

Cells, Sales, and Royalties: The Patient's Right to a Portion of the Profits

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For approximately seven years, John Moore underwent diagnosis, treatment, and care for "hairy cell leukemia." In the course of treatment, doctors at UCLA Medical Center drew Moore's blood, blood components, by-products, and genetic material, and removed bodily tissues and spleen. Although the primary purpose of this medical care was to cure his cancer, the doctors received his consent to use his blood and bodily substances in research unrelated to treating Moore's illness. Dr. David Golde and Shirley Quan, a technician and inventor, eventually used Moore's unique cells as the basis for the development of the "Mo-cell Line,"¹ which they patented and sold to biotechnology companies for considerable profit.² Dr. Golde has stated that "to our knowledge, this is the only human cell-line that produces these factors."³

Moore brought suit against Golde and Quan, the Regents of the University of California, the UCLA Medical Center, and a host of genetic, biomedical, and bioengineering firms, some known and some yet unknown to the plaintiff.⁴ He claims that had he known

1. A number of biologically valuable substances have been produced from the Mo-cell line. Among these are lymphokines, which are useful in the treatment of blood diseases, cancers, and immune system deficiencies, as well as other blood factors that are used in the development and proliferation of specialized blood cells. Appellant's Opening Brief at 5, *Moore v. Regents of the University of California*, App. No. B021195 (Cal. Ct. App., Aug. 1987) [hereinafter Brief].

2. Dr. Golde and the University of California Board of Regents sold exclusive access to Moore's cells and research being performed on them to Genetics Institute for a total of \$330,000, payable over a three-year period. Golde became a consultant to Genetics Institute in exchange for options on 75,000 shares of the company's stock at one cent per share. Another biotechnology company, Sandoz Pharmaceuticals Corporation, paid \$110,000 to Golde and the Regents to share in the exclusive access to Moore's cells for use in clinical testing and marketing. *Id.* at 12-13.

3. *Id.* at 5.

4. The case is pending in the California Court of Appeal. The first cause of action in the original complaint reads:

In addition to providing research material for countless scientific articles, plaintiff's blood and bodily substances were also utilized to develop and obtain a patent entitled 'Unique T-Lymphocyte Line and Products Derived Therefrom', commonly designated as the "Mo-Cell Line" and bearing United States patent number 4,438,032 . . . granted to David W. Golde, M.D. and Shirley G. Quan on March 20, 1984 and concurrently assigned to the Regents of the University of California, and was also sold, transferred, assigned, licensed, leased and otherwise made available to the

that his body was being used for economic profit he would have sought compensation, and that therefore he is entitled to the full value of his contribution.⁵ The defendants counter that Moore's consent to the research was adequate to permit the development of the cell line, and that in any event the fact that Moore donated the cells is irrelevant to the question of ownership rights in the cell line, since ownership rights hinge on who owns the patent rather than who contributed the cells.⁶ The case is still in litigation.

Issues raised by Moore's case are likely to reappear in the near future. According to a Commerce Department forecast, the market for genetically engineered products will amount to tens of billions of dollars by the 1990s.⁷ Such growth will certainly be accompanied by a growing number of claims by patients asserting a right to share in the profits gained from research and development using their cells. Several claims similar to Moore's have already been brought but have been settled out of court.⁸

Biogenetic Defendants and the other remaining defendants, and each of them, for substantial economic and commercial value. Plaintiff's Complaint at ¶ 9, *Moore v. Regents of University of California*, No. 0513755, (Cal. Super. Ct., Los Angeles County, 1984) *reprinted in* 3 *Biotechnology L. Rep.* 242, 243 (Nov. 1984) [hereinafter *Complaint*]. Although Moore does not raise many of the claims addressed in this Current Topic, his case serves as a starting point for a discussion of the issues that are likely to arise in similar contexts.

5. Brief, *supra* note 1, at 15, 17-18. Moore also claims that as a direct and proximate result of the defendants' conduct, he has sustained economic loss and incurred expenses and elements of special damages and has suffered mental and emotional distress and will continue to suffer such distress in the future. *Complaint, supra* note 4, at ¶ 15. He also seeks declaratory relief to the respective right, title, duties and obligations of each of the parties to the action. Prayer for Relief at ¶ (b) in *id.*

6. Culliton, *MoCell Case Has Its First Court Hearing*, 226 *Science* 813 (1984).

7. Dolnick, *Spare Parts*, 195 *The New Republic* 16 (1986). "Industry analysts expect that the products now in litigation will, by the mid-1990s, be part of a market serving millions of patients and worth tens of billions of dollars." *N.Y. Times*, Mar. 9, 1987, § 1 at 1, col. 6.

