A Paper Tiger: Lawsuits against Doctors for Non-Disclosure of Economic Interests in Patients' Cells, Tissues and Organs

Anne T. Corrigan
A PAPER TIGER: LAWSUITS AGAINST DOCTORS FOR NON-DISCLOSURE OF ECONOMIC INTERESTS IN PATIENTS' CELLS, TISSUES AND ORGANS

In 1990, the California Supreme Court set a precedent that limits patients' ability to sue doctors who ultimately profit from medical research using tissue matter removed from patients. Concerned that causes of action for breach of fiduciary duty and lack of informed consent are inadequate to protect patients from exploitation by physician-researchers, the authors suggest that legislation coupled with stronger self-regulation by the medical community offers a better solution.

In July 1990, the California Supreme Court threw a bone to John Moore of Seattle, a leukemia patient seeking a share of the profits his California doctor derived from Moore's surgically removed tissue. The court rejected the patient's cause of action for conversion, but allowed Moore to proceed against his physician on remand under either of two theories, breach of fiduciary duty or lack of informed consent.

The Moore decision attempts to resolve the issue of patients' property rights in their cells, tissues and organs. The Moore court found that patients in situations like Moore's do not own tissue removed from their bodies and, further, that such patients do not

3. Id. at 489. The Court reserved the possibility for a contrary finding under other circumstances. The court stated: "we do not purport to hold that excised cells can never
have rights to share in any profits derived from the commercialization of that tissue. The California Supreme Court’s opinion partially overturned the 1988 appellate decision which had ruled that Moore’s complaint stated a cause of action for conversion. By rejecting the argument that human tissue is property belonging to the person from whom it has been removed, the California Supreme Court limited patients’ ability to sue physicians who profit from medical research using removed tissues. But the court did not foreclose the possibility of suits against researchers altogether, since the Moore court noted that Moore would be able to proceed with his suit alleging lack of informed consent or breach of fiduciary duty. However, the opinion failed to specify what Moore must prove in order to succeed under these causes of action or how damages would be measured under these theories.

For the purposes of this note, “tissue” includes organs and cells.

4. \textit{See id.} at 493 (reasoning that the patent issued for the cell line evidences “that the cell line is the product of invention” unique from Moore’s cells).


6. \textit{See id.} at 493 (refusing to extend the theory of conversion to the use of human cells in medical research).

7. Moore, 793 P.2d at 497.

In Justice Mosk’s opinion, the failure-to-disclose cause of action is “largely illusory” because the patient must demonstrate a causal relationship between the physician’s failure to inform and his injury. \textit{Id.} at 519 (Mosk, J., dissenting). For Moore, the causal connection between his physician’s failure to inform and the injury he alleged would be established only if Moore could show that, had he known of the ongoing commercialization of his tissue, he would have refused treatment. \textit{See infra} text accompanying notes 74-75.

8. Moore, 793 P.2d at 497. The majority concluded that since the doctor breached his fiduciary duty by not disclosing his research interests in plaintiff’s bodily specimens, the removal of plaintiff’s spleen and the subsequent removal of blood, semen, bone marrow, etc., constituted compensable injuries. \textit{Id.} at 485.

In a concurring and dissenting opinion, Justice Broussard noted that Moore could, in the alternative, demonstrate that the breach of fiduciary duty caused some other type of compensable damage. \textit{Id.} at 499 (Broussard, J., concurring and dissenting). Broussard argued that plaintiff could use the breach of duty as the basis for a cause of action for conversion under traditional common law principles because he believed that the plaintiff had a property interest in his body parts even after their removal. \textit{Id.} at 501.

9. \textit{See DeBenedictis, supra} note 1, at 22 (noting that Justice Panelli’s majority opinion does not discuss the elements of a failure-to-disclose cause of action). The majority opinion offered this sentence regarding the remaining causes of action available to Moore: “Any injury to [Moore’s] right to make an informed decision remains actionable through the fiduciary-duty and informed-consent theories.” Moore, 793 P.2d at 496.
The Moore case illustrates a growing controversy: whether patients who are the source of raw material for the rapidly expanding biotechnology industry have any right to share in the financial rewards of the patents and products generated from research in which those tissues are used. Moore's claim to a share of the profits failed because the California Supreme Court refused to recognize any patient ownership interest in the removed tissue, thus precluding a tort claim for conversion.

This note explores the causes of action available to Moore and to other patients who discover that their tissues have been used for medical research. Providing background information regarding the Moore case and the surrounding controversy, this note discusses the doctrine of fiduciary responsibility and the consequences of breaching those duties. Further, this note examines the doctrine of informed consent and the elements required to establish a basis for compensable damages. It applies these theories to the factual situation presented in Moore, and then propounds the various arguments a patient might present. Finally, this note concludes that the doctrines of informed consent and fiduciary duty offer no real basis

10. Andrew Pollack, Living Cells Enter Commerce; Now, Who Has a Claim to Profits?, N.Y. TIMES, Aug. 12, 1990, at 6E; see also Brotherton v. Cleveland, 923 F.2d 477, 481 (6th Cir. 1991) (citing Moore as an example of the problems arising in conjunction with the explosion in the market for human tissue). In Brotherton, the Sixth Circuit examined property rights in tissue removed from dead bodies. Brotherton, 923 F.2d at 479. The plaintiffs in that case argued that an Ohio statute permitting county coroners to remove corneas for anatomical gifts without the consent of autopsy subjects' next of kin violated the due process clause of the United States Constitution. Id. at 478-79. Unlike the Moore court, the Sixth Circuit was able to avoid the question of whether or not dead bodies should be classified as property. Id. at 481. The court determined that the rights granted to the decedent's surviving custodian under the Ohio law governing gifts of organs and tissue for research constitute a "legitimate claim of entitlement" protected by the due process clause of the Fourteenth Amendment. Id. at 482.

Issues surrounding gifts and donations of organs are beyond the scope of this note.


The Restatement (Second) of Torts defines conversion as "an intentional exercise of dominion or control over a chattel which so seriously interferes with the right of another to control it that the actor may justly be required to pay the other the full value of the chattel." RESTATEMENT (SECOND) OF TORTS § 222A(1) (1965). From this definition, the California courts derive three elements for a conversion action: (1) the plaintiff must own or have a right to possess the property at the time of the alleged conversion; (2) the defendant must have acted wrongfully in taking or disposing of the plaintiff's property rights; and (3) the defendant's wrongful conduct must have caused damages to the plaintiff. Baldwin v. Marina City Properties, Inc., 145 Cal. Rptr. 406, 416 (Ct. App. 1978).

For an examination of the doctrine of conversion as applied to the facts in Moore, see generally Jennifer Lavoie, Note, Ownership of Human Tissue: Life After Moore v. Regents of the University of California, 75 VA. L. REV. 1363, 1373-81 (1989).
for compensating the patient. Patients in situations like Moore’s have no enforceable right to share in profits gained from the commercialization of their tissues under either doctrine. This note argues, however, that patients do have a right to adequate disclosure of doctors’ economic interests in those tissues before consenting to treatment.

This note proposes that legislative intervention coupled with stronger self-regulation by the medical community would more effectively protect patients’ interests than the causes of action left to them by the California Supreme Court. Legislation and self-regulation would not produce the severe economic repercussions in the biotechnology industry that the Moore court feared would occur if patients’ property rights in their tissues were recognized. Rather, steps aimed at regulating doctors’ use of diagnostic specimens in medical research would assure that patients receive full disclosure regarding the intended use of any tissue removed during medical treatment.

I. **Moore v. Regents of the University of California**

In 1976, John Moore was diagnosed by UCLA hematologist David Golde\(^1\) as having a rare form of cancer known as hairy cell leukemia.\(^2\) Golde removed Moore’s spleen as a necessary part of the treatment for his disease.\(^3\) Golde and Shirley Quan, a medical researcher and UCLA employee, determined that Moore’s spleen had unique qualities.\(^4\) Golde and Quan, applying genetic engineering to cells from the spleen, developed a cell-line\(^5\)

---

12. Dr. Golde was the head of the Hematology-Oncology Department of the UCLA Medical Center when he treated Moore. See David G. Savage, *Court Backs Doctors’ Right to Use Patient Tissues*, L.A. TIMES, Mar. 26, 1991, at A3.

