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COMMERCIALIZATION OF HUMAN TISSUES: HAS BIOTECHNOLOGY CREATED THE NEED FOR AN EXPANDED SCOPE OF INFORMED CONSENT?

INTRODUCTION

"Every human being of adult years and sound mind has a right to determine what shall be done with his own body . . ."¹

Overruling the lower court decision in *Moore v. Regents of University of California*, the California Court of Appeal, Second District, reaffirmed Justice Cardozo's 1914 pronouncement in *Schloendorff*.² In *Moore*, the court found that the plaintiff, John Moore, had a property interest in his body and bodily tissues equal to a right of control.³ This right gave Moore a cause of action against his doctor and the University of California for conversion⁴ of his tissues, which Moore alleged were appropriated and developed into valuable commercial products without his consent.⁵

The California Supreme Court reversed the court of appeal decision that Moore had a cause of action for conversion, but held that he did state a cause of action for lack of informed consent.⁶ While acknowledging that most suits alleging lack of informed consent arise when physicians fail to fully disclose the risks of a medical procedure,⁷ the court stated that in addition to risks, a physician must also disclose "personal interests unrelated to the patient's health, whether research or economic, that may affect the physician's professional judgment."⁸ Failure to disclose these interests "may give rise to a cause of action for performing medical procedures without informed consent."⁹ This

1. *Schloendorff v. Society of New York Hospital*, 211 N.Y. 125, 129, 105 N.E. 92, 93 (1914).
2. *Moore v. Regents of University of California*, 202 Cal. App. 3d 1230, 1247, 249 Cal. Rptr. 494, 505 (1988) ("*Moore I*"), *aff'd in part, rev'd in part*, 51 Cal. 3d 120, 271 Cal. Rptr. 146 (1990) ("*Moore II*").

3. *Moore I*, 202 Cal. App. at 1248, 249 Cal. Rptr. at 507.

4. Conversion is any act of dominion wrongfully exerted over another's personal property in denial of or inconsistent with his rights therein. *Culp v. Signal Van & Storage*, 142 Cal. App. 2d Supp. 859, 862, 298 P.2d 162, 164 (1956); *Igauey v. Howard*, 114 Cal. App. 2d 122, 126, 249 P.2d 558, 561 (1952).

5. *Moore I*, 202 Cal. App. 3d at 1254, 249 Cal. Rptr. at 511.

6. *Moore II*, 51 Cal. 3d at 148, 271 Cal. Rptr. at 164. The California Supreme Court characterizes the cause of action "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." *Id.* at 129, 271 Cal. Rptr. at 150. The court noted that in the present context, the term "fiduciary" was "overly broad" and only signified "that a physician must disclose all facts material to a patient's decision." *Id.* at 131 n.10, 271 Cal. Rptr. at 152 n.10. For clarity and conciseness, this paper will refer to the cause of action as "lack of informed consent."

7. *Id.* at 129, 271 Cal. Rptr. at 150.

8. *Id.*

9. *Id.*

holding is the focus of this Comment.

Prior to the advent of biotechnology, the prospect of significant financial gain from scientific research on human tissues or cells was unheard of. Now, however, "the biotechnology revolution has moved us literally or figuratively, from the classroom to the board room and from the *New England Journal* to the *Wall Street Journal*."¹⁰ The potential for commercialization and profit from research on human bodily products raises novel issues.¹¹ This Comment addresses one of these issues, informed consent, and suggests that new advances in biotechnology have created a need to expand the right of informed consent to protect the right of self-determination.

This Comment first briefly examines the influence of biotechnology on human tissue research. Next, in analyzing the case of *Moore v. Regents of University of California*, this Comment identifies new issues that biotechnology and commercialization bring to the law of informed consent. Section III provides a brief overview of the history of informed consent in medical and research settings, focusing on access to, and use of, human tissues for research. Finally, concluding that present consent laws do not meet the presumed purpose and need which they are intended to fulfill with regard to research on human tissues, this Comment proposes legislation which would expand existing consent requirements in order to correct the present deficiency.

I. BIOTECHNOLOGY AND HUMAN TISSUE RESEARCH

Biotechnology has had a tremendous impact on scientific research and in particular, on research using human cells and tissues. Biotechnology is broadly defined to include "any technique that uses living organisms to make or modify products, to improve plants or animals, or to develop microorganisms for specific uses."¹² This Section describes new procedures in biotechnology and explains how these new procedures affect longstanding scientific values and the doctor-patient relationship.

10. Rosenberg, *Using Patient Materials for Product Development: A Dean's Perspective*, 33 CLINICAL RESEARCH 452, 453 (1985).

11. One question raised is whether the person whose tissue is utilized in the profit-producing research has the right to share in the market value realized from his tissue. That issue is beyond the scope of this paper, but the answer will depend on answers to the problems discussed in this Comment. One San Diego biotechnology firm which uses blood from healthy research subjects discloses to these subjects how they will use the blood and offers each donor between fifty and one hundred dollars per unit for their service. *Who Owns Human Cells?*, San Diego Tribune, Dec. 18, 1989, at AA-2, col. 3.

12. OFFICE OF TECHNOLOGY ASSESSMENT, NEW DEVELOPMENTS IN BIOTECHNOLOGY: OWNERSHIP OF HUMAN TISSUES AND CELLS--SPECIAL REPORT, OTA-BA-337 at 24 (Mar. 1987) [hereinafter OTA REPORT].

A. New Procedures in Biotechnology

The majority of research being done on human cells and tissues utilizes three technologies:¹³ (1) tissue and cell culture technology; (2) hybridoma technology,¹⁴ and (3) recombinant DNA technology,¹⁵ commonly referred to as genetic engineering. These new scientific techniques can transform human biological material into valuable commercial products.¹⁶

For example, in the *Moore* case, the defendant, Dr. Golde, used biotechnology procedures in his research on Moore's cells.¹⁷ Through the methods of tissue and cell culture technology and genetic engineering, Golde cultivated and transformed a sample of Moore's diseased spleen into a human cell line.¹⁸ The cell line developed from Moore's tissues ultimately produced products¹⁹ that defendants estimated would be valued at three billion dollars by 1990.²⁰

B. Effect on Traditional Scientific Values

Biotechnology has not only introduced new techniques and procedures into the realm of scientific research, it has also altered the traditional incentives, practices, and relationships characteristic of the scientific research community. Two events in 1980 were primary catalysts of this process. First, the Patent and Trademark Amendment Act of 1980²¹ gave universities and other nonprofit

13. *Id.* at 4.

14. *Id.* at 31. Hybridomas are hybrid cells, created by the fusion of two types of cells, one from a particular kind of immortal tumor cell line called a myeloma and an antibody producing B lymphocyte. Hybridoma cultures can be made to grow continuously and produce monoclonal antibodies. These important commercial products are proteins which aid the body's immune mechanism. *Id.* at 44. See Royston, *Cell Lines From Patients: Who Owns Them? A Case Report*, 33 CLINICAL RESEARCH 442 (1985) (describing a case involving proprietary rights to a hybridomal cell line).

15. DNA is the material of which genes are composed. Genes are responsible for the inheritance of characteristics in successive generations. OTA REPORT, *supra* note 12, at 44. Recombinant DNA refers to the formation of new combinations of DNA molecules in the laboratory by genetic engineering. Pinon, *Recombinant DNA: Controversy and Promise, A Scientist's Overview*, in FROM RESEARCH TO REVOLUTION 3 (R. Bohrer ed. 1987). Already several commercial medical products have been developed by recombinant DNA techniques. OTA REPORT, *supra* note 12, at 45.