8. Dolnick, *supra* note 7, at 16. One example of such a claim arose in 1982 when doctors at the University of California, San Diego, produced a human monoclonal antibody from the lymph cells of the mother of a post-doctoral student, Dr. Hideaki Hagiwara. The antibody was designed to attack the mother's cervical cancer. The Hagiwara family claimed co-ownership rights to the cell-line that was developed. A settlement between the two sides was eventually reached. The patent was assigned to the University of California, and the Hagiwara Institute of Health in Japan received exclusive license for the use of the cell-line in Asia, paying the University royalties on any commercial product sales resulting from its use. Royston, *Cell Lines From Human Patients: Who Owns Them?*, 33 *Clinical Res.* 442, 442-43 (October 1985).

Several companies are working to develop the new method of producing monoclonal antibodies for treating cancer patients. To create a monoclonal antibody, scientists inject a cell from a patient's cancer into a laboratory mouse that produces specific antibodies against the cancer. The antibodies are then taken from the mouse's spleen and injected into the cancer patient. The antibody is also fused with a cancer cell to form a "hybridoma" that can live in the lab and produce antibodies to act against a specific cancer cell. See Henig, *In Business to Treat Cancer*, *N.Y. Times Magazine*, Nov. 23,

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If such claims are allowed to succeed, research in this area may slow significantly. The mere prospect of litigation may burden research, and financial incentives for hospitals and researchers will decrease even more if the plaintiffs are successful. In addition to the cost of litigation and/or settlement, the time and energy spent on these cases will drain resources that might otherwise be spent in research.⁹ It is therefore crucial to formulate a coherent legal response that will not unduly burden this beneficial research.

This Current Topic examines the strength of plaintiffs' claims to share in profits from the sale of products derived from their cells.¹⁰ Existing informed consent doctrine, statutory and constitutional rights to privacy, property law, and patent law provide principles on which these patients can make creative yet powerful claims. Biotechnology, however, raises many new and difficult questions that our legal system has yet to answer specifically. Analysis of the issues in this field is, therefore, limited to imperfect analogies.

The concerns raised by cell and biogenetic research can be divided roughly into two questions. First, does a patient have a right to exercise control over future use of his or her body in research through the mechanism of specific consent? Second, if a patient does consent to be used as a product base, ought he or she to be compensated?

To answer these questions, it is necessary to explore a number of interrelated issues. The question of consent involves: (1) professional medical standards; (2) common law and constitutional privacy interests; (3) moral and philosophical views of the human body; and

1986, at 82; Henig, A New Treatment, in *id.* The process of cloning is slow and imperfect. Doctors hope eventually to have a large enough library of hybridomas available so that patients will not have to be the source of their own tumor-specific antibodies. The related question that may arise is whether the original donor of the cell from which the hybridoma was made will have a claim to any of the profits made by the doctors through use of the antibody in the treatment of future cancer patients.

9. This sentiment was expressed in the context of the Hagiwara case by I. Royston, who developed the monoclonal antibody in that case. Royston flagged the need for "new laws which delineate the rights, if any, of patients to commercial products of cell lines derived from their tissues . . . If the patient does not wish to waive his rights I would have to ask the University to negotiate an agreement with him so that my time will not be taken up in subsequent litigation." See Royston, *supra* note 8, at 443.

10. It is possible to limit the discussion of patients' claims to royalties to this particular area of research. It may be that any patient whose case has helped to advance medical knowledge either directly or indirectly could make some claim to the researcher's grant money, salary, or any other monetary gain linked to that knowledge. Administration of such a system would be nearly impossible and would cripple medical research because of the sheer volume of claims. What differentiates Moore's claim is the existence of the patented cell-line in which an actual body substance has provided the basis for the product. It is the royalties from the patent, not the unquantifiable gain in medical understanding or advance in technology, that Moore seeks to share.

(4) property-based interests in the body. In turn, positing property-based interests in the body helps to answer the question of compensation. Patent law principles also suggest that a donor should be fairly compensated for his or her unique contribution to the valuable end product. Finally, patent law demonstrates that the most equitable legal solution to the problem is a licensing system between the patient and the doctor that establishes a fixed rate of profit-sharing.