13. Moore, 793 P.2d at 481. Due to the procedural nature of the appeal, the court’s review of the facts in this case was limited to the pleadings. Id. at 480. For the purposes of this analysis, the facts presented by the court are accepted as true.

14. Moore, 793 P.2d at 481. (noting that Moore’s cells over-produced certain lymphokines, enabling researchers to more easily identify the corresponding genetic material).

15. Id. A cell line is defined as “a sample of cells [that have] undergone the process of adaptation to artificial laboratory cultivation . . . [making them] capable of sustaining
known as the "Mo-cell line" which was capable of indefinite regeneration.\textsuperscript{17} Moore travelled from Seattle to Los Angeles periodically between 1976 and 1983 for blood work-ups\textsuperscript{18} in Golde's office, believing that these visits were necessary for his treatment.\textsuperscript{19}

In 1983, Golde filed an application to patent the Mo-cell line.\textsuperscript{20} Subsequently, he presented Moore with previously unseen consent forms intended to secure the release of any rights Moore had in all cell lines or products made from his blood or bone marrow.\textsuperscript{21} Moore signed one of two forms presented to him during his last two visits with Golde, but refused to sign the second form because he felt the answers he received to questions regarding the purpose and potential value of the research involving his tissue continuous, long-term growth in culture." \textsuperscript{1} 1 U.S. Congress, OFFICE OF TECHNOLOGY ASSESSMENT, NEW DEVELOPMENTS IN BIOTECHNOLOGY: OWNERSHIP OF HUMAN TISSUES AND CELLS — SPECIAL REPORT 3 n.1 (1987) [hereinafter OTA REPORT].


18. Cells are "the basic structure and functional units of all living organisms," and carry within their nuclei an individual's unique genetic information in DNA (deoxyribonucleic acid) macro molecules. DNA cloning is "the production of billions of copies of a piece of DNA as part of a plasmid introduced into a microorganism . . . ." Technology [has] emerged allowing manipulations of genetic material, or, as in the [Moore] case, utilized the genetic material of a unique individual to produce substances of great benefit to humankind. The process involves the joining together of segments of the DNA from the human cells with those of a microorganism . . . to create 'recombinant DNA.' This process of genetic engineering, or gene splicing, produces a cell which divides, and which, in the [Moore] case, produced cells 'shown to be capable of continuous culture for an indefinite period of time.'

\textit{Id.} at 498 n.3 (citation omitted).

19. Tissue and cell culturing is a technique essential for studying the complexity of the human biological structure and the materials which comprise it. Culturing isolates cells from the whole organism before examination. OTA REPORT, supra note 16, at 5.

\textsuperscript{18} Moore, 793 P.2d at 481. During each visit, blood and other bodily substances, including blood serum, skin, bone marrow aspirate and sperm, were withdrawn from Moore's body. \textit{Id.}

19. See \textit{id.} (noting that Golde represented to Moore that the tissue sampling was "necessary and required for his health and well-being").

20. \textit{Id.} at 481-82.

21. The Use of Human Biological Materials in the Development of Biomedical Products: Hearings before the Subcomm. on Investigations and Oversight of the House Comm. on Science and Technology, 99th Cong., 1st Sess., at 268 (1985) (statement of John Moore). The waiver form read as follows: "I (do, do not) voluntarily grant to the University of California any and all rights I, or my heirs, may have in any cell line or any other potential product which might be developed from the blood and/or bone marrow obtained from me." \textit{Id.}
were evasive. In 1984, the Mo-cell line was granted a patent naming Golde and Quan as inventors and the Regents of the University of California as assignee. After receipt of the patent, Golde negotiated agreements with two biotechnology firms for commercial development of the Mo-cell line. In addition to making Golde a paid consultant, one of the firms offered Golde "the rights to 75,000 shares of common stock." Reports from biotechnology industry periodicals have predicted a potential market worth more than three billion dollars for Mo-cell line derivatives, the profits from which Golde will likely share.

The facts presented in the Moore case reveal several problems that can arise when physicians not only provide therapeutic treatment for their patients but also have economic interests in the commercial value of the diagnostic specimens obtained from that treatment. Two key issues arise in this context: (1) whether or not full disclosure of the potential conflict of interest between patients' well-being and any potential financial gain to physicians should be required as part of the informed consent process; and (2) whether the fiduciary responsibility to protect patients' interests requires complete disclosure by physicians of the prospect of their economic gain.

The Moore case serves as a paradigm to illustrate these conflicts. Because tissue is one of the key raw materials driving the

22. Id. at 254-55.
23. Moore, 793 P.2d at 482 (citing U.S. Patent No. 4,438,032 (Mar. 20, 1984)).
24. Id.
25. Id. Golde obtained options to purchase 75,000 shares of stock of Genetics Institute, one of the firms involved in commercial development of the Mo-cell line. Additionally, Genetics Institute agreed to pay Golde and the Board of Regents "at least $330,000 over three years, including a pro-rata share of [Golde's] salary and fringe benefits, in exchange for . . . exclusive access to the materials and research performed." Id. See also Sandra Blakeslee, Patient's Right to Tissue is Limited, N.Y. Times, July 10, 1990, at C8, col. 4 ("Golde negotiated an agreement with Genetics Institute Inc., a biotechnology firm in Cambridge, Mass., to develop drugs from the cells . . . Golde received 75,000 shares of Genetics Institute stock for a penny each.").
26. Moore, 793 P.2d at 482. The Moore complaint cited published reports from industry periodicals forecasting the range of uses for lymphokines, the overproduction of which was a key characteristic of Mo-cell line. Id. at 482 & n.2.
27. See Deborah M. Levy, Biotech and the Breakdown of the Doctor-Patient Relationship, MANHATTAN LAW., Feb. 7-13, 1989, at 12 (noting that the physician-patient relationship is compromised by a lack of information about the physician's research and commercial activities).
28. See OTA REPORT, supra note 16, at 93-111 (analyzing informed consent and disclosure in the context of physicians who treat patients and also conduct research).
biotechnology industry, physicians who have the opportunity to supply unique tissue samples, such as the Mo-cell line, have the potential to realize significant economic gain. The conflict between a patient's therapeutic best interests and a physician's economic best interests surfaces where the physician discovers that the patient has tissue with special characteristics. In these cases, the potential for economic gain may impair that physician's objectivity regarding proper treatment for the patient.

Yet the Moore case is considered an anomaly by the biotechnology industry; typically, the sources of a cell line are numerous and difficult to trace. Most patients could not successfully identify their cells as the source of a particular cell line and would never know to bring suit. Because the existence of a conflict of interest normally remains hidden from most patients, it is necessary that existing legal doctrines or new legislation protect patients' interests. Patient protection becomes increasingly important as technology expands researchers' abilities to discover more information from each sample of tissue, thereby creating an increased risk for patients to be caught in a Moore-like situation.

II. THE PHYSICIAN AS A FIDUCIARY

The relationship between a doctor and a patient has often been characterized as fiduciary in nature. The patient depends on the physician for medical information and relies on him or her to be truthful and candid. The fiduciary relationship between physician and patient is interwoven with tenets of informed consent, such as

---

29. Levy, supra note 27, at 14 (quoting Dr. Larry Palmer, a professor at Cornell Law School, who noted that the Moore court of appeal "[didn't] quite understand the economics of research"). See also OTA REPORT, supra note 16, at 5 ("Establishing human cell culture directly from human tissue is a relatively difficult enterprise and the probability of establishing a cell line from a given sample varies, ranging from 0.01 percent for some liver cells to nearly 100 percent for some human skin cells.").

30. See, e.g., Canterbury v. Spence, 464 F.2d 772, 782 (D.C. Cir. 1972), cert. denied, 409 U.S. 1064 (1972) (finding that the fiduciary nature of the physician-patient relationship gives rise to a "duty to reveal to the patient that which is in his best interests ... [to] ... know." (quoting Emmett v. E. Dispensary & Cas. Hosp., 396 F.2d 931, 935 (D.C. Cir. 1967)); Cobbs v. Grant, 502 P.2d 1, 10 (Cal. 1972) (requiring any defense raised by a physician who has failed to disclose available choices and risks of particular treatments to be consistent with the fiduciary qualities of the patient-physician relationship).

the patients' right to self-determination and promotion of individual autonomy. Before further consideration of physicians' fiduciary responsibilities with respect to patients' understanding of their doctors' potential commercial interest in tissue, it is useful to examine the role of the fiduciary in its basic legal form.