16. Human biological materials are human body parts, replenishable and nonreplenishable, whether healthy or diseased. Replenishable parts include hair, blood, bone marrow, milk, urine, saliva, tears, perspiration, semen, and skin. Nonreplenishable parts are body organs like the brain, kidney, and bone. OTA REPORT, *supra* note 12, at 24.

17. *Moore I*, 202 Cal. App. 3d at 1236, 249 Cal. Rptr. at 498.

18. *Id.* A cell line, which has the capability of continuous and indefinite growth, may be used to study biological processes, to test new drugs, to test the toxicity of various chemicals, and to produce products which may be of value. OTA REPORT, *supra* note 12, at 35. Some cells and tissues are difficult to culture and establish into a cell line. Most successful cultures are derived from malignant tissue, but not all tumors can develop into continuous cultures. *Id.* at 33.

19. These products, called lymphokines, help control the immune system and may have potential therapeutic value for certain cancers and viral diseases. *Id.* at 40.

20. *Moore I*, 202 Cal. App. 3d at 1239, 249 Cal. Rptr. at 500.

21. 35 U.S.C. § 201 (1988).

institutions patent rights to inventions arising out of federally funded research. Second, in 1980, the United States Supreme Court in *Diamond v. Chakrabarty* held that a live, human-made "micro-organism plainly qualifies as patentable subject matter."²² Following the *Chakrabarty* decision and the passage of the Patent and Trademark Act, a huge amount of capital was invested in technology utilizing human tissues.²³ A survey conducted by the U.S. House of Representatives Science and Technology Committee revealed that fifty percent of the eighty-one medical institutions responding to the survey used patient tissues and fluids in their research.²⁴ In addition, the survey reported 211 patent applications were filed between 1980 and 1985,²⁵ a 300 percent increase over the previous five year period.²⁶

The potential of tissue commercialization and the expanded scope of patentable material, which now includes cell lines and their products,²⁷ have changed the practice of intellectual sharing in the academic research setting. The traditional rewards for research have been professional recognition, academic stature, the acquisition of research grants,²⁸ the advancement of knowledge, and the betterment of mankind. These rewards have become inadequate as the prospect of commercialization and profit from the labors of research has become a distinct possibility.²⁹ After *Chakrabarty*, and the passage of the Patent and Trademark Amendment Act, the sharing and disseminating of new knowledge with fellow researchers at other universities gave way to a trend of protective non-disclosure of research until rights were secured by filing for a patent. Without a patent filing, researchers who published their new findings lost the exclusive use of their scientific discoveries.³⁰

The biotechnology industry has eagerly added patent protection to its arsenal of protective devices.³¹ Instead of promoting immediate sharing of new inventions, patent law encourages researchers to delay publication of new

22. *Diamond v. Chakrabarty*, 447 U.S. 303, 309 (1980).

23. Hardiman, *Toward the Right of Commerciality: Recognizing Property Rights in the Commercial Value of Human Tissue*, 34 U.C.L.A. L. REV. 207, 211 (1986).

24. Stone, *Cells For Sale*, DISCOVER 33, 39 (Aug. 1988).

25. *Id.*

26. Sherman, *The Selling of Body Parts*, NAT'L L.J. 1, 33 (Dec. 7, 1987).

27. Hardiman, *supra* note 23, at 211.

28. *Id.* at 210.

29. Rosenberg, *supra* note 10, at 453. Rosenberg believes that growing public awareness of the physician/researcher's conflict of interest and attempts to commercialize his research will result in an increase in litigation as the individual wishes to share in the profit derived from his tissues.

30. Eisenberg, *Proprietary Rights and the Norms of Science in Biotechnology Research*, 97 YALE L.J. 177, 184 (1987).

31. *Id.* at 230. Industry had long utilized trade secrecy as well as actual secrecy to protect new inventions. A trade secret is a protective device by which reasonable efforts are taken to preserve the secrecy of information that derives independent economic value from not being generally known. Unlike patent protection, trade secrets afford only limited rights; others may independently discover and use the same invention. Israelson, *Current Issues in Proprietary Rights to Biotechnology*, in FROM RESEARCH TO REVOLUTION 61 (R. Bohrer ed. 1987).

discoveries until they have secured and protected their inventions by filing for a patent. Once the patent is issued, the knowledge enters the public domain, but the inventor retains the exclusive right to make, use, and sell the invention in the U.S. for seventeen years.³² Considering that over 2,000 biotechnology patents have been filed since *Chakrabarty* held that living organisms were not precluded from patent protection,³³ intellectual property law now shapes the sharing, dissemination, and advancement of scientific knowledge.

C. Effect on the Doctor-Patient Relationship

The biotechnology revolution has not only altered the incentives and practices of the medical research community, but it has also impacted the doctor-patient relationship.³⁴ When physicians are also researchers whose work on patient tissues ties them to industry through consulting positions, stock options, and research grants,³⁵ the profit motive may take priority and conflict with the physician's fiduciary duty to his patient.³⁶ The physician/researcher's fiduciary duty has been eloquently defined by Hans Jonas, who has written extensively on human subject experimentation:

In the course of treatment, the physician is obligated to the patient and to no one else. He is not the agent of society, nor of the interests of medical science, nor of the patient's family, nor of his co-sufferers, or future sufferers from the same disease. By the simple rule of bilateral contract (analogous, for example, to the relation of lawyer to client and its "conflict of interest" rule), the physician is bound not to let any other interest interfere with that of the patient in being cured. . . .³⁷

The conflict of interest encountered by the physician/researcher when presented with the opportunity to commercialize a patient's tissues may greatly strain his fiduciary duty to his patient/research subject.³⁸ The danger increases

32. Eisenberg, *supra* note 30, at 185; 35 U.S.C. §§ 111, 154, 271 (1988).

33. Israelson, *supra* note 31, at 60. These filings include patent applications for genetic engineering, hybridoma techniques and gene splicing. One may patent a process or method, a product such as a new drug or chemical, or an apparatus. After *Chakrabarty*, one may also patent living organisms or genetic material so long as they are not naturally occurring or have been altered by man. *Id.*

34. OTA REPORT, *supra* note 12, at 97.

35. Hardiman, *supra* note 23, at 212. More than half of all molecular biologists and immunologists in the National Academy of Science have consulting or equity relationships with the business sector. Rosenberg, *supra* note 10, at 453.

36. Caplan, *Blood, Sweat, Tears, and Profit: The Ethics of the Sale and Use of Patient Derived Materials in Biomedicine*, 33 CLINICAL RESEARCH 448, 450 (1985).

37. Schneyer, *Medical Disclosure Practices*, WISC. L. REV. 124, 160 n.153 (1976) (quoting Jonas, *Philosophical Reflections on Experimenting with Human Subjects*, in EXPERIMENTATION WITH HUMAN SUBJECTS 21 (P. Freund ed. 1970)).

38. OTA REPORT, *supra* note 12, at 97.

that a physician may relax his unyielding duty to put the patient's interest above all else because of his dual loyalty as a researcher seeking knowledge, recognition, and/or profit.³⁹ For example, the physician could be tempted to perform tests or remove body tissues or fluids in situations where previously he would have hesitated.

