloses in writing such interest to the patient, client or customer. The written disclosure shall indicate that the patient may choose any clinical laboratory for purposes of having any laboratory work or assignment performed.

CAL. BUS. & PROF. CODE, § 654.1 (West 1986).

See also CAL. BUS & PROF. CODE § 654.2 stating in its pertinent part:
   a) It is unlawful for any person licensed under this division or under any initiative act referred to in this division to charge, bill, or otherwise solicit payment from a patient on behalf of, or refer a patient to, an organization in which the licensee, or the licensee's immediate family, has a significant beneficial interest, unless the licensee first discloses in writing to the patient, that there is such an interest and advises the patient that the patient may choose any organization for the purpose of obtaining the services ordered or requested by the licensee.
   b) The disclosure requirements of subdivision (a) may be met by posting a
have also recognized that the scope of disclosure required under the 
informed consent doctrine may require the disclosure of additional 
information beyond that directly related to the patient's medical 
treatment. Indeed, the recent California Supreme Court decision in 
*Moore v. The Regents of the University of California* clearly 
extends the informed consent doctrine to require the disclosure of eco-
nomic or research interests in the proposed medical procedure. 

This Note will review the informed consent doctrine and the scope 
of disclosure traditionally required under that doctrine. The in-
formed consent doctrine, as it applies to economic and research in-
terest in a particular medical situation, derives from both case law and 
international, federal, and state statutes. The scope of disclo-
sure required by the informed consent doctrine under both case law 
and statutes will be reviewed.

This Note will then discuss the conflicting loyalties that a physi-
cian having either an economic or research interest in a particular 
patient faces when obtaining that patient's informed consent. 
Ultimately, this Note will conclude that, in light of the decision in 
*Moore v. The Regents of the University of California*, any interest 
causing the physician to have conflicting loyalties must be disclosed 
under the California doctrine of informed consent.

This Note will not directly address the claims for conversion of 
physically cells presented in *Moore* because the supreme court denied 
the conversion claims. In addition, several commentaries specifically 
address the claim for conversion of bodily cells presented in *Moore*.

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4. *Moore v. Regents of the University of California*, 51 Cal. 3d 120, 793 P.2d 
5. *See infra* notes 11-21 and the accompanying text.
6. *See infra* notes 22-41 and the accompanying text.
7. *See infra* notes 42-52 and the accompanying text.
8. *See infra* notes 105-26 and the accompanying text.
9. *Moore v. Regents of the University of California*, 51 Cal. 3d 120, 121, 793 
P.2d 492, 493, 271 Cal. Rptr. 146, 147 (1990). Typically, the "knowledge of risks in-
*Food Drug Cosm. L.J.* 331 (1989) (addressing the property issues raised by the Court of 
Appeal decision in the Moore Case.); Danforth, *Cells, Sales, and Royalties: The Pa-
II. SUMMARY OF CALIFORNIA INFORMED CONSENT LAW

In California, the informed consent doctrine requiring a physician to obtain a patient's informed consent to a particular medical procedure or face liability for malpractice was articulated in Salgo v. Leland Stanford, Jr. University Board of Trustees. The court required the physician to disclose all the facts necessary for patients to give their informed consent to the procedure. This decision, together with the requirement that a patient's informed consent be obtained before proceeding with a medical procedure, placed a significant duty of disclosure upon the physician.

The rationale behind placing a duty of disclosure on a physician was further articulated by the California Supreme Court in Cobbs v. Grant:

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.

The court in Cobbs v. Grant also stated that the listed rationale produced a requirement "for divulgence by the physician to his patient of all information relevant to a meaningful decisional process." In addition, the court considered this duty of disclosure to be "an integral part of the physician's overall obligation to the patient.

The scope of the physician's disclosure to the patient "must be measured by the patient's need, and that need is whatever information is material to the decision." The extent of what information that patients should share in profits made from their tissue based on a property right in the body; Note, Toward the Right of Commerciality: Recognizing Property Rights in the Commercial Value of Human Tissue, 34 UCLA L. REV. 207 (1986) (arguing for a limited property right in the commercial value of the body).

12. Id. at 578, 317 P.2d at 181.
13. 8 Cal. 3d 229, 502 P.2d 1, 104 Cal. Rptr. 505 (1972).
14. Id. at 242, 502 P.2d at 9, 104 Cal. Rptr. at 513.
15. Id.
16. Id. at 243, 502 P.2d at 10, 104 Cal. Rptr. at 514.
17. Id. at 245, 502 P.2d at 11, 104 Cal. Rptr. at 515 (emphasis added). See also
might be material to the patient's decision has been addressed by the court. In *Truman v. Thomas*, the court defined material information as "that which the physician knows or should know would be regarded as significant by a reasonable person in the patient's position when deciding to accept or reject the recommended medical procedure."

The California courts and the legislature have determined the type and extent of the information that must be disclosed to the patients regarding their treatment. Some courts have used the terms "full and complete" disclosure and have stated that any "material concealment or misrepresentation will amount to fraud . . . ." The courts have recognized that in addition to disclosing the nature, risks of, and alternatives to the proposed treatment, additional information not directly related to the patient's treatment may have to be disclosed.

In *Magan Medical Clinic v. California State Board of Medical Examiners*, the court specifically recognized that if a physician stood to profit from the sale of the therapeutic drugs to the patient, this fact must be disclosed to the patient. The court further stated that the disclosure of this sort of information was required because "[c]ertainly a sick patient deserves to be free of any reasonable suspicion that his doctor's judgment is influenced by a profit motive." The court recognized that failure to disclose such potential profits would be a violation of section 654.2 of the California Business and Profession Code and thus thwart the legislature's intentions.