A. Basic Principles of Fiduciary Law

Fiduciary is defined alternately as "[a] person having [a] duty, created by his undertaking, to act primarily for another's benefit in matters connected with such undertaking" or as "a person holding the character of a trustee, or a character analogous to that of a trustee, in respect to the trust and confidence involved in it and the scrupulous good faith and candor which it requires." Fiduciary duties are implied into relationships where high degrees of trust are required. The usual fiduciary relationships include that of trustee and beneficiary, guardian and ward, agent and principal, attorney and client, executor and legatees, directors and officers of a corporation and the corporation and its shareholders, partners and the partnership itself, and doctor and patient. Thus, the concept of a fiduciary relationship between parties touches many areas of the law.

Rules governing the various forms of fiduciary relationships, many of which have evolved over centuries, share several identi-

---

32. See id. (noting that the right of self-determination entitles individuals to refuse medical treatment for "any reason, no matter how silly or unsound it may seem to the physician"). The issue of self-determination usually arises with respect to causation, where the patient is attempting to prove that she would have declined the medical treatment alleged to be the basis of her injury had the physician fully disclosed the nature of the procedure. Id. at 31. Courts have been hesitant to adopt a subjective rule which asks whether or not the particular patient involved in the suit would have refused treatment if full disclosure had been made. Id. Instead, a more objective "reasonable person in the patient's position" standard is used. Id.

33. See id. at 35. According to Annas, "[the purpose of autonomy is to protect the individual's integrity as a person or 'human being' by denying anyone the right to invade [her] body without [her] consent." Id. Autonomy can be viewed as the right to privacy in making decisions about one's own body or as the right to be left alone. Id. For further discussion of individuals' autonomy, see infra text accompanying notes 129-38.


35. Id.

36. See MERTON FERSON, PRINCIPLES OF AGENCY § 295 n.49 (1954).


38. Tamar Frankel, Fiduciary Law, 71 CAL. L. REV. 795, 795 (1983). The earliest fiduciaries were trustees, bailiffs and administrators whose practices pre-date the Statute of Uses of 1536. Id. While the concept of agency did not appear until the end of the eigh-
fiable characteristics. Courts tend to design the rules governing fiduciaries and the scope of their duties within the context of the substantive areas of law in which the fiduciary relationship occurs. Nonetheless, courts consistently look for the qualities of trust, confidence, good faith and loyalty to define a relationship as fiduciary. One of the basic precepts of all fiduciary relationships is the duty of loyalty. This duty requires the fiduciary to act solely in the interest of the principal. The scope of a fiduciary's duty of loyalty increases as the independent authority exercised by the fiduciary increases.

The term "entrustor" has been used by one commentator to describe the role of the principal because it highlights the basic dependence characteristic of fiduciary relationships. Dependence by the principal on the fiduciary sets the relationship apart from the typical arm's-length dealings that occur in the marketplace. Because of the entrustors' dependence, situations will arise in which fiduciaries can take advantage of their principals. Further

---

39. See Frankel, supra note 38, at 796 n.8 ("For example, the principles governing the fiduciary duty of corporate directors are treated as part of corporate law.").
40. See Arthur A. Chaykin, Mediator Liability: A New Role For Fiduciary Duties?, 53 U. CIN. L. REV. 731, 740 (1984) ("Some relationships are so typically imbued with qualities of trust, confidence and good faith that courts have been able comfortably to assume that, in the absence of evidence to the contrary, a fiduciary relationship must exist.").
42. See Scott, supra note 37, at 540 (quoting Josiah Royce, THE PHILOSOPHY OF LOYALTY 16 (1930) who defines loyalty as "'[t]he willing and practical and thorough-going devotion of a person to a cause . . . '").
43. Id. at 541. "Thus, a trustee is under a stricter duty of loyalty than is an agent upon whom limited authority is conferred or a corporate director who can act only as a member of the board of directors or a promoter acting for investors in a new corporation." Id.
44. Frankel, supra note 38, at 800 n.17.
45. Scott, supra note 37, at 541.
thermore, principals will frequently be unable to detect abuses of trust, such as self-dealing and undue influence, because their fiduciaries possess superior knowledge.46

Self-dealing, perhaps the most blatant breach of fiduciary duty, occurs when fiduciaries act without the consent of their principals and where those actions serve to benefit the fiduciaries, themselves.47 For example, a fiduciary entrusted with the sale of property who buys the property herself48 or a fiduciary who sells his own property to his principal engages in self-dealing.49 Self-dealing is a breach of the fiduciary duty of loyalty.50 The term self-dealing is used because the fiduciary is positioned on both sides of the transaction, representing personal interests on one side and the interests of the principal on the other.51 Thus, interests of fiduciary and principal are in direct conflict. In the case of the fiduciary who buys her principal’s property, the principal/seller wants to get the highest sale price possible, while the fiduciary/buyer wants to purchase the property for as little as possible.52 Fiduciaries, then, cannot act opportunistically, because doing so invariably leads to conflicts of interest.53

46. See Canterbury v. Spence, 464 F.2d 772, 780 n.14 (D.C. Cir. 1972), cert. denied, 409 U.S. 1064 (1972) ("Patients ordinarily are persons unlearned in the medical sciences . . . [and] it is only in the unusual case that a court could safely assume that the patient's insights were on a parity with those of the treating physician.").
47. Scott, supra note 37, at 543.
48. Id. at 543-45.
49. Id. at 544-45.
50. Id. at 545.
51. Id.
52. The rules for real estate brokers, for example, are clear with respect to self-dealing. A broker cannot, without the seller’s informed consent, purchase the property, split a commission or take a rebate from a buyer. D. BARLOW BURKE, JR. LAW OF REAL ESTATE BROKERS §§ 4.2-3 (1982 and Supp. 1991). For example, in Wendt v. Fischer, 154 N.E. 303, 304 (N.Y. 1926), real estate brokers sold a particular piece of property to a corporation in which one of the brokers served as president and manager. Judge Cardozo said of the transaction:

As broker for the seller, the duty of this fiduciary was to make the terms as favorable to his employer and the price as high as possible. As president and manager of the buyer corporation, its sole representative in the transaction, his duty was just the opposite.

Id.

53. Chaykin, supra note 40, at 742-43. A “fiduciary must not act opportunistically, even if his actions would otherwise be regarded as fair competition in a normal business setting.” Id.
B. Fiduciary Law Applied to Physicians

Discovery of the hidden value in human tissue and cells has been cited as a "signal [of] a further breakdown in the relationship between doctors and patients and [the need for] a further extension of the legal system to mend that breach." On remand, John Moore will have an opportunity to argue that Golde had an undisclosed research interest in Moore's cells at the time he sought Moore's consent to the splenectomy or to subsequent blood work-ups. This undisclosed research interest would be an opportunistic conflict of interest:

(1) a physician must disclose personal interests unrelated to the patient's health, whether research or economic, that may affect the physician's professional judgment; and (2) a physician's failure to disclose such interests may give rise to a cause of action for performing medical procedures without informed consent or breach of fiduciary duty.

Thus, the Moore court defined physicians' obligations with respect to their personal economic interests in terms of the fiduciary relationship between physicians and their patients.

A conflict of interest between fiduciary and principal need not end the fiduciary relationship. Where a conflict exists, the fiduciary may continue in that capacity if full disclosure of the conflict is made to the principal.

54. Levy, supra note 27, at 12. Dr. Gladys White, director of the 1987 Congressional Office of Technology Assessment study on the ownership of human tissue and cells, has speculated that "if the patient-doctor relationship [between John Moore and Golde] had not been so compromised by the information about the physician's research and commercial activities, the conversion issue would not have been prominent." Id. at 14. See also OTA REPORT, supra note 16, at 93-111 (discussing the adequacy of disclosure by a physician regarding research and commercial activities).