Adequate informed consent, however, could safeguard the patient against this potential conflict of interest.⁴⁰ If the physician must disclose and obtain consent for planned research involving potential profit, then unnecessary testing and tissue removal would be forestalled. Although current federal regulations provide some protection to research subjects,⁴¹ no statute clearly requires a physician to reveal to a patient the possible commercial value and intended use of his body parts.⁴² This lack of a clear statutory duty to inform patients of potential commercialization is precisely what triggered the dispute in the *Moore* case.

II. THE *MOORE* CASE

In 1984, John Moore initiated a lawsuit, naming as defendants Dr. David Golde, Shirley Quan, the Regents at the University of California at Los Angeles, Sandoz Pharmaceutical Corporation, and Genetics Institute Corporation.⁴³ Diagnosed as having hairy cell leukemia in 1976,⁴⁴ Moore sought confirmation of the diagnosis and medical treatment from Dr. David Golde at the University of California at Los Angeles.⁴⁵ In October of 1976, as part of the treatment, Golde removed Moore's spleen.⁴⁶ Moore alleged that prior to surgery, Golde, Shirley Quan, and other defendants arranged to receive a piece of the spleen for their research without informing Moore or obtaining his consent.⁴⁷ Ultimately, they used Moore's spleen cells to establish cell lines and products which they proceeded to patent as the Mo cell-line.⁴⁸ The defendants also entered into

39. *Id.*

40. Hardiman, *supra* note 23, at 235.

41. OTA REPORT, *supra* note 12, at 110. The Food and Drug Administration requirements for informed consent are set forth in 21 C.F.R. § 50 (1990). The Department of Health and Human Services basic policy for protection of human research subjects are listed in 45 C.F.R. § 46 (1990).

42. Stone, *supra* note 24, at 33.

43. *Moore I*, 202 Cal. App. 3d at 1236, 249 Cal. Rptr. at 499.

44. Stone, *supra* note 24, at 33. Hairy cell leukemia is a rare form of cancer which results in the proliferation of B lymphocytes (white blood cells that produce antibodies). *Id.*

45. *Moore I*, 202 Cal. App. 3d at 1235, 249 Cal. Rptr. at 498.

46. Stone, *supra* note 24, at 34. Removal was not a cure, but a way to normalize patient's blood count, since the spleen of a hairy cell leukemia patient can destroy healthy blood cells. *Id.*

47. *Moore I*, 202 Cal. App. 3d at 1237, 249 Cal. Rptr. at 499.

48. Stone, *supra* note 24, at 34. Rather than the B lymphocytes produced in excessive amounts by most hairy cell leukemic patients, Moore produced large quantities of T lymphocytes (cells that fight viruses and affect the immune system). The cell line also produced large amounts of proteins called lymphokines which may be able to aid the immune function in certain cancer and AIDS patients. *Id.*

contracts with commercial firms who wished to develop and market the Mo cell-line.⁴⁹

Before his initial surgery in 1976, Moore signed a surgical consent form authorizing the hospital to dispose of any severed tissue or member by cremation.⁵⁰ However, he never consented to research or commercialization of his spleen or tissues.⁵¹ Nonetheless, Golde managed to obtain Moore's tissues for almost seven years without his consent. Between November 1976 and September 1983, Moore traveled from Washington state to UCLA approximately every six months at Golde's request for testing of his blood and other bodily products.⁵² Moore became suspicious when, upon telling Golde that he could not afford the trips and preferred to have his blood tested in Washington, Golde offered to and paid for two of these trips.⁵³ On his second to the last visit to UCLA on April 11, 1983, Moore, for the first time, was asked to sign a consent form acknowledging that information from the research on his blood or bone marrow might not benefit him directly.⁵⁴ The form also stated that he voluntarily granted "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."⁵⁵ Although Moore signed the form, he alleged that he did not know the defendant's true research and commercial interests, and that if he had known, he would not have consented.⁵⁶

On September 20, 1983, the defendants asked Moore to sign another form, identical to the one he signed on April 11, 1983. This time, Moore consented to the removal of his blood, but refused to grant the defendants any rights to his cell-line.⁵⁷ Defendants, nonetheless, continued to exploit the cell-line.⁵⁸ Moore decided to investigate after Golde informed him that he had missigned the April consent form, requested that he re-sign it, and mailed him another form with a letter urging him to grant the university all rights to any cell line or

49. *Moore I*, 202 Cal. App. 3d at 1239, 249 Cal. Rptr. at 500. Genetics Institute Inc. and Sandoz Pharmaceuticals Corporation entered into agreements with Golde for rights to the cell line and its products. On March 20, 1984, Golde and Quan received a patent to the cell line and its products which they assigned to the Regents of the University of California. *Id.* at 1240, 249 Cal. Rptr. at 500.

50. Stone, *supra* note 24, at 35.

51. *Id.* Not only was he not informed of any potential commercial use of his tissues, Moore also alleged that Golde denied such use when Moore later asked him whether there was any potential financial or commercial value of his tissues. In fact, Golde discouraged such questioning. *Moore II*, 51 Cal. 3d at 132, 271 Cal. Rptr. at 152.

52. *Moore I*, 202 Cal. App. 3d at 1238, 249 Cal. Rptr. at 500. Besides blood, doctors also removed skin, bone marrow, and sperm. Stone, *supra* note 24, at 35.

53. Stone, *supra* note 24, at 35.

54. *Id.* See *Moore I*, 202 Cal. App. 3d at 1289, 249 Cal. Rptr. at 531.

55. *Moore I*, 202 Cal. App. 3d at 1289, 249 Cal. Rptr. at 531.

56. *Id.* at 1239, 249 Cal. Rptr. at 501.

57. *Id.*

58. *Id.* at 1240, 249 Cal. Rptr. at 501.

product that might be developed.⁵⁹ Moore's lawyers reviewed scientific articles by Golde and read about a Mo cell-line from a Seattle patient with hairy cell leukemia.⁶⁰ They also learned that a patent was pending on this cell line.⁶¹

On September 11, 1984, Moore initiated his lawsuit. His complaint alleged thirteen causes of action, including conversion, lack of informed consent, and breach of fiduciary duty.⁶² The defendants demurred to all the causes of action. Acting upon Moore's third amended complaint, the trial court sustained the demurrer to the first cause of action, conversion, and held that the other causes of action were defective because they incorporated the first one.⁶³ Moore appealed.⁶⁴ On July 21, 1988, the California Court of Appeal, Second District, reversed the lower court decision and held that Moore had stated a cause of action for conversion.⁶⁵ The court concluded that Moore had a property interest in his bodily tissues,⁶⁶ and that Moore's consent to surgery was not consent to commercial exploitation and research of his tissues that was not directly related to his treatment.⁶⁷ The appellate court also held that any use of his removed tissue for purposes other than treatment required his consent.⁶⁸

The California Supreme Court reversed that part of the appellate court's decision finding a cause of action for conversion, but held that Moore had stated a cause of action for lack of informed consent.⁶⁹ The court relied on three

59. Stone, *supra* note 24, at 35.

60. *Id.*

61. *Id.*

62. *Moore I*, 202 Cal. App. 3d at 1236, 249 Cal. Rptr. at 499.

63. *Id.* at 1241, 249 Cal. Rptr. at 502. Other alleged causes of action include fraud and deceit, unjust enrichment, quasi-contract, breach of implied covenant of good faith and fair dealing, intentional infliction of emotional distress, negligent misrepresentation, interference with prospective advantageous economic relationship, slander of title, accounting, and declaratory relief. *Id.*

64. *Id.* at 1242, 249 Cal. Rptr. at 502.