The California courts and legislature have clearly contemplated that a physician must disclose any direct or indirect interests in pharmacies, drug manufacturers, medical supply companies, medical

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Canterbury v. Spence, 464 F.2d 772, 786 (D.C. Cir.), cert. denied, 409 U.S. 1064 (1972) (holding that a medical practitioner must inform a patient of any information a reasonable patient would consider material to the decision of whether to undergo the proposed medical treatment).

20. *Id.*
22. *Id.*
23. *Id.* at 132, 57 Cal. Rptr. at 262.
24. *Id.*
diagnostic laboratories, and dispensing optical businesses. The test for whether a physician’s relationship with a particular entity must be disclosed appears to be whether that entity or organization provides services or supplies for the physician-patient relationship.

The requirement that information material to the patient’s decision must be disclosed is sufficiently broad to encompass a physician’s research interest in a patient. The Nazi atrocities carried out under the pretext of scientific research together with several reports of research subject abuse in the United States have led to both international, federal and state regulations governing human experimentation.

All of the above regulatory systems rely on informed consent as one of the principal methods to prevent the abuse of human research subjects. For example, the judgment of the Nuremburg Military Tribunal included the Nuremburg Code which indicated that voluntary consent was an essential component of preventing human subject abuse while conducting human experimentation. The scope of the disclosure to the research subject was stated in general terms and included disclosure of “the nature, duration, and purpose of the ex-

26. See supra notes 2-3 and the accompanying text.
27. See supra note 23.
29. The atrocities included high-altitude, malaria and sterilization experiments. For a chilling description of the exact atrocities, see J. AREEN P. KING, S. GOLDBERG & A. CAPRON, LAW, SCIENCE AND MEDICINE 907-24 (1984) [hereinafter J. AREEN, LAW, SCIENCE AND MEDICINE].
31. The Nuremberg code explained the importance of informed consent as follows:
   I. The voluntary consent of the human subject is absolutely essential.
   This means that the person involved should have legal capacity to give consent; should be so situated as to be able to exercise free power of choice, without the intervention of any element of force, fraud, deceit, duress, over-reaching, or other ulterior form of constraint or coercion; and 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. This latter element requires that before the acceptance of an affirmative decision by the experimental subject there should be made known to him 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 experiment.

Nuremberg Case, reprinted in J. AREEN, LAW, SCIENCE, AND MEDICINE, supra note 29, at 925.
experiment.”32 In addition, the Nuremburg Code required that information as to the exact methods used to conduct the experiment be disclosed to the human subject.33

The first federal regulations governing research using human subjects34 required that the informed consent of each human subject be obtained and documented.35 The scope of disclosure required by these federal regulations includes the purpose, duration, procedures used, risks, any discomfort and benefits to the research subject or any benefits to others.36 A complete description of any benefits to others that might “reasonably be expected from the research”37 ap-

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32. Id.
33. Id.
36. The Department of Health and Human Services, the successor to the Department of Health, Education and Welfare, requires informed consent to contain eight basic elements as follows:
(1) A statement that the study involves research, an explanation of the purposes of the research and the expected duration of the subject's participation, a description of the procedures to be followed, and identification of any procedures which are experimental; (2) A description of any reasonably foreseeable risks or discomforts to the subject; (3) A description of any benefits to the subject or to others which may reasonably be expected from the research; (4) A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject; (5) A statement describing the extent, if any, to which confidentiality of the records identifying the subject will be maintained; (6) for research involving more than minimal risk, an explanation as to whether any compensation and an explanation as to whether any medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained; (7) An explanation of whom to contact for answers to pertinent questions about the research and research subjects' rights, and whom to contact in the event of a research-related injury to the subject; and (8) a statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled. 45 C.F.R. § 46.116(a)(1)-(8) (1988)(emphasis added).
37. 45 C.F.R. § 46.116(a)(3) (1988). For a discussion of the financial disclosure required by federal employees, see infra note 52 and the accompanying text.
pears to cover a physician's financial gains. Under this particular language, the financial gains would have to be disclosed if they were reasonably expected. Thus, extremely speculative financial gains or very indirect financial gains would not have to be disclosed.

In California, the Protection of Human Subjects in Medical Experimentation Act governs human research that is exempt from the federal regulations. This Act requires a scope of disclosure to the research subject, similar to that which is required under the federal regulations. However, the California Act does not specifically men-

39. For financial gains to be reasonably expected, it would appear that the chances of gain occurring must be reasonably certain. Speculation is defined as hope. BLACK'S LAW DICTIONARY 1255 (5th ed. 1979).
41. The Protection of Human Subjects in Medical Experimentation Act requires that a research subject:
   (a) Be informed of the nature and purpose of the experiment.
   (b) Be given an explanation of the procedures to be followed in the medical experiment, and any drug or device to be utilized.
   (c) Be given a description of any attendant discomforts and risks reasonably to be expected from the experiment.
   (d) Be given an explanation of any benefits to the subject reasonably to be expected from the experiment, if applicable.
   (e) Be given a disclosure of any appropriate alternative procedures, drugs or devices that might be advantageous to the subject, and their relative risks and benefits.
   (f) Be informed of the avenues of medical treatment, if any, available to the subject after the experiment if complications should arise.
   (g) Be given an opportunity to ask any questions concerning the experiment or the procedures involved.
   (h) Be instructed that consent to participate in the medical experiment may be withdrawn at any time and the subject may discontinue participation in the medical experiment without prejudice.