56. Id.

57. WILLIAM F. FRATCHER, SCOTT ON TRUSTS § 170 at 311-12 (4th ed. 1987). For example, an attorney whose interests conflict or potentially conflict with the interests of a client can still represent the client if, after full disclosure of the nature of the conflict to the client, informed consent is obtained. See MODEL CODE OF PROFESSIONAL RESPONSIBILITY DR 5-101(A) (1981), which states:

Except with the consent of his client after full disclosure, a lawyer shall not accept employment if the exercise of his professional judgment on behalf of his client will be or reasonably may be affected by his own financial, business,
ciary relationship, anything less than full disclosure of a potentially conflicting interest, especially an economic interest, is a breach of the relationship. A fiduciary remains liable if the disclosure is indefinite, equivocal or inadequate.\textsuperscript{58}

The adequacy of disclosure in medical relationships must take into account the physician’s actual statement to a patient and the patient’s particular ability to comprehend.\textsuperscript{59} Though disclosure requirements usually refer to the adequacy of information conveyed about medical risks, the law also recognizes disclosure as being applicable to a physician’s personal interests.\textsuperscript{60} The Moore court indicated that the economic interests of a physician are material to

\begin{quote}
property, or personal interests. See also Model Rules of Professional Conduct Rule 1.7(b)(1) & (2) (1983), which states:

\begin{quotation}
A lawyer shall not represent a client if the representation of that client may be materially limited by the lawyer’s responsibilities to another client or to a third person, or by the lawyer’s own interests, unless: (1) the lawyer reasonably believes the representation will not be adversely affected; and (2) the client consents after consultation . . . .
\end{quotation}
\end{quote}

\textsuperscript{58} See Wendt v. Fischer, 154 N.E. 303, 304 (N.Y. 1926) (“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 . . . .” (citation omitted)).

\textsuperscript{59} Canterbury v. Spence, 464 F.2d 772, 780 n.15 (D.C. Cir. 1972), cert. denied, 409 U.S. 1064 (1972). “[T]he fact finding process on performance of the duty [to disclose] reaches back to what the physician actually said, [and while the] adequacy of the revelation will vary as between patients, . . . the fluctuations are attributable to the kind of divulgence which may be reasonable under the [particular] circumstances.” Id. See also Dunham v. Wright, 423 F.2d 940, 946 (3d Cir. 1970) (finding that disclosure of alternative treatment means disclosure of alternatives for the particular patient, not a recital of medical theory); Campbell v. Oliva, 424 F.2d 1244, 1251 (6th Cir. 1970) (“[E]ach patient presents a separate problem, . . . the patient’s mental and emotional condition is important and in certain cases may be crucial, and . . . in discussing the elements of risk a certain amount of discretion must be employed consistent with the full disclosure necessary for an informed consent.” (quoting Ball v. Mallinkrodt Chem. Works, 381 S.W.2d 563, 567 (Tenn. Ct. App. 1964))).

\textsuperscript{60} See, e.g., Magan Medical Clinic v. California State Bd. of Medical Examiners, 57 Cal. Rptr. 256, 262 (Ct. App. 1967) (“Certainly a sick patient deserves to be free of any reasonable suspicion that his doctor’s judgment is influenced by a profit motive.”).

The Moore Court noted that a physician must disclose all facts that are material to a patient’s decision about treatment. Moore v. Regents of the Univ. of Cal., 793 P.2d 479, 485 n.10 (Cal. 1990), cert. denied, 111 S. Ct. 1388 (1991). It is important to distinguish physicians’ obligations with respect to patients’ medical needs from patients’ other interests. The Moore court was concerned not with protecting patients’ financial interests, but rather with certain personal interests of physicians which, if not disclosed, could affect the physicians’ professional judgments. Id. Whether or not a physician has a duty to disclose a personal interest depends on the materiality of that interest to the doctor’s recommendation of a particular medical procedure. Id. at 485 n.9.
a patient's treatment decision. Furthermore, a physician has an affirmative duty to make adequate disclosure of all information material to a patient's decision prior to commencing treatment.

It is the fiduciary relationship between doctor and patient that imposes upon the doctor the obligation to disclose to the patient all material facts necessary for the patient to make an informed decision. As in other fiduciary relationships, the physician as fiduciary cannot profit from the relationship absent full disclosure even if the patient also benefits from the course of treatment prescribed.

III. THE DOCTRINE OF INFORMED CONSENT

The doctrine of informed consent is a product of tort law stemming from the fundamental principle "volenti non fit injuria — to one who is willing, no wrong is done." In the context of the doctor-patient relationship, the doctrine can be defined as a physician's duty to inform a patient of the risks, expected results, potential but unexpected results and potential complications of the proposed medical treatment. Informed consent is necessary in order to assist the patient in deciding whether to undergo or refuse medical treatment.

61. Moore, 793 P.2d at 483.
62. OTA REPORT, supra note 16, at 98 (discussing timing of disclosure necessary for informed consent). According to Annas, a breach of a physician's duty to disclose occurs when any of the specific disclosure requirements adopted in a particular jurisdiction are not followed. ANNAS et al., supra note 31, at 30. For a sample disclosure checklist a physician might use, see infra note 73.
63. Lambert v. Park, 597 F.2d 236, 239 n.7 (10th Cir. 1979) ("The duty of the doctor to inform the patient is in the nature of a fiduciary duty . . . ."); Roebuck v. Steuart, 544 A.2d 808, 821 (Md. App. 1988).
64. Id.
66. Id. at 112.
68. See Griffith, supra note 67, at 976 (quoting Judge Cardozo's dictum "[e]very human being of adult years and [sic] mind has a right to determine what shall be done with his own body . . . ." in Scholoendoff v. Society of N.Y. Hosp., 105 N.E. 92, 93 (N.Y. 1914)).
A. Traditional Informed Consent Doctrine

In Canterbury v. Spence, the court noted that "the average patient has little or no understanding of the medical arts, and ordinarily has only his physician to whom he can look for enlightenment with which to reach an intelligent decision." This characterization is consistent with basic tenets of fiduciary law, such as the principal's dependence on the fiduciary and the disparity of special knowledge between the parties. The doctrine of informed consent reflects concerns other than fiduciary obligations as well.

Informed consent refers to legal rules that prescribe behaviors for physicians in their interactions with patients and provide for penalties, under given circumstances, if physicians deviate from those expectations; to an ethical doctrine, rooted in our society's cherished value of autonomy, that insures to patients their right of self-determination when medical decisions need to be made; and to an interpersonal process whereby physicians interact with patients to select an appropriate course of medical care.

The doctrine of informed consent has traditionally been applied to protect patients from risky medical procedures that may result in physical injuries. Consistent with that purpose, the law generally

70. Id. at 780.
71. See supra text accompanying notes 44-46. Relationships that stem from specialization, such as the physician-patient relationship, "are often classified as fiduciary because they pose the problem of abuse of power that is common to fiduciary relations." Frankel, supra note 38, at 804. Where specialization characterizes the relationship, the superior knowledge of the fiduciary justifies disclosure requirements. See id. at 803. There is an inherent risk that the power a fiduciary derives from expertise will be misused to the injury or detriment of the principal. Id. at 809.
73. Informed consent requires disclosure by a physician of the nature of a medical treatment according to prevailing standards of practice. Mary T. Danforth, Cells, Sales, and Royalties: The Patient's Right to a Portion of the Profits, 6 YALE L. & POL'Y REV. 179, 182 n.11 (1988). The standard for disclosure varies according to jurisdiction, but usually falls into one of three categories: (1) customary practice in the area; (2) a reasonable physician standard; or (3) a standard which asks "what the reasonable patient would need to know to make an intelligent choice." Id. (citing Raymond D. Cotton & Andrew L. Sandler, The Regulation of Organ Procurement and Transplantation in the United States, 7 J. LEGAL MED. 55, 73-74 (1986)). See also FAY A. ROZOVSKY, CONSENT TO TREATMENT A PRACTICAL GUIDE 9 (2d ed. 1990) (describing the elements of a traditional negligence-based claim for lack of informed consent). See generally infra text accompany-
denies "recovery for inadequate disclosure in the absence of bodily harm." Where a lack of informed consent is alleged, a patient must demonstrate that the insufficiency of information was the effective cause of his or her harm. In other words, the patient must prove that the treatment undertaken would have been refused had the patient known of risks not disclosed. An objective standard applies to test this element of causation; the patient-plaintiff must prove that a reasonable person in the patient's position would have withheld consent to treatment if all material risks had been disclosed. Furthermore, the patient may recover damages only if the resultant bodily harm is "one the risk of which was not explained or known to the patient prior to the [defendant's] medical intervention."