65. *Id.* at 1242, 249 Cal. Rptr. at 503.

66. *Id.* at 1244, 249 Cal. Rptr. at 504. A recent Comment uses the California Court of Appeal's *Moore* decision to argue that a property right in one's own bodily tissues is a prerequisite to the maintenance of autonomy and control over one's person. Comment, *The Autonomy of the Human Body*, 61 U. OF COLO. L. REV. 659, 661 (1990). The California Supreme Court, however, held that such a property interest is not essential. Present laws of informed consent, as modified and expanded by the California Supreme Court in *Moore*, can sufficiently protect an individual's autonomy over his body. *Moore II*, 51 Cal. 3d at 144, 271 Cal. Rptr. at 164. To protect individual autonomy over his body from possible adverse effects of commercialization, the Comment suggests alterations in present federal requirements governing informed consent in the research setting. Unfortunately, such regulations only apply to federally sponsored research. Comment, *supra*, at 674. Patients like Moore, who derive some therapeutic benefit from the tissue removal and whose physicians do not receive federal funds for their research, would remain unprotected.

67. *Id.* at 1254, 249 Cal. Rptr. at 510.

68. *Id.* at 1255, 249 Cal. Rptr. at 511.

69. *Moore II*, 51 Cal. 3d at 147, 271 Cal. Rptr. at 164. The court explained that a conversion cause of action requires the plaintiff to prove interference with his ownership or right of possession. Moore did not have possession of his removed tissues; nor did he establish any ownership interest in them. In addition, California statutes severely limit a patient's interest in excised cells. In refusing to recognize a cause of action for conversion, the California Supreme Court expressed concern that allowing conversion liability for the commercialization of human cells would adversely affect medical

principles in reaching its conclusion. First, a competent adult has the right to decide whether or not to undergo medical treatment based on his "right in the exercise of control over his own body."⁷⁰ Second, a patient's consent must be informed.⁷¹ Third, the physician has a duty to reveal "all information material to the patient's decision."⁷²

Considering these principles, the court concluded that physicians must disclose their research or economic interests which might influence their professional judgment.⁷³ The *Moore* court reasoned that such personal interests which might influence the performance of medical procedures unrelated to the patient's health create a potential conflict of interest and materially affect the patient's decision.⁷⁴ The court held that failure to disclose such interests may give rise to liability for "performing medical procedures without informed consent. . . ."⁷⁵

Moore is a case of first impression and may be but a harbinger of the litigation that will ensue once the public becomes aware of the commercial value of their bodily tissues.⁷⁶ In general, patients trust their doctors and do not want to feel taken advantage of and exploited.⁷⁷ Specifically, they do not want to be treated as "containers of useful and commercially attractive biological materials" to be mined without their permission.⁷⁸ For example, Moore stated that, if he had been informed at the outset of the potential use of his tissues, he would have understood and would have felt that he had "made a contribution to medical science."⁷⁹ Instead, he felt dehumanized and exploited. Moore's negative feelings could have been avoided with proper informed consent.

III. INFORMED CONSENT

The doctrine of informed consent⁸⁰ manifests the high value our society

research. The court felt that its decision adequately protected a patient's right to make autonomous informed medical decisions by requiring physicians to disclose any research or economic interests in the patient's tissues as part of the informed consent process; therefore, a conversion cause of action was not needed. *Id.* at 144, 271 Cal. Rptr. at 161.

70. *Id.* at 129, 271 Cal. Rptr. at 150.

71. *Id.*

72. *Id.*

73. *Id.*

74. *Id.* at 133, 271 Cal. Rptr. at 153.

75. *Id.* at 129, 271 Cal. Rptr. at 150.

76. Rosenberg, *supra* note 10, at 453. Class action lawsuits by those whose specimens were pooled for use in research is another distinct threat to biotechnical companies, researchers, and universities. Sherman, *supra* note 26, at 33.

77. Caplan, *supra* note 36, at 450.

78. *Id.*

79. Stone, *supra* note 24, at 37. Moore describes feeling "shocked," "taken advantage of," and "humiliated" to be thought of as "Mo—a cell-line, like a piece of meat." *Id.* at 35.

80. Informed consent is a set of legal rules which physicians must abide by in their interactions with patients. It is also an ethical doctrine and a process which affords patients the right to participate in medical decisions affecting their health and well being. P. APPELBAUM, C. LIDZ & A. MEISEL, INFORMED CONSENT 3 (1987).

places on individual autonomy. Informed consent requires the physician, absent an emergency, to make a reasonable disclosure of the risks of any proposed treatment or surgery. The patient, in turn, can decide intelligently whether or not to submit to the suggested procedure.⁸¹ This Section examines the historical development of informed consent for medical treatment as well as medical research. It then considers the government's failure to establish regulations governing informed consent of tissue commercialization and describes the dangers that arise from this deficiency.

A. Historical Development: Informed Consent to Treatment

Patient consent to medical treatment dates back to the late eighteenth century case of *Slater v. Baker and Stapleton*,⁸² where two surgeons were held liable for operating on a patient without his permission. However, the doctrine of informed consent is of more recent origin. The term was first used in a 1957 California case, *Salgo v. Leland Stanford Jr. University Board of Trustees*.⁸³ In *Salgo*, the court instructed the jury that a physician has a duty to inform his patient of "all the facts which mutually affect his rights and interests and of the surgical risk, hazard, and danger, if any. . . ."⁸⁴ The *Salgo* court went on to state that the doctor may not withhold "any facts which are necessary to form . . . an intelligent consent by the patient to the proposed treatment."⁸⁵ Nor may the physician minimize known risks in order to obtain consent.⁸⁶

Although courts universally agree that a physician has a duty to the patient to disclose and inform, courts are split as to the proper standard to apply in determining whether a physician has fulfilled his duty. Under the traditional standard,⁸⁷ ("the professional standard"), the court uses the custom of disclosure by competent physicians in the medical community as the criteria against which the defendant's disclosure is measured.⁸⁸ A slight majority of jurisdictions favors this "professional," "objective," or "community" standard.⁸⁹ This standard is more favorable to the medical profession because the patient must rely on

81. Schwartz, *A Malpractice Antidote*, 9 TRIAL 32, 33 (1973).

82. P. APPELBAUM, C. LIDZ & A. MEISEL, *supra* note 80, at 36 (discussing *Slater v. Baker and Stapleton*, 95 Eng. Rep. 860 (K.B. 1767)). The two physicians in *Slater* disunited a partially healed fracture. The need for the patient's cooperation when anesthesia was not used was probably an important factor in the evolution of informed consent. *Id.*

83. *Salgo v. Leland Stanford Jr. University Board of Trustees*, 154 Cal. App. 2d 560, 578, 317 P.2d 170, 181 (1957).

84. *Id.*

85. *Id.*

86. *Id.*

87. Landsverk, *Informed Consent As A Theory of Medical Liability*, WIS. L. REV. 879, 894 (1970).

88. D. WARREN, PROBLEMS IN HOSPITAL LAW 125, 126 (1978).

89. OTA REPORT, *supra* note 12, at 98.

expert testimony to establish the standard of disclosure⁹⁰ and physicians are often unwilling to testify against other physicians.