  Id. at § 24172(a)-(h).

Additional requirements include:
   (a) Except as otherwise provided in this section, no person shall be subjected to any medical experiment unless the informed consent of such person is obtained.
   (b) If a person is under a conservatorship of the person or of the person and estate, pursuant to Division 4 (commencing with Section 1400) of the Probate Code, informed consent for a medical experiment involving such person shall be obtained:
      (1) As provided in Section 2354 of the Probate Code if the person has not been adjudicated to lack the capacity to give informed consent for medical treatment.
      (2) As provided in Section 2355 of the Probate Code if the person has been adjudicated to lack the capacity to give informed consent for medical treatment.
   (c) If an adult person is gravely disabled, as defined in subdivision (h) of Section 5008 of the Welfare and Institutions Code, and is under a conservatorship of the person or of the person and estate, pursuant to Chapter 3 (commencing with Section 5350) of Part 1 of Division 5 of the Welfare and Institutions Code.
tion disclosure of benefits to persons other than the research subject.

A. The Conflicts of the Physician-Researcher

Several professional codes and governmental regulations require that physicians act only for the good of their patients. This requirement is one of several reasons that physicians have been held to have a fiduciary relationship with their patients. Typically, a fiduciary (the physician) is required to act in good faith and with due regard for the interests of the beneficiary (the patient) who is dependent on and trusts the fiduciary. In fulfilling this duty of good faith, the

Code, informed consent for a medical experiment involving such person shall be obtained from such person, unless the conservator of such person has the right to consent to medical treatment on behalf of the conservatee, pursuant to subdivisions (c) and (d) of Section 5357 and Section 5358 of the Welfare and Institutions Code.

(d) If an adult person is developmentally disabled, as defined in subdivision (a) of Section 4512 of the Welfare and Institutions Code, and has no conservator and is mentally incapable of giving informed consent, informed consent shall be obtained for a medical experiment involving such person, pursuant to subdivision (c) of Section 4655 of the Welfare and Institutions Code.

(c) Informed consent given by a person other than the human subject pursuant to subdivisions (b) through (d), inclusive, of this section shall only be for medical experiments related to maintaining or improving the health of the human subject or related to obtaining information about a pathological condition of the human subject.

Id. § 24175.

42. See, e.g., the ancient Hippocratic oath states, "I will apply dietetic measures for the benefit of the sick according to my ability and judgement; I will keep them from harm and injustice . . . Whatever houses I may visit, I will come for the benefit of the sick, remaining free of all intentional injustice . . . ." The Hippocratic Oath reprinted in J. Areen, Law, Science & Medicine, supra note 29, at 273.

The preamble to the American Medical Association, Principles of Medical Ethics states, "The medical profession has long subscribed to a body of ethical statements developed primarily for the benefit of the patient." American Medical Association, Principles of Medical Ethics, reprinted in J. Areen, Law, Science and Medicine, supra note 29, at 275.

The Declaration of Helsinki made by the 18th World Medical Assembly in 1964 and subsequently revised in 1975 and 1983 provides:

The Declaration of Geneva of the World Medical Association binds the physician with the words, "The health of my patient will be my first consideration," and the International Code of Medical Ethics declares that a physician shall act only in the patient's interest when providing medical care which might have the effect of weakening the physical and mental condition of the patient.

The Declaration of Helsinki, reprinted in, J. Areen, Law, Science and Medicine, supra note 29, at 927.


fiduciary is required to give the beneficiary full disclosure of any adverse interest.45

The goals of a researcher are naturally different from those of a physician. The researcher wants to produce new knowledge that will either benefit the current research subject or future patients.46 This is different than a physician who is only concerned with treating that particular patient. In addition, the researcher may be motivated by the desire for recognition, promotion, or to obtain funding.47 Given these additional conflicts inherent to the researcher, the doctrine of informed consent requires a more rigorous disclosure in the research setting. For example, the federal regulations require the disclosure of “the benefits the subject or others may receive from the research”48 and whether financial compensation for research or treatment is available.49

The physician and the researcher may be consciously or unconsciously motivated by the desire for financial gain. The physician is required by California law to disclose direct and indirect interests in entities that provide medical services and products.50 This requirement helps assure that the patient’s consent to the particular medical procedure is truly informed.51 The researcher is also required by governmental regulations to make a disclosure of various direct and in-

45. Wendt v. Fischer, 243 N.Y. 439, 440, 154 N.E. 303, 304 (1926) (Justice Cardozo described the disclosure requirements of a fiduciary duty, “[d]isclosure so indefinite and equivocal does not set the agent free to bargain for his own account... If dual interests are to be served, the disclosure to be effective must lay bare the truth, without ambiguity or reservation, in all its stark significance.”); Berkey v. Anderson, 1 Cal. App. 3d 790, 804, 82 Cal. Rptr. 67, 77 (1969) (requiring full disclosure); Stafford v. Shultz, 42 Cal. 2d 767, 773, 270 P.2d 1, 7 (1954) (requiring full and complete disclosure).
50. See supra notes 21-25 and the accompanying text.
51. CAL. BUS. & PROF. CODE § 654.1 (West 1986) (requiring written disclosure of certain interests), true informed consent requires the disclosure of any information a patient would consider material to his or her decision of whether to undergo the proposed medical procedure. Canterbury v. Spence, 464 F.2d 772 (D.C. Cir. 1972), cert. denied, 409 U.S. 1064 (1972).
III. Exposition of the Case