The paradigm presented by Moore offers a unique twist in applying informed consent analysis. Under traditional analysis, Moore's claim for lack of informed consent will fail notwithstanding nondisclosure of the commercial use of Moore's tissue unless Moore can also demonstrate that a reasonable patient would have refused treatment, i.e., the splenectomy, had he had known of the research project. As a practical matter, Moore will be unable to satisfy that burden because removal of Moore's spleen was instrumental in saving his life. Nevertheless, two key questions re-
main: to what did Moore consent and in what capacity did Golde act, physician or researcher?

The Moore case addresses indirectly the issue of whether a patient must specifically consent to a physician using tissue removed from the patient's body for commercial purposes. Yet, the facts do not lend themselves to traditional informed consent analysis because the disclosure owed to Moore from his physician pertaining to a conflict of interest regarding potential profits, not risk of bodily harm. When Golde continued to take blood samples from Moore not for a medical purpose beneficial to Moore but rather for Golde's research, Moore ceased being a patient in the therapeutic sense and become more like a research subject.\textsuperscript{79}

The hybrid situation typified by Moore, where a physician treats a patient and simultaneously uses the related diagnostic specimens for research, defies traditional informed consent analysis.\textsuperscript{80} Was Moore consenting as a patient to medical treatment, was Moore consenting to be the subject of research or was Moore consenting to the use of his tissue as the subject matter of research? Apparently, Moore himself became similarly confused about his status with respect to Golde's work and refused to sign consent forms offered at the time of later visits to the Medical Center without complete answers to questions about his role in Golde's work.\textsuperscript{81}

B. Informed Consent to Human Research

With respect to medical treatment, the doctrine of informed consent focuses on adequate disclosure of the risks and benefits of proposed medical procedure. In comparison, disclosure requirements with respect to medical research aim at ensuring that subjects understand the nature of the studies, the level of involvement required of them and any risks involved.\textsuperscript{82}

After World War II, human research became a topic of serious discussion world-wide.\textsuperscript{83} This elevated level of interest led to the

\textsuperscript{79} See supra text accompanying notes 18-19.

\textsuperscript{80} See Danforth, supra note 73, at 184 (contending that Moore's case would "fail under traditional informed consent doctrine").

\textsuperscript{81} See supra text accompanying notes 20-26.

\textsuperscript{82} See OTA REPORT, supra note 16, at 100, 102 (describing the need for a detailed disclosure of risk information in the research setting).

\textsuperscript{83} Id. at 94.
creation of a myriad of guidelines, statutes and regulations to oversee those conducting human research.\textsuperscript{84} Regulations governing medical research incorporate notions of informed consent. “Both statutory law and related administrative regulations define informed consent as a primary independent principle for the regulation of research on human subjects.”\textsuperscript{85} However, informed consent in the research context differs from informed consent in the treatment context. The statutory and administrative definitions of informed consent for research have moved away from the tort-based concept of informed consent for medical treatment. Instead of focusing on the personal liability of physicians and on redressing harms already done, the law governing human research is designed to prevent harm to research subjects.\textsuperscript{86}

In this country, federal regulations have been promulgated to protect human subjects participating in federally-sponsored research. The agencies primarily responsible for these regulations are the Department of Health and Human Services (HHS)\textsuperscript{87} and the Food and Drug Administration (FDA).\textsuperscript{88} The HHS regulations are “recognized as being the primary Federal requirements governing the protection of human research subjects.”\textsuperscript{89} The HHS regulations address explicitly the general requirements for informed consent, reflecting regulators’ concern that any undue influence or coercion of the subject be minimized, and specify when waiver is permissi-

\textsuperscript{84} Id. See infra notes 86-90 and accompanying text.

\textsuperscript{85} BERNARD BARBER, INFORMED CONSENT IN MEDICAL THERAPY AND RESEARCH 41 (1980). Informed consent is considered a relatively new development in this area of patient/subject — doctor/researcher interaction. In the late 1960’s, a long-time observer of developments affecting law and medicine offered this commentary:

\begin{quote}
In the years prior to the current decade [the 1960’s], there was little “law” in the United States concerning medical research. There were no specific federal or state statutes purporting to regulate research organizations or investigators in their research methods, their areas of research, or the use of subjects or patients in such work. There were also no reported court actions involving liability issues of criminal actions against research organizations or personnel.
\end{quote}

\textit{Id.} (citation omitted) (quoting Professor William Curran of the Harvard Medical School).

\textsuperscript{86} Id. at 44 (quoting Curran).

\textsuperscript{87} 45 C.F.R. §§ 46.101-.124 (1990) (governing research conducted or funded by HHS, which includes the National Institutes of Health).

\textsuperscript{88} 21 C.F.R. §§ 50.1-.48 (1991) (governing clinical investigations to support applications for research or marketing permits for products including drugs, food additives, biological products and medical devices).

\textsuperscript{89} OTA REPORT, supra note 16, at 94 (“The Interagency Human Subjects Coordinating Committee, which has representatives of 17 Federal agencies, has proposed that the DHHS regulations serve as a model policy for all Federal departments and agencies . . . .”).
ble and under what circumstances verbal consent can be accept-
ed.\textsuperscript{90}

The objectives of these regulations serve the valuable purpose of protecting human research subjects. However, these regulations, even when properly executed, reach only those research programs subject to federal regulation.\textsuperscript{91} In \textit{Moore}, these regulations did not appertain.\textsuperscript{92}

IV. \textit{MOORE} REVISITED

A. Breach of Fiduciary Duty

As previously discussed, the physician-patient relationship is a fiduciary one; physicians owe a special duty of care to patients not to act in any way contrary to patients' best interests or in any way that would jeopardize patients' rights or welfare.\textsuperscript{93} Physicians' fiduciary obligations have been construed to pertain not only to protection of patients from physical harm, but to protection of patients from any conflict of interest that might impair the physicians' ability to provide optimal treatment.\textsuperscript{94} In \textit{Moore}, Golde's judgment was conflicted by the inherent tension between

\begin{footnotes}
\item[90] See 45 C.F.R. §§ 46.116-.117. The relevant sections provide:

\begin{quote}
Except as provided elsewhere in this or other subparts, no investigator may involve a human being as a subject in research covered by these regulations unless the investigator has obtained the legally effective informed consent of the subject or the subject's legally authorized representative. An investigator shall seek such consent only under circumstances that provide the prospective subject or the representative sufficient opportunity to consider whether or not to participate and that minimize the possibility of coercion or undue influence . . .
\end{quote}

\textit{Id.} § 46.116. The regulations continue:

(a) Except as provided in paragraph (c) . . . informed consent shall be documented by the use of a written consent form . . .

(b) [specifies the written consent form requirements]

(c) An IRB [Institutional Review Board] may waive the requirement for . . . a signed consent form for some or all subjects if it finds either:

(1) . . . [T]he principal risk would be potential harm resulting from a breach of confidentiality . . . [or]

(2) That the research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context.

\textit{Id.} § 46.117.

\item[91] See \textit{id.} § 46.101. See also \textit{supra} text accompanying notes 87-88.

\item[92] See \textit{infra} text accompanying notes 123-25.

\item[93] See \textit{supra} text accompanying note 52.

\item[94] See \textit{supra} text accompanying notes 60-64.
\end{footnotes}
treating Moore for the sake of Moore's health under the auspices of continued therapy and treating Moore for the sake of medical research driven by the unique character of Moore's tissue and its potential to yield results having substantial commercial value.

In a therapeutic setting, "the physician may have more influence over his patient ..." than a physician would have in a strictly nontherapeutic, experimental setting. Therefore, a physician treating a potential research subject may be ideally situated to exercise undue influence to coax or even coerce the patient to participate in research. The prospect of commercial gain provides a motive which could lure a physician to compromise a patient's therapeutic needs in favor of using the patient as an "invaluable source of scientific knowledge . . . ."96

1. Physicians' Liability

If Moore brings a cause of action for breach of fiduciary duty, his claim will be tested against the traditional rules guiding the rights and obligations of each party in a fiduciary relationship. Moore will have to prove that Golde's breach — his failure to disclose the conflict of interest — was the proximate cause of some harm to him.97 Under traditional principles of fiduciary law, Moore could argue that Golde, as fiduciary, secured a benefit for himself at a cost to Moore, his principal, and that Golde therefore violated the basic duty of loyalty owed by fiduciary to principal when he failed to disclose his own interest.98 But, the Moore court framed the conflict of interest issue to reflect a concern for patients' physical well-being rather than for patients' financial interest in the raw materials supplied to physician/researchers.