The modern and growing trend⁹¹ is for courts to base the standard for informed consent on the needs of a reasonable patient⁹² rather than on the standards of the medical community. The United States Court of Appeals for the District of Columbia Circuit first used this "reasonable person test" in *Canterbury v. Spence*.⁹³ The *Canterbury* court held that the patient's right of self-decision requires that he be given "enough information to enable an intelligent choice."⁹⁴ The duty to disclose is based on what a reasonable person in the patient's position would want to know in order to make an informed decision.⁹⁵

Regardless of the standard used, in a treatment situation, physicians must usually reveal the following:

1. the nature and purpose of the diagnostic, medical or surgical procedure;
2. probable risks and benefits;
3. reasonable alternative procedures and their probable risks and benefits; and
4. probable risks if one foregoes all interventions.⁹⁶

Both standards excuse the physician's duty to disclose in the following situations: when an emergency exists, when the patient is legally or mentally incompetent, or when disclosure might be harmful to the patient's well being.⁹⁷

B. Informed Consent to Research

Although "[i]t is clearly against the law to experiment on a patient without obtaining his informed consent,"⁹⁸ there are no clear guidelines concerning disclosure of the researcher's intent to commercialize his research results. While the rules of informed consent to treatment are governed by case law, consent to research is governed mainly by codes, regulations, and statutes.⁹⁹ The first attempt to formally codify consent to research occurred at the end of World War II. Outraged and shocked by the Nazi tortures performed under the guise of medical experimentation, the American military tribunal presiding at the Nuremberg trials in 1946 asked its expert witnesses to formulate ethical

90. D. WARREN, *supra* note 88, at 126. This rule was modified in many states to measure a physician's disclosure against that of competent physicians in the same or similar communities. Such a change facilitates the ability of plaintiffs' to obtain a medical expert willing to testify against a fellow physician. It also recognizes that physicians must be nationally certified and that there are national standards for the practice of medicine. *Id.* at 126, 127.

91. OTA REPORT, *supra* note 12, at 98.

92. *Id.*

93. *Canterbury v. Spence*, 464 F.2d 772 (D.C. Cir. 1972).

94. *Id.* at 786.

95. OTA REPORT, *supra* note 12, at 98.

96. *Id.* (summarizing F. ROZOVSKY, *CONSENT TO TREATMENT: A PRACTICAL GUIDE* (1984)).

97. OTA REPORT, *supra* note 12, at 99.

98. G. ANNAS, *ACLU GUIDE TO PATIENT RIGHTS* 103 (1975).

99. P. APPELBAUM, C. LIDZ & A. MEISEL, *supra* note 80, at 211.

standards for human research.¹⁰⁰ These standards, known as the Nuremberg Code, were recited in the judgment against the Nazi physicians in *United States v. Karl Brandt*.¹⁰¹ Besides limiting the power of researchers to inflict physical harm, two of the ten sections of the Nuremberg Code discussed informed consent.¹⁰² Although the Code was intended to apply only to the Nuremberg trials,¹⁰³ it prompted other countries to create their own codes for ethical research.¹⁰⁴

The Declaration of Helsinki, adopted by the World Health Organization in 1964, attempted to express common international concerns and principles about ethical standards for clinical research.¹⁰⁵ Whereas the Nuremberg Code required informed consent in all cases, the Declaration of Helsinki was more lenient. For example, under the declaration, nontherapeutic research, which would not directly benefit the individual, could not be performed unless the subject freely consented after being fully informed of the nature, purpose, and risk of the research.¹⁰⁶ However, informed consent for research in conjunction with patient care was recommended, but was only required when "consistent with patient psychology."¹⁰⁷

While the Nuremberg Code and the Declaration of Helsinki were nonbinding, successive U.S. regulations which followed had more weight, albeit some loopholes.¹⁰⁸ Following congressional hearings to study procedures for regulating the testing of new medications, Congress passed the Drug Amendments of 1962.¹⁰⁹ The amendments required researchers to disclose the investigative purpose of experimental medications to research subjects.¹¹⁰ Researchers also had to obtain consent unless they felt that "in their professional judgment, disclosure and consent would be contrary to the best interest" of the individual.¹¹¹ Professional judgment, however, afforded researchers much discretion.

Four years later, additional regulations were enacted for research funded by the National Institutes of Health ("NIH"), and later by the U.S. Department of

100. *Id.* at 212.

101. *Id.* at 213.

102. *Id.*

103. *Id.*

104. *Id.* at 214.

105. *Id.*

106. *Id.*

107. *Id.* Although the Helsinki standards were intended to safeguard individuals in research settings, standards for those research subjects also receiving medical care fell below the common law standard for consent to treatment, due to such ambiguous phrases as "if at all possible" and "consistent with patient psychology." *Id.* at 215.

108. *Id.* at 216.

109. *Id.* This law tightened the regulatory procedures of the Food and Drug Administration governing the testing of new medications, food additives, biological products, and medical devices. OTA REPORT, *supra* note 12, at 94.

110. P. APPELBAUM, C. LIDZ & A. MEISEL, *supra* note 80, at 216.

111. *Id.*

Health and Human Services ("DHHS"). The regulations required a prospective review of research methodology by a committee from the institution doing the research.¹¹² Each committee, known as the Institutional Review Board ("IRB"),¹¹³ was to determine whether appropriate methods to obtain informed consent from research subjects were included in the research protocol.¹¹⁴ Between 1966 and 1981, governmental agencies made several revisions in their regulations. These changes resulted in a uniform standard for medical research funded by NIH and for clinical trials of new medicines conducted under Food and Drug Administration ("FDA") regulations by researchers seeking FDA approval.¹¹⁵

On the issue of informed consent, the requirements of NIH and FDA regulations are virtually identical. Both require the researcher to disclose:

1. the research involved, its purposes, expected duration, procedures, and any experimental procedures;
2. reasonably foreseeable risks or discomfort to the subject;
3. reasonably expected benefits to the subject or to others;
4. appropriate alternative procedures or treatment;
5. the extent to which confidentiality will be maintained;
6. where risk is more than minimal,¹¹⁶ what compensation or medical treatment is available;
7. the name of an individual to contact for answers about the research and the subject's rights; and
8. the voluntary nature of participation, and the absence of penalty for refusal.¹¹⁷

There are some situations where the mandated disclosures and informed consent are not required. Under the FDA regulations, an unapproved experimental medicine or medical device may be used without obtaining informed consent only when: (1) a life threatening situation necessitates the use of the experimental item; (2) the researcher cannot obtain consent because of an inability to communicate with the subject; (3) time is not sufficient to obtain consent from the subject's legal representative; and (4) there is no approved alternative therapy that provides an equal or greater chance of saving the subject's life. The researcher and a physician not involved in the research must

112. *Id.* at 217. OTA REPORT, *supra* note 12, at 94.

113. P. APPELBAUM, C. LIDZ & A. MEISEL, *supra* note 80, at 218.

114. *Id.* at 217.

115. *Id.* The FDA regulations govern clinical trials that support applications for research or marketing permits for FDA regulated products. These products include food and color additives, medical devices for human use, biological products for human use, and electronic products as well as new medications. 21 C.F.R. § 50.1(a) (1990).

116. 45 C.F.R. § 46.116(a)(6) (1990); 21 C.F.R. § 50.25(a)(6). Minimal risk means that the risks of anticipated harm "are not greater considering probability and magnitude, than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests." 45 C.F.R. § 46.102(g); 21 C.F.R. § 50.3(1).