A. The Facts

The requirement that a physician researcher disclose to the patient any research interests in, and possible future financial benefits flowing from a patient's tissue, was recently set forth by the California Supreme Court in Moore v. The Regents of the University of California. In 1974 John Moore, the plaintiff, started experiencing various symptoms of his illness, including fevers, abdominal pains and increased incidences of bruising. These symptoms continued until 1976 when he was diagnosed as having hairy-cell leukemia. His physician referred him to the University of California, Los Angeles Medical Center (UCLA) for treatment of the hairy-cell leukemia. Mr. Moore's primary physician at UCLA was Dr. David Golde, who confirmed the diagnosis of hairy-cell leukemia. Both Dr. Golde and Shirley Quan, a researcher that collaborated with Dr. Golde, were employed by the Regents of the University of California, which owns and operates UCLA.

Dr. Golde hospitalized Mr. Moore and ordered that blood, bone marrow and other bodily substances be withdrawn in order to confirm that Mr. Moore did indeed have hairy-cell leukemia. Because Mr. Moore had massive splenomegaly when he was first examined at UCLA, Dr. Golde recommended that his spleen be removed "to slow down the progress of the disease."

Dr. Golde and Ms. Quan had made arrangements "to obtain portions of [Mr. Moore's] spleen following its removal." Dr. Golde gave written instructions on October eighteenth and nineteenth of 1976 indicating that the spleen portions removed from Mr. Moore

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52. A significant number of researchers are federal employees or receive federal support and thus are required to disclose "the interest, if any, of a spouse, minor child, or other member of your immediate household." Executive Order No. 11222, § 403, of May 8, 1965, 3 C.F.R. 306 (1964-1965), 30 Fed. Reg. 6469. See also Kurt, FDA Issues Concerning Conflicts of Interest, 12 IRB, A Review Of Human Subjects Research 6 (1990); CAL. HEALTH AND SAFETY CODE § 24173(c)(9) (West 1982) (requiring disclosure of the funding source of the research).
53. Moore v. Regents of the University of California, 51 Cal. 3d 120, 271 Cal. Rptr. 146, 793 P.2d 479 (1990). This description of the facts is derived from the Supreme Court's opinion, which is based on the plaintiff's third amended complaint that was on review before the Supreme Court because of a demurrer by the defendants.
54. Golde and Quan, U.S. Patent No. 4,438,032, at col. 6, l. 65 (1984).
55. Moore, 51 Cal. 3d at 125, 793 P.2d at 401, 271 Cal. Rptr. at 148.
56. Id.
57. Id.
58. Id., 51 Cal. 3d at 126, 271 Cal. Rptr. at 148, 793 P.2d at 481.
59. Id. Splenomegaly is the enlargement of the spleen.
60. Id.
should be taken to a separate research unit. Neither Golde nor Quan informed Mr. Moore of this research plan; and they did not obtain his permission to do so.

During the next several years, Dr. Golde directed Mr. Moore to return to the UCLA Medical Center so that additional samples of blood, serum, skin, bone marrow and sperm could be obtained. Dr. Golde indicated that these samples were required for Mr. Moore's "health and well-being, and based upon the trust inherent in and by virtue of the physician-patient relationship." In addition, Dr. Golde asked Mr. Moore to travel from his home in Seattle to the UCLA Medical Center, because Dr. Golde wanted the procedures performed only at the UCLA Medical Center under his personal direction.

Golde and Quan produced the Mo cell line from Mr. Moore's spleen cells sometime before August of 1979. The Mo cell line constitutively produces a number of lymphokines including colony-stimulating factor, erythroid-potentiating activity, Type II immune interferon, neutrophil migration-inhibition factor, T-cell growth factor, macrophage activating factor and fibroblast

61. Id.
62. Moore, 51 Cal. 3d at 126, 793 P.2d at 481, 271 Cal. Rptr. at 148.
63. Id.
64. Id. (quoting Moore's third amended complaint).
65. Id.
66. Id. at 127, 793 P.2d at 481, 271 Cal. Rptr. at 148. When cells are first removed from the body, they will not grow indefinitely in vitro and are called primary cells. Primary cells can be adapted to grow in vitro using various techniques to produce a cell line. See generally, U.S. CONGRESS, OFFICE OF TECHNOLOGY ASSESSMENT, NEW DEVELOPMENTS IN BIOTECHNOLOGY: OWNERSHIP OF HUMAN TISSUES AND CELLS, 31-46 (1987) [hereinafter OTA REPORT].
67. Moore, 51 Cal. 3d at 127 n.2, 793 P.2d at 481 n.2, 271 Cal. Rptr. at 148 n.2. Lymphokines are proteins that regulate the immune system. See generally OTA REPORT, supra note 66.
68. Colony stimulating factor is a protein that causes granulocyte-macrophage progenitors to proliferate in vitro. See Golde and Quan, US. Patent No. 4,438,032, col. 1, 1.20 (1984).
70. Immune interferon is a protein that enhances natural killer cell activity and thus has anti-tumor activity. See D. STITES, J. STOBO, H. FUDENBERG & J. WELLS, BASIC & CLINICAL IMMUNOLOGY, 720 (4th ed. 1982) [hereinafter D. STITES].
71. Neutrophil migration-inhibition factor is a protein that inhibits the migration of neutrophils. See Golde and Quan, U.S. Patent No. 4,438,032, col. 4, 1.61 (1984).
72. T-cell growth factor (Interleukin-2 or IL-2) is a protein that promotes the growth of T lymphocytes. See D. STITES, supra note 66, at 740.
73. Macrophage activation factor is a protein that stimulates macrophages so they
growth-stimulating factor.\textsuperscript{74} The Regent of the University of California applied for a patent on the Mo cell line on January 30, 1981, naming Dr. Golde and Ms. Quan as joint inventors.\textsuperscript{76}