95. ANNAS et al., supra note 31, at 54. See also OTA REPORT, supra note 16, at 97 ("The danger of undue influence is as real in the research setting as it is in the medical treatment context.").

96. OTA REPORT, supra note 16, at 97. The OTA Report also notes that commercial gain is not the only motivation for undue influence used by physician/researchers.

For some, the potential for public or scientific recognition may be more of an impetus to unduly influence subjects than the thought of reaping financial reward. While it may be difficult to discern public or peer recognition as a cause for concern, the potential exists for the physician/researcher to conduct himself/herself in a manner that unduly influences the subject.

Id.

97. See, e.g., Roebuck v. Stewart, 544 A.2d 808, 821 (Md. App. 1988) (holding that a lawyer breached his fiduciary duty by not revealing a conflict of interest which was the proximate cause of a damage award against the lawyer’s client).

98. See supra text accompanying notes 40-53.
So long as a physician discloses research and economic interests that may affect his judgment, the patient is protected from conflicts of interest. Aware of any conflicts, the patient can make an informed decision to consent to treatment, or to withhold consent and look elsewhere for medical assistance.  

Thus, even if Moore clears one hurdle by proving Golde failed to disclose a conflict of interest, he faces yet another obstacle in proving that failure to disclose the conflict caused the type of injury intended to be prevented by traditional disclosure requirements between physicians and patients.  

2. Damages for Breach of Fiduciary Duty

The question remains as to what damages Moore would be entitled to receive if he were to prove Golde’s liability for breach of fiduciary duty. Moore may have incurred unnecessary expenses in travelling between Seattle and Los Angeles. Therefore, Moore’s visits for blood work-ups may be compensable if lack of full disclosure regarding their purpose was the proximate cause of Moore spending time and money to make these trips. In contrast, it is unlikely Moore can successfully argue that he would have refused the initial life-saving operation to remove his spleen. In other words, even if Golde’s financial interest in Moore’s spleen created a conflict of interest that should have been disclosed, the conflict was not the proximate cause of any harm to Moore. While full disclosure of Golde’s potential economic interest may have led him to choose another physician, Moore would have undergone the splenectomy in any event. Because Moore was not really harmed by the loss of his spleen, he could claim no damages arising from the loss.


100. See id. at 496-97.

101. It is not the purpose of this note to discuss damages in detail, but rather to raise the reader’s awareness that the causes of action “available” to Moore in light of the California Supreme Court’s opinion would either be impossible to prove based on the existing legal theory or inadequate.

102. Golde may also argue that there was no conflict to disclose at the time of the splenectomy because Golde was unaware of the potential commercial value of Moore’s tissue until after surgery had been performed. This argument would not be true with respect to subsequent blood work-ups requested by Golde.
ing from that particular procedure in his treatment.

As a result, Moore's damages for breach of fiduciary duty would probably be nominal, limited to harm he experienced after removal of his spleen.

B. Lack of Informed Consent

1. Traditional Informed Consent to Medical Treatment

As discussed above, a cause of action for lack of informed consent is tested against an objective standard asking whether a reasonable patient would have undergone a particular procedure had the patient known of the undisclosed risk realized in the plaintiff's case. The traditional informed consent claim was not designed to accommodate the situation illustrated in Moore — commercialization of a patient's tissue and organs without the patient's consent.

The elements of a claim for monetary damages based on lack of informed consent vary from jurisdiction to jurisdiction. Generally, these criteria address such issues as the standard of conduct required of the physician, the standard of causation and the necessity of expert testimony. These rules of recovery guide the litigation process in suits brought by patients seeking damages from physicians who have allegedly violated their duty to obtain informed consent.

103. See supra text accompanying notes 75-76.
104. See supra text accompanying notes 77-81.
105. The standard typically imposed is "one of 'good medical practice,' which is to say, what is customary and usual in the profession." KEETON et al., supra note 65, at 189. This legal standard gives the medical community the ability to establish customary conduct in the profession by merely adopting its own usual practice. Id.
106. Two standards of causation in informed consent cases have emerged. APPELBAUM et al., supra note 72, at 119. Decision-causation exists when it "can be said that if the physician had made proper disclosure, a decision would have been made to decline treatment . . . ." Id. at 121. Injury-causation exists if the patient can show "that the medical procedure performed by the defendant [physician] led to the injury. This requirement is merely a specific instance of the general one in negligence cases that the plaintiff prove cause-in-fact . . . ." Id. at 119-20.
107. Most jurisdictions require that testimony of an expert witness be presented to assist the jury in understanding the questions of medical science and technique it will consider in reaching its verdict. KEETON et al., supra note 65, at 188. Expert testimony is used to establish the standard of care and the fact that a physician's conduct in any particular case did not measure up to the applicable standard. Id.
108. APPELBAUM et al., supra note 72, at 15. According to Appelbaum and his co-authors,
Causes of action for violation of the informed consent doctrine have been prosecuted in two forms: as intentional tort sounding in battery or as professional negligence. Battery occurs when a person engages in intentional conduct resulting in an offensive, but not necessarily harmful, touching of another person. Contact is considered offensive if it occurs without consent. Therefore, a physician commits a battery if he or she fails to obtain proper consent to any procedure involving touching. Negligence, on the other hand, requires the injured party to meet more rigorous criteria to establish physician liability. A patient alleging negligence must first establish that the physician failed to use reasonable care to prevent harm to the patient. Then the patient must prove that the physician's failure to act with reasonable care was the proximate cause of some injury. The distinction between the two theories for informed consent liability has been described as follows:

If lack of informed consent is remediable as a battery rather than negligence, a patient has a right to recover damages for inadequate disclosure alone, even if not physically injured by the physician's treatment. The wrong to the patient is the deprivation of a right of personal choice based upon adequate information, sometimes called a dignitary harm. In contrast, with negligence theory the right vindicated is the right to be free from bodily injury caused by substandard medical practice. If the negligence causes no bodily injury to the patient, no remediable wrong is considered to have occurred.

The problem Moore faces in asserting a violation of informed consent [the rules of recovery] are largely technical issues, most of which should have only indirect (though not necessarily insubstantial) effect on the manner in which physicians seek to comply with their duties to inform patients and obtain their consent. [The rules] deal, in effect, not with the right to informed consent, but with the remedy for the violation of that right.

Id. at 116.
110. RESTATEMENT (SECOND) OF TORTS § 18.
111. See id. § 18 cmt. c.
112. APPELBAUM et al., supra note 72, at 114.
113. See supra text accompanying notes 73-76. See also APPELBAUM et al., supra note 72, at 115 (describing the negligence theory of a physician's failure to obtain informed consent).
114. APPELBAUM et al., supra note 72, at 117.
consent centers on this distinction. Courts have tended to overlook the battery action in favor of the professional negligence theory. The general unwillingness of courts to invoke the rules of battery means that without some showing of physical harm, Moore has no viable claim for damages. As already noted, the argument that Moore was harmed is quite tenuous because the splenectomy performed by Golde saved Moore's life.

As an alternative to the battery theory, Moore could sue Golde for inadequate disclosure of the true nature of his post-surgery therapy under other torts that recognize a patient's dignitary rights. These possible actions include intentional infliction of emotional distress, negligent infliction of emotional distress and inva-
sion of privacy. Each of these causes of action will present different problems in practice, but they all highlight the same weakness in the law of informed consent: a patient must proceed outside traditional law to obtain recovery for a wrongful act by a physician. As one commentator notes, however, the expansion of these alternative approaches to patient recovery in the absence of bodily harm demonstrates courts' concern with protecting patients' dignitary interests. Nevertheless, the scramble for other theories to redress nonphysical harms indicates the failure of traditional informed consent doctrine to adequately protect the interests of those patients faced with new problems that are the by-products of an expanding technology.

2. Informed Consent to Participate in Research

Despite the existence of federal regulations pertaining to research involving human subjects, those rules do not resolve the issues raised in Moore with respect to physicians who treat patients and conduct research. First, these regulations apply only to research involving human subject matter which is conducted or funded by the federal government. Second, the regulations exempt many types of research involving human subjects, including research on

---

120. See Meisel, supra note 74, at 213. Meisel notes that "[t]he right to privacy — when viewed as a right to be let alone — is a more straightforward approach for protecting the interests which the law of informed consent does and should protect than battery or infliction of emotional distress." Id. As between battery and negligence, however, the theory of recovery preferred by the courts, negligence, fails completely to protect a patient's right to be let alone, the very human dignity which is demeaned by inadequate disclosure. Id. at 214.