117. 45 C.F.R. § 46.116(a)(1-8); 21 C.F.R. § 50.25(a)(1-8).

attest that all of the above requirements are met.¹¹⁸ Exempt from the NIH regulations for informed consent is research that involves collecting existing data, or pathological or diagnostic specimens and records, if these sources are publicly available or if the information is recorded in such a way that subjects cannot be identified.¹¹⁹ In addition, the IRB may waive or alter informed consent requirements if it finds that: (1) the research involves only minimal risk; (2) the waiver or alteration will not adversely affect subjects; and (3) the research could not practicably be performed without waiver.¹²⁰

C. Consent for Human Tissue Commercialization

There are two methods for legally acquiring access to human tissue from living persons for research purposes.¹²¹ Physicians may remove tissue for diagnostic or therapeutic purposes as part of medical treatment, or they may remove tissues for express research purposes.¹²² Both methods require that informed consent be obtained for the physical risks involved in tissue removal.¹²³

Prior to *Moore*, in a treatment situation, physicians were not expressly required to disclose potential uses of excised tissues,¹²⁴ or potential commercial value of removed body parts.¹²⁵ In a research setting, however, the nature of the research as well as the associated risks, must be revealed with two exceptions.¹²⁶ "Research using publicly available pathological or diagnostic specimens is exempt from the DHHS informed consent policy, as is research recorded in such a way that subjects cannot be identified."¹²⁷ In addition, when the research involves only minimal risk, the consent requirement may be altered or waived.¹²⁸ In all other instances, the nature of the research must be revealed, but there is no express requirement to disclose intent to commercialize. DHHS does require the researcher to inform the subject of "significant new findings developed during the course of the research which may relate to the subject's willingness to continue

118. 21 C.F.R. § 50.23(a).

119. 45 C.F.R. § 46.101(b)(5).

120. 45 C.F.R. § 46.116(d)(1-3).

121. Wagner, *Human Tissue Research: Who Owns the Results?*, 14 J. COLL. & UNIV. L. 260, 270 (1987). There are also two statutory methods of post mortem tissue access. The Uniform Anatomical Gift Act (UAGA) provides for donation of body parts upon death of the donor to advance medical science and state statutes provide access to tissues from unclaimed dead bodies. *Id.*

122. *Id.*

123. *Id.*

124. Sherman, *supra* note 26, at 33. Of course, informed consent for the research would be required in addition to consent to removal if access to the tissue for research purposes poses a greater risk due to the need for more extensive removal for research than for purely medical therapeutic or diagnostic purposes. Wagner, *The Legal Impact of Patient Materials Used for Product Development in the Biomedical Industry*, 33 CLINICAL RESEARCH 444, 446 (1985).

125. Sherman, *supra* note 26, at 33.

126. OTA REPORT, *supra* note 12, at 106; 45 C.F.R. § 46.101(b)(5).

127. 45 C.F.R. § 46.101(b)(5).

128. 45 C.F.R. § 46.116(d)(1-3). *See supra* note 120 and accompanying text.

participation."¹²⁹

Physician/researchers and patient/subjects might differ as to whether the prospect of commercialization of the patient/subject's tissues is a "significant new finding" within the meaning of the NIH regulations.¹³⁰ In the *Moore* case, the defendants could have argued that removal of Moore's tissues over a period of years was merely necessary for treatment and that the marketability of his tissues was purely incidental. Thus, the resulting commercialization was not a significant new finding. In response, Moore could have argued that the marketability of his tissues was a significant new finding and therefore should have been disclosed. Since Moore did assert that disclosure of the commercial value of his cells would have affected his willingness to have his tissues removed and used,¹³¹ this argument would have been reasonable.

D. Risks Where Informed Consent is Not Obtained

Scientific research and medical training and education, which in theory benefit mankind, may actually pose a risk to those individuals and patients who are the subjects of the research or educational process. Moreover, a physician/researcher's pursuit of personal financial gain may pose yet another risk. This latter risk is magnified by the potential of highly profitable commercialization of products derived from patient material which biotechnology has made possible.

The law of informed consent evolved to protect the rights of individuals in their bodies, not to prevent researchers from profiting from research involving human cells.¹³² However, biotechnology has unleashed a market potential in certain human tissues, thereby creating a conflict of interest that puts the human sources of these tissues at risk when they are not aware of the possibility of commercialization.¹³³ The more freedom a physician/researcher has with regard to his research and duty to disclose, the less protection is available to his subjects.¹³⁴ This inverse relationship has proven to be particularly true when the physician/researcher's goals become distinct from those of his patient/subject.¹³⁵

Thomas Duffy discusses this negative aspect of conflict of interest as he analyzes a clinical situation described in a book by Jay Katz, *The Silent World of*

129. *Id.* § 46.116(b)(5).

130. OTA REPORT, *supra* note 12, at 102. A significant new finding arguably is one which might affect a person's willingness to continue to participate as a research subject. *Id.*

131. *Moore I*, 202 Cal. App. 3d at 1238, 249 Cal. Rptr. at 500.

132. OTA REPORT, *supra* note 12, at 107.

133. *Id.* at 97; *see also* Hardiman, *supra* note 23, at 235.

134. P. APPELBAUM, C. LIDZ & A. MEISEL, *supra* note 80, at 238; Eser, *The Researcher as "Offender" and "Victim"—Comparative Observations as to Freedom and Responsibility of Science and Technology*, B.Y.U. L. REV. 571, 583 (1987).

135. Duffy, *Agamemnon's Fate and the Medical Profession*, 9 W. NEW ENG. L. REV. 21, 22 (1987).

Doctor and Patient.¹³⁶ A young woman patient, Iphigenia Jones, nearly lost her breast because her physician had failed to disclose alternatives to mastectomy for breast cancer.¹³⁷ Only by a chance conversation did she discover and select an alternative breast-sparing procedure. The name Iphigenia was selected by the author as an allusion to the daughter of Agamemnon, the Greek mythological hero who nearly sacrificed his daughter to appease the gods so that he and his beached fleet might set sail for Troy.¹³⁸ Like the breast cancer patient, only through an accidental intervention was Iphigenia saved. When Agamemnon's paternal responsibilities conflicted with his desire to maintain his "reputation as a leader and his avaricious need to conquer Troy,"¹³⁹ his fatherly tendencies were eclipsed.

Physician/researchers are not immune to the "Agamemnon factor." Although their goals may be far nobler than those of the Greek hero, the result is the same—the patient's individual autonomy and right of self-determination are sacrificed to promote the physician's personal interests. Medical journals are replete with examples of patients being sacrificed to medical research and education. In one study, researchers studying immunity injected live cancer cells into twenty-two debilitated patients without their informed consent.¹⁴⁰ The patients were told they would be injected with "some cells" but the fact that these were live cancerous cells was withheld.¹⁴¹ The researcher declared that he believed the research posed no risk to his patients and, in fact, none suffered any ill effects.¹⁴² When asked why he did not use himself and his colleagues as subjects, he responded, "I did not regard the experiment as dangerous. But let's face it, there are relatively few skilled cancer researchers, and it seemed stupid to take even the little risk."¹⁴³

Research goals often influence a physician's disclosure pattern.¹⁴⁴ While misrepresentation probably is rare, frequently patients are not fully informed of their role in a research project or significant risks may not be fully explained.¹⁴⁵ Numerous cases document situations where proven treatments or medications were withheld in order to test a new method or drug. In one study, twenty-five persons, from whom medications were withheld, contracted rheumatic fever.¹⁴⁶

136. *Id.* at 21 (referring to J. KATZ, *THE SILENT WORLD OF DOCTOR AND PATIENT* (1984)).