Dr. Golde negotiated agreements with Genetics Institute to commercialize the Mo cell line and any products derived from that cell line.\textsuperscript{78} Under these agreements, Dr. Golde became a paid consultant and acquired a significant amount of Genetics Institute's common stock.\textsuperscript{77} The agreements also provided that Genetics Institute would pay Dr. Golde and the Regents $330,000 over three years to obtain exclusive access to Mr. Moore and research performed on the Mo cell line and any product derived from that cell line.\textsuperscript{78}

Dr. Golde and the Regents of the University of California made a second agreement with Sandoz Pharmaceuticals Corporation whereby Sandoz was added to the Genetics Institute agreement and Dr. Golde and the Regents received $110,000 in additional compensation.\textsuperscript{79} It appears that at least a portion of the compensation was given directly or indirectly to Dr. Golde.\textsuperscript{80}

Dr. Golde, Shirley Quan, and the Regents of the University of California, together with Genetics Institute, Inc. and Sandoz Pharmaceutical Corporation, were named as defendants in the original complaint.\textsuperscript{81}

\section*{B. The Trial Court Decision}

Mr. Moore plead thirteen causes of action, including conversion and lack of informed consent.\textsuperscript{82} The defendants demurred to each alleged cause of action. The Superior Court only considered the validity of the conversion cause of action because the allegations for conversion formed the foundation for the other causes of action.\textsuperscript{83} The trial court then sustained Genetics Institute's and Sandoz's de-

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\textsuperscript{74} Fibroblast growth stimulating factor is a protein that stimulates the growth of fibroblast cell. See Moscatelli, U.S. Patent No. 4,994,559 (1991).

\textsuperscript{75} Golde and Quan, U.S. Patent No. 4,438,032 (1984). U.S. Patent No. 4,438,032 was filed on January 6, 1983 and claimed priority of a prior application filed by Golde, Quan and the Regents of the Univ. of California on January 30, 1981.

\textsuperscript{76} \textit{Moore}, 51 Cal. 3d at 127, 793 P.2d at 482, 271 Cal. Rptr. at 149.

\textsuperscript{77} Id.

\textsuperscript{78} Id.

\textsuperscript{79} Id. at 128, 793 P.2d at 482, 271 Cal. Rptr. at 149.

\textsuperscript{80} Id. at 127, 793 P.2d at 483, 271 Cal. Rptr. at 149.

\textsuperscript{81} Id. at 125, 793 P.2d at 480-81, 271 Cal. Rptr. at 147-48.

\textsuperscript{82} Id. at 128 n.4, 793 P.2d at 482 n.4, 271 Cal. Rptr. at 149 n.4. The 11 additional causes of action were (1) breach of fiduciary duty (2) fraud and deceit; (3) unjust enrichment; (4) quasi-contract; (5) bad faith breach of the implied covenant of good faith and fair dealing; (6) intentional infliction at emotional distress; (7) negligent misrepresentation; (8) intentional interference with prospective advantageous economic relationships; (9) slander of title; (10) accounting; and (11) declaratory relief.

\textsuperscript{83} Id. at 128, 793 P.2d at 482, 271 Cal. Rptr. at 149.
murrers without leave to amend and took the remaining demurrers off the calendar.\textsuperscript{84}

The court sustained the Regents', Golde's and Quan's joint demurrer to the conversion cause of action. In addition, because the same allegations were the foundation of the other causes of action, the court also sustained the demurrers to the additional actions.

\underline{C. The Court of Appeal Decision}

The Court of Appeal reversed, holding that a cause of action for conversion was stated.\textsuperscript{85} The Court of Appeal dismissed all the allegations against Genetics Institute and Sandoz with leave to amend.\textsuperscript{86} In addition, the Court of Appeal instructed the trial court to decide the remaining causes of action on which it had declined to rule.\textsuperscript{87}

\underline{D. The Decision of the Supreme Court}

The Court of Appeal decision was affirmed in part and reversed in part by the California Supreme Court.\textsuperscript{88} The Supreme Court ordered the trial court to overrule Dr. Golde's demurrers to the breach of fiduciary duty and lack of informed consent causes of action.\textsuperscript{89} The Supreme Court sustained the demurrers with leave to amend by the Regents, Quan, Genetics Institute and Sandoz to the breach of fiduciary duty and lack of informed consent.\textsuperscript{90}

The court held that a physician trying to obtain a patient's consent for a medical procedure has a fiduciary duty to disclose facts material to the patient's consent.\textsuperscript{91} To fulfill that fiduciary duty and to obtain informed consent, the physician must disclose personal interests unrelated to the patient's health, including research and economic interests that could affect the physician's medical judgment.\textsuperscript{92}