121. See id. at 211-12 (stating that the law of battery has historically been the remedy for offensive physical contact which does not result in bodily harm, but courts have been reticent to apply those standards to the doctor-patient relationship).

122. Id.

123. See supra text accompanying notes 87-92.

124. 45 C.F.R. § 46.101. The research must be linked to HHS by direct financial support or through staffing with government employees. Id. § 46.101(a).
diagnostic specimens.\textsuperscript{125}

Even if the research was subject to federal regulation, it is likely Moore's spleen would have been considered a diagnostic specimen exempt from federal controls. Thus, because the facts of \textit{Moore} do not seem to fit within the province of the regulations, the regulatory informed consent provisions protecting research subjects would be unhelpful to Moore's cause.

Only a few states have enacted similar statutes regulating human research; those that have acted exempt from state regulation research subject to federal rules.\textsuperscript{126} While numerous state statutes address the traditional view of informed consent, none specifically addresses a physician's obligation to disclose commercial interests in patients' tissues.\textsuperscript{127} In 1987, a report issued by the congressional Office of Technology Assessment speculated that the lack of

\textsuperscript{125} \textit{Id.} § 46.101(b)(5).

Research activities in which the only involvement of human subjects will be in one or more of the following categories are exempt from these regulations...[research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are made publicly available or if the information is recorded by the investigator in such a manner that the subjects cannot be identified, directly or through identifiers linked to the subjects.}

\textit{Id.}

\textsuperscript{126} \textit{See CAL. HEALTH & SAFETY CODE §§ 24,170-79.5 (West 1990) (Protection of Human Subjects in Medical Experimentation Act).}

[T]his chapter shall not apply to any person who is conducting a medical experiment as an investigator within an institution which holds an assurance with the Department of Health, Education and Welfare pursuant to Part 46 of Title 45 of the Code of Federal Regulations and who obtains informed consent in the method and manner required by such regulations.

\textit{Id.} § 24,178. \textit{See also N.Y. PUB. HEALTH LAW §§ 2440-46 (McKinney 1985) (Protection of Human Subjects).}

The provisions of this article shall not apply to the conduct of human research which is subject to, and which is in compliance with, policies and regulations promulgated by any agency of the federal government for the protection of human subjects.

\textit{Id.} § 2445.

\textsuperscript{127} \textit{See, e.g., COLO. REV. STAT. § 25-1-121 (1989). The Colorado statute provides for patient grievance mechanisms in state licensed institutions that require appointment of patient representatives and posting of the institution's policy statement in a conspicuous place. The policy statement must include language stating that every physician has an obligation to provide their patients with information regarding research, experimental or educational projects relating to that particular patient's case. The Colorado statute illustrates states' awareness that some physicians both treat patients and conduct research or experimentation. However, regulations like Colorado's are still inadequate because the requirement that doctors disclose the existence of a research project does not mean they will disclose their potential commercial gains.}
state regulation in this area of the law "may reflect a belief that the states are not equipped to regulate or monitor human research . . . [or] that state legislators do not believe the subject is so pressing as to require legislative initiatives."  

V. PROPOSAL

Common law recovery for breach of fiduciary duty or lack of informed consent is simply inadequate for patients whose rights to full disclosure of physicians' commercial interests in their tissues have been violated. Patients need some other form of protection for these interests. A clear signal must be sent to physicians regarding the extent of their duty to disclose economic interests in tissues removed from patients under their medical care.

A. The Case for Disclosing Commercial Gain

Should physicians be required to disclose prospects of commercial gain to their patients? If so, how much information must be disclosed? Arguments can be made on both sides of the disclosure issue.

The argument in favor of disclosure requirements with respect to commercial interests stems largely from the concept of patients' right to self-determination, a fundamental idea which permeates the doctrine of informed consent at many levels. This argument holds that a patient should be able to make an informed and intelligent decision regarding medical treatment. Professors Katz and Capron argue that informed consent to medical intervention performs six distinct functions:

1. To promote individual autonomy;
2. To protect the patient-subject's status as a human being;
3. To avoid fraud and duress;
4. To encourage self-scrutiny by the physician-investigator;
5. To encourage rational decisionmaking; and
6. To involve the public.

---

128. OTA REPORT, supra note 16, at 95.
129. See SHEILA MCCLEAN & GERRY MAHER, MEDICINE, MORALS AND THE LAW 79 (1983) ("Traditionally [consent] is deemed to be a means of protecting the right to self-determination which it is held all people have."). See also supra note 32 and accompanying text.
130. Capron, supra note 75, at 364.
131. ANNAS et al., supra note 31, at 33 (condensing the point headings of JAY KATZ &
Numbers one through three essentially restate the same proposition — a patient has a right to individual autonomy which protects his or her body from invasion without consent.\textsuperscript{132} Numbers four and five address the concept of rational decisionmaking from both sides of the doctor-patient relationship.\textsuperscript{133} Finally, number six describes the role consent plays with regard to a physician's reputation and society's awareness of human research.\textsuperscript{134} Thus, the primary functions of informed consent from a moral standpoint are to protect the patient's individual autonomy, to promote rational decisionmaking by both parties and to encourage public awareness.\textsuperscript{135}

In the context of the Moore paradigm, these considerations support the position that patients have a right to full disclosure of physicians' commercial interests in their tissue and cells. Both the right to individual autonomy and the need for rational decisionmaking require that all material information regarding medical intervention be disclosed to the patient before consent is given for treatment. Some patients may have strong opinions regarding particular types of research or commercialization of their tissues that would lead them to forego treatment if such information were disclosed. Alternatively, patients may choose to have the procedure performed by another physician who does not have an economic interest related to research with diagnostic specimens from the patient.

Once a patient receives full disclosure about a physician's potential commercial gain and consents to treatment despite the conflict, the patient would not be entitled to share in profits resulting from the research. In other words, patients would not be allowed to bargain for a share of potential profits in exchange for their consent to medical treatment. The purpose of disclosure is to preserve patients' right to make informed and rational decisions re-

\textsuperscript{132} Id. at 33-34. For additional information describing a person's right to individual autonomy, see \textit{supra} note 33 and accompanying text.

\textsuperscript{133} \textit{ANNAS et al., supra note 31, at 34.}

\textsuperscript{134} Capron, \textit{supra} note 75, at 376. Capron notes that obtaining consent can either enhance a physician's reputation for treating patients with equity and fairness or harm the physician's reputation by labelling the doctor as using patients "as guinea pigs for [medical] studies or . . . innovations . . . ." \textit{Id.} at 376 n.86.

\textsuperscript{135} See \textit{ANNAS et al., supra note 31, at 33-34.} Annas comments, however, that the public awareness "function" of informed consent is really just a "potential byproduct, rather than a function." \textit{Id.} at 33.
regarding treatment, not to encourage speculation by patients and physicians about the profitability of particular medical procedures.\textsuperscript{136} Furthermore, removing the prospect of financial reward for the patient helps to ensure that the patient’s judgment will not be clouded and that his or her ability to examine and assess the medical risks of the proposed treatment will not be impaired.

The Moore court essentially eliminated patients’ ability to secure a stake in a “highly theoretical windfall” under existing causes of action by refusing to recognize property rights in patients’ tissue.\textsuperscript{137} It directed parties interested in pursuing the issue to the legislature.