137. Duffy, *supra* note 135, at 21.

138. *Id.* at 22.

139. *Id.*

140. Mulford, *Experimentation on Human Beings*, 20 STAN. L. REV. 99 (1976).

141. Beecher, *Ethics and Clinical Research*, 274 NEW ENG. JOUR. OF MEDICINE 1354, 1358 (1966).

142. Mulford, *supra* note 140, at 99.

143. *Id.* (quoting Southam, *Human Experimentation: Cancer Studies at Sloan-Kettering Stir Public Debate on Medical Ethics*, in 143 SCIENCE 551, 551 (1964)).

144. Schneyer, *supra* note 37, at 160.

145. Beecher, *supra* note 141, at 1354.

146. *Id.* at 1356.

In another study, twenty-three percent of patients died after being denied medication to treat typhoid fever, compared to an eight percent death rate in those treated with the proven medication.¹⁴⁷ These examples suggest that the practice of nondisclosure may not be a rare occurrence. Furthermore, a survey by the Pharmaceutical Manufacturers Association revealed that only fifty-seven percent of the responding physicians always obtained a patient's consent before using experimental drugs.¹⁴⁸

Medical education may also influence the physician's disclosure patterns.¹⁴⁹ For example, in a ward situation where student doctors practice newly learned skills on indigent patients, these patients often are not forewarned that they will be examined and questioned by a series of medical students, interns, and residents merely to aid the learning process of the examiners. The more "interesting" or rare the disease, the more the patient will be subjected to these multiple inquiries without explanation of why they are being inconvenienced.¹⁵⁰ In the past, medical and surgical tests, often with significant risk, were performed for the primary purpose of teaching students the proper procedural methods.¹⁵¹ The goal of medical training at times overshadowed concern for the patient's right of self-determination.¹⁵²

Just as education and research can influence the physician's choice of treatment, so can financial considerations.¹⁵³ Surgical decisions may hinge partly on payment schedules determined by insurance companies.¹⁵⁴ For example, in the early 1970s, doctors in Europe had nearly given up radical mastectomy as the preferred treatment for breast cancer and adopted less mutilating procedures. In the United States, however, where Blue Shield paid two to three times as much for the radical surgery than it paid for simpler procedures, surgeons did not relinquish the more disfiguring technique until women demanded alternatives after learning of less drastic options via reports in popular magazines and on television.¹⁵⁵ Apparently, monetary valuing of different surgical procedures may bias treatment recommendations.¹⁵⁶

Finally, biotechnology has created new financial incentives which put patients at risk of being subjected to unnecessary procedures or to procedures with

147. *Id.*

148. Mulford, *supra* note 140, at 100.

149. Landsverk, *supra* note 87, at 893.

150. *Id.*

151. *Id.*

152. *Id.*

153. At least one researcher believes that unnecessary surgical procedures are more likely to be performed where there is an overabundance of surgeons relative to the needs of the community and financial pressures are therefore quite strong. Schneyer, *supra* note 37, at 168.

154. Schneyer, *supra* note 37, at 167.

155. *Id.*

156. *Id.* at 166.

greater risk than warranted.¹⁵⁷ Unless new laws are created, patients like Moore will be forced to make decisions without being fully informed of all extraneous interests that could affect their doctor's recommendation. Specifically, patients face the risk of losing their right of self-determination and control over their own body and tissues.¹⁵⁸

E. Assessing Damages

Evaluating the risk of losing self-determination and control poses a problem. Risk is "commonly defined as a product of the probability of adverse consequences and the value of those adverse consequences."¹⁵⁹ But what is the value of the risk of loss of self-determination where there may be no actual measurable physical injury? Loss of informed self-determination can be analogized to loss of other process rights.¹⁶⁰ Process rights, such as the right of free speech and the right to vote, have been evaluated by juries which, with the court's permission, have assigned damages for violation of these constitutional rights.¹⁶¹ The right to vote was considered so valuable that damages were allowed solely for "the wrongful deprivation of it without evidence of actual loss of money, property, or any other valuable thing. . . ."¹⁶² The court declared that the jury could determine the amount of damages because "each member of the jury has personal knowledge of the value of the right."¹⁶³ Like other process rights, the right of informed consent is worthy of protection.

Physicians have a duty to provide sufficient and material information to patients to allow those patients to participate in decisions concerning their body.¹⁶⁴ Patients who are not fully informed about the use and possible commercialization of their tissues are deprived of the right to consider all material information before making decisions concerning their bodies and tissues.¹⁶⁵ Biotechnology creates a major conflict of interest in the physician. He or she may feel reluctant to fully inform if the patient might refuse access to possibly valuable tissues upon full disclosure. Fearing such a refusal, the

157. Hardiman, *supra* note 23, at 235. The California Supreme Court stated that a physician who has research interest, might order procedures "that offer marginal or no, benefits to the patient." *Moore II*, 51 Cal. 3d at 130, 271 Cal. Rptr. at 151. It also stated that a "reasonable patient would want to know whether a physician had an economic interest that might affect the physician's professional judgment." *Id.* at 129, 271 Cal. Rptr. at 150.

158. *Id.*

159. Bohrer, *The Future Regulation of Biotechnology*, in FROM RESEARCH TO REVOLUTION 103 (R. Bohrer ed. 1987).

160. Twerski & Cohen, *Informed Decision Making and The Law of Torts: The Myth of Justiciable Causation*, 1988 U. ILL. L. REV. 607, 651 (1988).

161. *Id.* at 649.

162. *Wayne v. Venable*, 260 F. 64, 66 (8th Cir. 1919).

163. *Id.*

164. Twerski & Cohen, *supra* note 160, at 651.

165. *Id.* at 649. Hardiman, *supra* note 23, at 235.

physician may decide not to reveal that the tissues may have market potential. Thus, patients are denied full information with which to decide what they wish done with their body. Deprivation of self-determination through inadequate disclosure and informed consent must be avoided. New federal and state regulations which provide clear standards are one way to facilitate this goal.

IV. PROPOSAL

Although federal regulations require researchers to reveal more information in order to obtain valid consent in a research situation than in a medical treatment setting,¹⁶⁶ disclosure of the commercial value of an individual's tissues is not required in either situation. In the research setting, section 46.116(b)(5) of the Code of Federal Regulations requires disclosure if the information is considered a "significant new finding" that might influence the subject's continued participation in the research.¹⁶⁷ In the medical setting, using the traditional professional standard, a patient would have to be informed only if such disclosure was the custom in the medical community.¹⁶⁸ The modern trend of the "reasonable person standard"¹⁶⁹ would require disclosure if the information was necessary to enable a reasonable person in the patient's position to make an intelligent choice. Tissue donors in the research setting may argue that the knowledge that their tissues may become the source of valuable commercial products is a "significant new finding." In the medical setting, they would allege that such knowledge is necessary for the formation of intelligent decisions regarding their bodies.¹⁷⁰ Such knowledge could alert the donors to their physicians' possible conflicts of interest. Also, for moral, religious, or ethical reasons, some individuals may prefer not to have their tissues developed into marketable commodities. Other donors might consent to commercial use of their tissues, contingent upon receiving a share in any profit derived from such use.

A. Protection of Medical Patients

The Office of Technology Assessment ("OTA") performed an intensive study analyzing the economic, legal, and ethical rights of tissue donors as well as the rights of physicians and researchers, and concluded that "the opportunity to

166. OTA REPORT, *supra* note 12, at 100. This stricter standard for research subjects is logical since, unlike patients, voluntary subjects altruistically submit themselves to research procedures which do not directly benefit them.