\textsuperscript{84} Id.
\textsuperscript{86} Id.
\textsuperscript{87} Id.
\textsuperscript{88} Id. Moore v. Regents of the University of California, 51 Cal. 3d 120, 793 P.2d 479, 271 Cal. Rptr. 146 (1990).
\textsuperscript{89} Id.
\textsuperscript{90} Id. The Supreme Court reasoned that because these defendants were not physicians, they did not have a fiduciary duty to Mr. Moore and could only be liable through Dr. Golde. \textit{Id.} at 133, 793 P.2d at 486, 271 Cal. Rptr. at 153. The court also sustained all of the defendants' demurrer without leave to amend the cause of action for conversion. \textit{Id.} at 120, 793 P.2d at 479, 271 Cal. Rptr. at 146.
\textsuperscript{91} Id. at 129, 793 P.2d at 483, 271 Cal. Rptr. at 150.
\textsuperscript{92} Id.
The court noted that Mr. Moore’s cause of action could be “characterized either as the breach of a fiduciary duty to disclose facts material to the patient’s consent or, alternatively, as the performance of medical procedures without first having obtained the patient’s informed consent.”

The court’s analysis rested on three principles of informed consent: (1) adults have the right to control their bodies and they can determine whether to submit to a particular medical procedure; (2) the patient must give informed consent to the medical procedure; and (3) the physician has a fiduciary duty to disclose all information that is “material to the patient’s decision” of whether to consent to a particular medical procedure. Based on these principles, the court concluded: (1) a physician must disclose personal research or economic interest that may affect the professional judgment of the physician; and (2) the failure to disclose these unrelated personal interests “may give rise to a cause of action for performing medical procedures without informed consent or breach of fiduciary duty.”

The court then went on to explore the scope of the disclosure required to obtain a patient’s informed consent. It concluded that the scope of disclosure required to obtain informed consent is broad enough to include non-medical personal interests of the physician. The court also pointed out that the case law and legislation already recognize that some of a physician’s economic interests could affect the professional judgement of that physician.

The court also considered the potential conflict of a physician-researcher who conducts research in the same scientific area that the physician practices in. Because the physician’s research interests potentially affect the physician’s medical judgment, the court concluded that a “reasonable patient would want to know” of the research interest when “deciding whether to consent to a proposed course of treatment.”

The court then applied these conclusions to the allegations made in Mr. Moore’s third amended complaint against Dr. Golde. It concluded that Dr. Golde had an undisclosed research interest in Mr. Moore’s spleen cells when he obtained Mr. Moore’s consent for the splenectomy. Thus, Mr. Moore’s spleen was removed without

93. Id.
94. Id.
95. Id.
96. Id.
97. Id.
98. Id. at 129, 793 P.2d at 483-84, 271 Cal. Rptr. at 150-51.
99. Id. at 130, 793 P.2d at 484, 271 Cal. Rptr. at 151.
100. Id.
101. Id. at 132, 793 P.2d at 485, 271 Cal. Rptr. at 152.
102. Id.
disclosing this research interest, in violation of informed consent principles.

In addition, the court concluded that Dr. Golde had a financial interest in Mr. Moore's cells when the patent application was prepared in May of 1979. Thus, the blood and body fluids extracted from Mr. Moore after May of 1979 were taken by Dr. Golde without the required disclosure of Dr. Golde's financial interest. This also violated informed consent principles.

1. The Scope of Disclosure Required After Moore v. The Regents of the University of California

The Supreme Court's unanimous ruling stated that "a physician who is seeking a patient's consent for a medical procedure must, in order to satisfy his fiduciary duty and to obtain the patient's informed consent, disclose personal interests unrelated to the patient's health, whether research or economic, that may affect his medical judgment." The court specifically states that the physician's fiduciary duty is not so broad as to make the physician the patient's financial advisor, but rather only requires disclosure of personal interests that "may affect professional judgment."

2. The Scope of Financial Disclosure Required

Under sections 654.1 and 654.2 of the California Business and Professions Code, physicians cannot receive any unearned monetary compensation for referring a patient to an entity in which they have a proprietary or co-ownership interest. The types of interests that must be disclosed to the patients under this statute include "any financial interest that is greater than $5,000." The form of that financial interest appears to include co-ownership, partnerships, limited partnerships, and licensees, but does not include stockholders of

103. Id.
104. Id. at 132, 793 P.2d at 485-86, 271 Cal. Rptr. at 152-53.
105. Id. at 131-32, 793 P.2d at 485, 271 Cal. Rptr. at 152.
106. Id. at 131 n.10, 793 P.2d at 485 n.10, 271 Cal. Rptr. at 152 n. 10 (emphasis added).
107. Cal. Bus. & Prof. Code § 654.1-2 (West 1990) (These statutes are intended to protect patients from a physician's conflict of interest as stated in Moore, 51 Cal. 3d at 129, 793 P.2d at 483, 271 Cal. Rptr. at 150.
108. Cal. Bus. & Prof. Code § 654.2(d)(2) (West 1990) states, "'significant beneficial interest' means any financial interest that is equal to or greater than the lesser of the following: (A) Five percent of the whole. (B) Five thousand dollars ($5,000)."
Dr. Golde had at least three distinct financial interests in Mr. Moore's cells: (1) the contracts with Genetics Institute and Sandoz which provided exclusive access to Mr. Moore's cells; (2) the Genetics Institute stock; and (3) Dr. Golde's consultant status with Genetics Institute. Dr. Golde's stock in Genetics Institute would probably not need to be disclosed to a patient because stockholders of a corporation are not a financial interest covered by section 654.1 of the California Business and Professions Code. However, other California statutes governing a physician's interest in a medical provider to which the physician refers patients, have been interpreted to require the disclosure of simple stock ownership worth over $25,000. This latter view of simple stock ownership appears to be