If the scientific users of human cells are to be held liable for failing to investigate the consensual pedigree of their raw materials, we believe the Legislature should make that decision. Complex policy choices affecting all society are involved and “[l]egislatures, in making such policy decisions, have the ability to gather empirical evidence, solicit the advice of experts, and hold hearings at which all interested parties present evidence and express their views . . . .”\textsuperscript{138}

Generally, physicians do not have an absolute duty to inform patients of any and all risks and resultant consequences of a medical intervention.\textsuperscript{139} Rather, physicians must not “deviate[] from what expert testimony [shows] to be the established, acceptable medical practice on disclosure in the community.”\textsuperscript{140} Alternatively, some courts state the physician’s duty to patients as requiring disclosure of “all material facts which reasonably should be known if his patient is to make an informed and intelligent decision.”\textsuperscript{141}

\begin{itemize}
\item[136.] Recall that financial gain attributable to tissue from a single individual is extremely unusual. See supra note 24 and accompanying text. Thus, undertaking treatment with an eye toward financial reward would be a highly speculative venture.
\item[137.] Moore v. Regents of the Univ. of Cal., 793 P.2d 479, 496 (Cal. 1990), cert. denied, 111 S. Ct. 1388 (1991).
\item[138.] Id. (quoting Foley v. Interactive Data Corp., 765 P.2d 373, 397 n.31 (Cal. 1988)).
\item[139.] Capron, supra note 75, at 404.
\item[140.] Id. at 404-05. See also supra note 73 and accompanying text.
\end{itemize}

Certain types of information are generally recognized as not being subject to the disclosure requirement:

- risks already known to the patient,
- obvious risks which the patient may be presumed to know,
Physicians argue that if they were to disclose potential commercial gain to a patient in need of medical intervention, that disclosure would detract from the more important medical aspects of the proposed treatment and could hamper the patient's “ability to reach an informed choice free of undue influence.” In addition, some physicians argue that patients will distort their medical histories, either by inclusion or omission, to qualify for a particular study. These arguments reflect concern for the patient’s ability to handle information regarding commercialization of their tissue.

Physicians and researchers also assert that they are not qualified to estimate the potential commercial value of a particular diagnostic specimen. Because the prospect of commercial gain is often highly speculative, the value of a particular patient’s contribution to a particular research project would be impossible to convey at the time of disclosure with any quantifiable accuracy. In light of these arguments, physicians would likely conclude that disclosure of commercial gain should not be required under either the informed consent doctrine or principles governing fiduciary relationships.

Despite physicians’ arguments against disclosure, patients’ rights to individual autonomy and self-determination must prevail. Physicians should not have unlimited discretion to decide what to disclose. “Unlimited discretion in the physician is irreconcilable with the basic right of the patient to make the ultimate informed decision . . . .” While participation in medical experimentation and research, which generally seeks to benefit all humankind, should be encouraged, the drive for medical advances should not be made at the expense of participants’ right to know of their involvement.

---

143. Id. at 102.
144. Id.
145. Id.
147. See ANNAS et al., supra note 31, at 261.
B. Effecting Adequate Disclosure

This note proposes a two-part approach to protecting patients from inadequate disclosure of their physicians’ conflicting commercial interests. On one level, physicians can address this problem within the profession through self-regulation and enforcement. On another level, the current language of the federal regulations guiding human research can be modified to include research performed on diagnostic specimens received from patients undergoing medical treatment.

1. Self-regulation by the Profession

Traditional codes of medical ethics focus on the moral obligations of physicians and health-care professionals rather than on the rights of patients. The Hippocratic Oath, for example, emphasizes the fundamental principles of beneficence and nonmaleficence. The ethical code of the American Medical Association (AMA) has, to some extent, moved away from the primacy of the physician’s obligation reflected in the Hippocratic Oath to account for patients’ right to self-determination.

Although the code of ethics promulgated by the AMA is not law, it is considered the standard by which “a physician [should] determine the propriety of his conduct in his relationship with [his] patients.” Language requiring full disclosure of possible economic conflicts of interest should be added to medical codes of ethics to ensure that physicians fulfill their fiduciary obligations. Doctors’ commercial interests in their patients’ tissues should be characterized as a material fact to be disclosed in obtaining general consent to treatment procedure. Such additional language could be enforced through sanctions by appropriate Medical Boards of Review in state professional associations.

148. See, e.g., THOMAS A. MAPPES AND JANE S. ZEMBATY, BIOMEDICAL ETHICS 45 (1981) ("Physicians are expected to perform those actions which will benefit their patients and to refrain from performing those that will harm them.").
149. Id. ("Benefit and do no harm to the patient.").
150. See Abstract of Proceedings of the House of Delegates of the American Medical Association at the Annual Meeting in New York, June 3-7, 1957, 164 JAMA 1099, 1119-20 (July 6, 1957) (noting that the 1957 version of the AMA ethical code characterizes the physician’s primary obligation as being “to render service to humanity with full respect for the dignity of man[1]").
151. Id. at 1119.
The effectiveness of additional language pertaining to the disclosure of commercial gain may, however, be limited. A recent survey of medical house officers' knowledge and attitudes regarding medical ethics indicates that most residency programs have only recently begun to include training with respect to the ethics of patient care. The findings further indicate that house officers' knowledge of ethical rules declines as the time since the officers' post-graduate training increases. This trend suggests that physicians who have been in practice for a number of years are less attentive to their ethical responsibilities. However, the study did show that ethical awareness is enhanced when educational intervention was provided for house officers who completed residency programs a number of years earlier. Therefore, educational intervention combined with the changes in the medical ethics codes would help to ensure that physicians are aware of their obligation to disclose commercial conflicts.

2. Legislative Response

At this time, the federal regulations guiding research involving human subjects specifically exempts research on diagnostic specimens. These regulations could be amended to eliminate this exemption so that research funded by the Department of Health and Human Services involving diagnostic specimens would also have to follow the statutory informed consent procedures. The OTA Report noted that identification of specific human sources would be difficult in many instances, and therefore suggested that disclosure of potential commercial gain be limited to those situations where there is a high probability of "marketable biological material" being extracted from the tissue of an identified sub-

152. Daniel P. Sulmasy et al., Medical House Officers' Knowledge, Attitudes, and Confidence Regarding Medical Ethics, 150 ARCHIVES INTERN. MED. 2509, 2509 (1990).

[The goals of such training are to enhance patient care by (1) imparting knowledge of ethics vocabulary and established principles of ethical analysis and of relevant legal and historical facts, and (2) fostering skills that enhance the ability of physicians to communicate with patients, with families, with colleagues, and with professionals outside the health care field regarding ethical issues.]

153. Id. at 2512.

154. Id.

155. See supra note 124 and accompanying text.

156. See 45 C.F.R. § 46.116 (requirements for informed consent).
ject.  

An easier alternative exists. Rather than undertaking identification of the potential value of any one research subject's tissue, physicians who choose to conduct research on tissues acquired through therapeutic procedures should be required to make a general disclosure to each patient from whom tissue might be used. Mere disclosure that the subject's tissue might be used in research that could result in financial gain to the attending physician would suffice. Patients who have strong concerns that their physicians' economic interests may compromise treatment decisions can have necessary procedures performed by other physicians.

Simply amending the federal regulations to reflect such a requirement presents some difficulties. First, the federal regulations will not affect every research situation because not all research is federally funded. Nevertheless, governments fund a significant amount of medical research and promulgating new disclosure regulations to accompany those funds is at least a step in the right direction. States could supplement federal regulations with analogous disclosure rules and could include sanctions in state licensing schemes to encourage compliance with all disclosure requirements.

Second, initiatives to protect patients' right to self-determination and to prevent abuse of trust by physicians-fiduciaries should not create a significant hindrance to the valuable research conducted on the specimens obtained from patients. However, if patients are entitled only to know of potential commercial gain but not to share in profits realized, the incentive to conduct research should not be inhibited.

Third, enforcement may be cumbersome because some type of verification disclosure form documenting compliance with the new regulations will have to accompany each diagnostic specimen. However, the benefits of preserving patients' basic disclosure rights

158. Federal and state governments contribute significant funds to support the biotechnology industry. In 1987, the federal figure exceeded $2.6 billion while some 33 states contributed over $100 million. OFFICE OF TECHNOLOGY ASSESSMENT, NEW DEVELOPMENTS IN BIOTECHNOLOGY: U.S. INVESTMENT IN BIOTECHNOLOGY 1-2 (1987).
159. See Lavoie, supra note 11, at 1368-69 (discussing the importance of governmental support for the biotechnology industry). See also Moore v. Regents of the Univ. of Cal., 793 P.2d 479, 487 (Cal. 1990), cert. denied, 111 S. Ct. 1388 (1991) (expressing concern that tort liability for use of patients' tissues in research could adversely affect medical research).
outweigh the burden on physicians of requiring their patients to read and sign one additional form prior to treatment.

VI. CONCLUSION

Requiring disclosure of potential commercial gain by physicians who treat patients and conduct research on specimens taken from them opens important lines of communication between doctor and patient with respect to the underlying medical procedures. This communication is consistent with the fiduciary role of physicians and enhances the patient's ability to make a fully informed decision regarding the treatment recommended and the physician best suited to provide the necessary care.

ANNE T. CORRIGAN*