167. 45 C.F.R. § 46.116(b)(5).

168. Warren, *supra* note 88, at 125. See also *supra* notes 87-90 and accompanying text.

169. See *supra* notes 91-95 and accompanying text.

170. OTA REPORT, *supra* note 12, at 102. Those opposed to disclosing the possibility of commercial gain argue that any gain is highly speculative at the time of tissue removal. They also claim that subjects might be unduly influenced by the prospect of financial gain and consent to the research solely for that purpose. *Id.* Another concern is that subjects might withhold consent or auction off their tissues to the highest bidder, thereby impeding medical research. *Id.*

identify potentially marketable tissues and cells in research may set a new but limited disclosure standard.¹⁷¹ Under the OTA standard, physicians must disclose where it is reasonably foreseeable that the tissue would be marketable or when information "material" to a subject's decision, rights, and welfare is available.¹⁷² Disclosure under the OTA proposed standard would permit the patient to weigh the conflict-of-interest factor along with the other risks and benefits to reach an autonomous and intelligent decision.¹⁷³ The patient could then consult with a physician who is detached from the tissue research or commercialization to arrive at an intelligent and informed choice.

At the present time in the medical setting, many patients who require excision of tissues for therapeutic or diagnostic purposes do not receive adequate information to allow a truly informed consent. Today, many consent-to-treatment forms vaguely describe what happens to human tissues once they are removed.¹⁷⁴ Standard form language may authorize the hospital "to examine and dispose of, or retain for medical purposes, any tissues or parts which are removed during the operation."¹⁷⁵ Equally vague is California's largest health maintenance organization's standard consent to operation form which authorizes the hospital and medical group "to dispose of any severed tissue or member in accordance with accustomed hospital practice."¹⁷⁶ When the tissue has potential market value, this consent clause is insufficient. This language does not suggest that the hospital or physician who disposes of the tissue may reap substantial profit from it.¹⁷⁷

Legislation or regulation should require that the medical purposes be expressly spelled out, disclosing that such purposes may include research with possible commercial value. Furthermore, disclosures in the written consent form must be considered merely an "adjunct"¹⁷⁸ to legislatively required oral disclosure if the physician believes there is a likelihood of commercialization.

It is not usually anticipated that a particular individual's tissue will have unique and important properties likely to result in successful commercial use. Rarely does a specimen from a single source yield a marketable commodity.¹⁷⁹

171. *Id.* at 105. The study was requested by the House Committee on Science and Technology and the House Committee on Energy and Commerce. *Id.* at iii.

172. *Id.* at 105.

173. *Id.* See *supra* notes 38-40 and accompanying text.

174. Warren, *supra* note 88, at 141, 145.

175. *Id.*

176. KAISER PERMANENTE CONSENT TO OPERATION, form 12-2163 (Dec. 1985).

177. The issue of the right to consent to the commercial use of one's bodily parts is also relevant when a request for autopsy is made to the deceased's next of kin. A widely used consent form for this purpose authorizes removal of tissues or organs and allows the physician "to retain, preserve and/or contribute the same for such diagnostic, therapeutic or other scientific purposes, as he shall deem proper." KAISER PERMANENTE NEXT OF KIN AUTHORIZATION FOR AUTOPSY, form NS-5735 (Feb. 1984). Again, these purposes are not elucidated.

178. P. APPELBAUM, C. LIDZ & A. MEISEL, *supra* note 80, at 181.

179. *Who Owns Human Cells?*, San Diego Tribune, Dec. 18, 1989, at AA-2, col. 2.

Often, new medical products and drugs result from the use of tissues from thousands of donors.¹⁸⁰ In these cases, a simple explanation on the consent form that one possible use of removed tissue is for scientific research would suffice to inform tissue donors.

When the tissue is more unusual and prior to removal there is a stronger likelihood that the research will lead to commercial gain, then the physician must disclose this information and obtain consent. In a situation where the physician discovers the commercial potential of a particular tissue after removal, and subsequently removes more for the purpose of further research and development, mandatory disclosure and consent must precede the additional removal. Lack of disclosure and consent under those conditions gave rise to the cause of action recognized in the *Moore* case. Additionally, when the physician/researcher initially has no indication of the value of the tissue, but later learns of such commercial value, he must make an effort to notify the patient and receive consent for further use even if no additional removal is needed. Such regulations would have protected Moore, as well as Dr. Golde, his physician.

B. Protection of Research Subjects

To attain similar results in the research setting, sections 46.116(a)(1-8)¹⁸¹ of the DHHS regulations covering informed consent should be amended to include disclosure of the possibility of commercial gain.¹⁸² Section 46.116(d)(1-3), which allows the IRB to waive informed consent under certain conditions of minimal risk, should be eliminated.¹⁸³ In addition, section 46.101(b)(5),¹⁸⁴ which exempts from federal regulations pathological or diagnostic specimens if they are publicly available or the investigator records information so that donors are unidentifiable, should be eliminated to further protect patients' rights.¹⁸⁵ If identification of all donors becomes mandatory and the scope of informed consent is expanded to encompass research and commercialization of human tissue, some additional record keeping and administrative supervision would be required. However, this additional administrative burden would be minimal since written consent for tissue removal for medical or research purposes already is required in most instances. The additional burden measured against the gain of an individual's right of self-determination over his body is a small price to pay.

180. *Id.*

181. 45 C.F.R. §§ 46.116(a)(1-8).

182. 45 C.F.R. §§ 46.116(d)(1-3).

183. *Id.* § 46.101(b)(5).

184. Such a change would be "consistent with the general spirit of the guidelines to protect the interests of the research subject." OTA REPORT, *supra* note 12, at 18.

185. *Salgo*, 154 Cal. App. 2d at 578, 317 P.2d at 181 (1957).

CONCLUSION

The purpose of the doctrine of informed consent is to provide a patient with all the information, including all the risks, that might affect "his rights and interests" in making an intelligent decision about the proposed medical treatment.¹⁸⁶ Ideally, researchers must inform their subjects of the nature and purpose of the research as well as the risks involved. When the medical procedure or research involves tissue removal, the physician/researcher must disclose the risk of such removal.

Biotechnology has created a new risk that necessitates an expansion of the traditional notion of informed consent disclosures. The seminal *Moore* case illustrates this need for broader disclosure requirements. Unfortunately, *Moore* is binding only in California, leaving patients living outside of California unprotected by this valuable precedent. Other states have not yet addressed the issues governing rights and obligations of those engaged in research and commercialization of human tissues.

In order to correct present inadequacies in the informed consent process, legislation and/or regulation need only slightly expand the required disclosures under current informed consent doctrine to protect patients in the medical setting. Modest alterations of DHHS regulations can achieve similar results for research subjects. When physicians or investigators plan to use human tissue in their research, they should be required to reveal this information as well as the possibility that the tissue may be developed into a marketable product. Such disclosure is essential to the preservation of the fiduciary nature of the doctor/patient and researcher/research subject relationships, as well as to the protection of the rights and interests of all parties.

*Linda Daniels, M.D.**

186. The California Supreme Court held that a physician must "disclose personal interests unrelated to the patient's health, whether research or economic, that may affect his medical judgment" when he seeks the patient's consent for a procedure. *Moore II*, 51 Cal. 3d at 131, 132, 271 Cal. Rptr. at 152.

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