110. See supra notes 76-78 and the accompanying text.


112. The Med-Cal requirements for avoiding conflicts of interests require disclosure of a significant financial interest defined as:

1) 'Significant beneficial interest' means any financial interest held by a provider, or a member of the provider's immediate family, in another provider that is equal to or greater than the lesser of the following:
   (A) Five percent of the whole.
   (B) $25,000.00

2) 'Immediate family' means spouse, son, daughter, father, mother, father-in-law, mother-in-law, son-in-law or daughter-in-law.

(d) Interests held by a provider and members of that provider's immediate family shall be combined and valued as a single interest.

1) The extent of financial interest shall be determined as follows:
   (A) Full ownership shall be considered as 100 percent financial interest and control regardless of mortgages or other incumbrances.
   (B) Interest in a partnership shall be determined on the basis of the percentage of ownership specified in either a written or verbal partnership agreement.
   (C) Interest in a corporation shall be determined by computing the percentage of stock or bonds owned of the total outstanding shares or bonds of the corporation as of the last working day of the month preceding compliance with (a).
   (D) All other financial arrangements shall require establishment of a fair and reasonable dollar value for both the interest and the whole. The percentage interest shall be computed as the percentage the dollar value of the interest represents of the whole.
2) The dollar value of the following types of interests shall be determined as follows:
   (A) Bonds, over-the-counter stocks and stocks listed on the major stock exchanges shall be valued at the closing selling price on the last working day of the month preceding compliance with (a).
   (B) Stocks in a closely held corporation shall be valued at the original purchase price, par value, or current market value, whichever is greater.
   (C) Partnership interests shall be valued at the total dollar amount invested in organizing the partnership. A fair and reasonable dollar equivalent shall be
better able to fulfill the legislature's intent of preventing conflicts of interest.

However, the contracts and Dr. Golde's consultant status are a different type of interest. The contract was for more than $25,000 and is the type of interest, that if it is in a medical clinic or other entity, must be disclosed pursuant to the California statutes. In addition, the fact that the contract directly affected Mr. Moore makes it material to Moore's decision.

The exact terms of Dr. Golde's consulting agreements are not known, but at least one appears to be directly related to the contract with Genetics Institute. That agreement appears to directly involve the commercialization of Mr. Moore's cells and was thus material to Mr. Moore's decisionmaking process. Therefore, the court would probably require the disclosure of any significant financial interest directly related to Mr. Moore or his cells regardless of the exact form of that interest.

3. The Scope of Research Disclosure Required

Under federal and California statutes, the scope of disclosure required to obtain informed consent is extremely broad. As stated, these regulations require the disclosure of potential benefits of the research to the patient and others, and the nature, purpose and procedures to be followed during the experiment.

Dr. Golde had arranged to obtain portions of Mr. Moore's spleen after it was removed and to obtain samples of Mr. Moore's body fluids and cells, years after the initial splenectomy. Dr. Golde made these arrangements without ever telling Mr. Moore of his research interests. Dr. Golde was required under current regulation to make such a disclosure, but none was given.

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113. See supra notes 2, 3, 108 and the accompanying text.
114. See supra note 17 and the accompanying text.
115. See supra note 78 and the accompanying text.
116. Id.
117. See supra notes 34-41 and the accompanying text.
118. See supra notes 34-41.
119. See supra notes 63-64 and the accompanying text.
120. Informed consent of experimental procedures is required under the current Health and Human Services regulation. See supra note 36. In addition, the California
Given the extremely rigorous disclosure requirements in the research setting, Dr. Golde failed to disclose either a benefit of the research or that he was even involved in an experiment. Disclosure of this research’s benefit to Dr. Golde was clearly required under both federal and state regulations. Informing Mr. Moore that he was involved in a research experiment is required under the regulations and professional codes. Either of the non-disclosed research interests could have affected Dr. Golde’s professional judgment and thus under Moore must be disclosed.

Here, the benefits that could potentially affect Dr. Golde’s professional judgment included a lucrative consulting contract and stock ownership. These benefits were a direct result of the research performed on Mr. Moore or his cells, and thus, directly affected him. Without such a direct cause and effect relationship, the “benefits” to Dr. Golde would have been very speculative. Speculative benefits appear to be so uncertain that a professional’s judgment probably would not be altered. Benefits that do not potentially affect professional judgment should not cause a conflict of interest, and thus do not have to be disclosed.

The scope of disclosure required under Moore seems to include all financial or research interests that are not speculative. Thus, concrete contracts, consulting agreements and stock ownership directly related to a patient, and thus certainly affecting a patient, must be disclosed. However, disclosure of interests that are not very likely to be benefitted by the particular research would not be required.

IV. The Moore Case on Remand

On remand, the superior court will probably conclude that direct financial interests and indirect financial interests, such as stock ownership, must be disclosed. The court will likely scrutinize the terms of Dr. Golde’s various contracts and consulting agreements to determine whether they directly affect Mr. Moore. In addition, the court will look at Dr. Golde’s other interests, such as research grants, to determine whether they are likely to benefit from the research on Mr. Moore or his cells. If these other interests would significantly

Protection of Human Subjects in Medical Experimentation Act also requires informed consent. See supra notes 37-38 and the accompanying text.

121. Disclosure of the benefits of the research is required under the Health and Human Services regulations. See supra note 36.
122. Disclosure that an experiment is being carried out is also required. See supra note 36.
123. See supra notes 36-41.
124. See id. and the accompanying text.
125. See supra note 42 and the accompanying text.
126. See supra notes 66-75 and the accompanying text.
127. See supra notes 105-06 and the accompanying text.
benefit from the research, Dr. Golde's failure to disclose them will result in additional damages or charges.

V. RECENT FEDERAL STATUTES AND REGULATIONS RECOGNIZE A PHYSICIAN'S FINANCIAL CONFLICT OF INTEREST

The Department of Health and Human Services recently issued regulations that clearly recognize that a physician's financial interest in diagnostic and treatment facilities is a potential conflict of interest.128 The newly issued regulations are intended to eliminate the physician's conflict of interest when physicians refer patients to treatment or diagnostic facilities in which they have a significant financial interest.129 According to the government, this type of financial conflict of interest encourages expensive medical procedures to be overused.130

The new regulations were issued pursuant to section fourteen of the Medicare and Medicaid Patient and Program Protection Act of 1987.131 This section required the development of regulations that clearly specified which Medicare payment practices would be protected from criminal prosecution or civil sanctions under the statute's anti-kickback provisions.132 These regulations were required because section 1128B(b) of the Social Security Act providing criminal penalties for receiving remuneration for inducing business reimbursed under the Medicare or State Health Care programs is extremely broad.133 The regulations specify ten different safe harbors

130. Id.
132. Id.
133. 42 U.S.C. § 1320a-7b(b) (1991). This statute states in its pertinent part:
(b) Illegal remunerations. (1) Whoever knowingly and willfully solicits or receives any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind —
(A) in return for referring an individual to a person for the furnishing or arranging for the furnishing of any item or service for which payment may be made in whole or in part under title XVIII [42 USC § 1395 et seq.] or a State health care program, or
(B) in return for purchasing, leasing, ordering, or arranging for or recom-
under which a person or an entity can be assured that they will not be subject to either criminal or civil actions.\textsuperscript{134}

The regulations state that an entity may be excluded from receiving Medicare or State Health Care program reimbursement if more than forty percent of the entity is owned by physicians or other businesses that are in a position to refer patients to that entity.\textsuperscript{135} In addition to the ownership limitation, the regulations also state that no more than forty percent of the gross revenues may come from patients referred to the entity by physicians or other businesses that own more than forty percent of the entity.\textsuperscript{136} The regulations do not make distinctions between the type of ownership or investment held by the physician in a position to refer patients to the entity and therefore consider active and passive investments consisting of partnership interest, limited partnership interests and stock ownership in a corporation to count towards the forty percent ownership limit.\textsuperscript{137}

The issuance of these regulations confirms the federal government’s recognition of a potential financial conflict of interest when physicians own an interest in a diagnostic or treatment facility that they can, and do refer patients to.\textsuperscript{138} Because the federal government has clearly recognized these financial conflicts of interest, a court in a state that does not have statutes, regulations or cases that clearly recognize financial conflicts of interest is more likely to look to the

\begin{verbatim}
...mending purchasing, leasing, or ordering any good, facility, service, or item for which payment may be made in whole or in part under title XVIII [42 USCS § 1395 et seq.] or a State health care program,
shall be guilty of a felony and upon conviction thereof, shall be fined not more than $25,000 or imprisoned for not more than five years, or both.
(2) Whoever knowingly and willfully offers or pays any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind to any person to induce such person—
(A) to refer an individual to a person for the furnishing or arranging for the furnishing of any item or service for which payment may be made in whole or in part under title XVIII [42 USCS § 1395 et seq.], a State health care program, or
(B) to purchase, lease, order, or arrange for or recommend purchasing, leasing, or ordering any good, facility, service, or item for which payment may be made in whole or in part under title XVIII [42 USCS § 1395 et seq.] or a state health care program, shall be guilty of a felony and upon conviction thereof, shall be fined not more than $25,000 or imprisoned for not more than five years, or both.

\textit{Id.}
\textsuperscript{136} Id.
\textsuperscript{137} Id.
\textsuperscript{138} Id.
\textsuperscript{139} The federal government recognized this potential financial conflict of interest when it passed the legislation at 42 U.S.C. § 1320a-7b(b), \textit{supra} note 6.
\end{verbatim}
federal statutes and regulations when presented with a lawsuit similar to the *Moore* case. Although only persuasive, the federal statutes and regulations, in addition to the *Moore* case itself, are likely to cause other state courts to expand the scope of informed consent to include these financial conflicts of interest.

VI. CONCLUSION

After the California Supreme Court's decision in *Moore v. The Regents of the University of California,* any research or economic interest physicians have that might affect their medical judgment of the physician must be disclosed. Economic interests such as stock ownership in a directly involved company, consulting contracts and contracts for access to a patient must be disclosed. Disclosure of financial information that does not directly involve the patient, the patient's treatment or the patient's body or body parts is not required. Such information would simply not be material to the patient's informed consent. In addition, because of the recently-issued Department of Health and Human Services regulations that clearly recognize financial conflicts of interests, other jurisdictions are likely to expand the scope of informed consent to include disclosure of these conflicts.

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