*I. The Patient's Specific Consent to Commercial
Use of His or Her Body*

The first question to explore is whether doctors violate a patient's right to control the disposition of his or her cells by using that patient's cells, without specific consent, to develop a marketable product. Four general arguments support a patient's right to retain control over his or her body parts. First, professional medical standards suggest that patients be fully and adequately informed of the nature of scientific research in which they participate. Second, common law and statutory rights of privacy suggest that patients should be protected from intrusion by researchers who would exploit their cells. Third, the constitutional right of privacy recognizes zones of personal activity into which the state cannot intrude without justification. Finally, and most generally, moral and philosophical arguments reject nonconsensual use of the human body.

A. Professional Medical Standards

It is axiomatic that patients must consent to their own medical treatment.¹¹ Here, however, the question is not whether one must consent to undergo certain treatment, but whether one must consent to the particular use of one's cells, i.e., incorporation of them into a valuable product. Moore claims that he was not fully informed of the researchers' intention to profit from his cells. He alleges that he agreed to "certain written and non-written forms of limited consent to the actual physical removal of his blood and bod-

11. In its present form, the informed consent doctrine requires physicians to disclose adequately the nature of the proposed treatment according to prevailing standards of medical practice. This standard is judged in some jurisdictions by customary practice in the area, in others by what the reasonable physician would disclose, and in others by what the reasonable patient would need to know to make an intelligent choice. Cotton & Sandler, *The Regulation of Organ Procurement and Transplantation in the United States*, 7 J. Legal Med. 55, 73-4 (1986). For a general discussion of the issues surrounding informed consent, see, e.g., J. Katz & A. Capron, *Catastrophic Diseases: Who Decides What?* (1975).

ily substances for medical purposes, but none of these constituted either an explicit or implicit authorization of consent to commercial exploitation of his bodily substances.”¹² The defendants counter that Moore did consent to their use of his cells in research and that the further use of them to develop a saleable product did not require another specific consent agreement.¹³

A variety of professional codes and government regulations prescribe the conduct of doctors in relation to their patients. Primary among these is the Hippocratic Oath, a general set of guidelines for doctors that prohibits them from acting contrary to their patients’ interests: “In every house where I come I will enter only for the good of my patients, keeping myself far from all intentional ill-doing and seduction.”¹⁴ In Moore’s case, although the professional responsibility issue suggested by the Hippocratic Oath was not raised, the doctors could argue that while they are prevented from hurting, manipulating, or coercing the patient in order to benefit themselves, such conduct was not present here. On the contrary, they could argue, Moore was treated successfully and had given his consent to their research. However, Moore did not consent to the doctors’ commercial use of his body; in fact, he knew nothing about it. In that sense, Moore could argue that he was “seduced” by the defendants to their benefit in a way arguably violative of professional standards.

The World Medical Assembly’s Declaration of Helsinki, updated in 1983, specifically addresses non-therapeutic biomedical research using human subjects. The relevant section states:

The rights of the research subject to safeguard his or her integrity must always be respected. . . . In any research on human beings, each potential subject must be adequately informed of the aims, methods, anticipated benefits and potential hazards of the study and the discomfort it may entail. He or she should be informed that he or she is at the liberty to abstain from participation in the study and that he or she is free to withdraw his or her consent to participation at any time. The physician should then obtain the subject’s freely-given informed consent, preferably in writing.¹⁵

12. Brief, *supra* note 1, at 27. Moore also argues that, “[b]ecause the Defendants misrepresented and actively concealed from Plaintiff the value of his unique cells and their commercial activities and patents based upon the cells, Plaintiff could not possibly have given any form of implied or express informed consent to those activities.” *Id.* at 14.

13. Culliton, *supra* note 6, at 813.

14. Reprinted in J. Areen, P. King, S. Goldberg & A. Capron, *Law, Science, & Medicine* 273 (1984).

15. *Id.* at 928.

The American Medical Association (AMA) has adopted similar guidelines.¹⁶ In addition, the Department of Health and Human Services (HHS) has promulgated regulations for the "Protection of Human Subjects" that are binding on all research conducted or funded in whole or in part by that department.¹⁷ According to the various HHS regulations, "If the researcher wishes to remove human material primarily to serve research interest . . . full informed consent is required ethically as well as by the regulations of HHS and The Food and Drug Administration (FDA)."¹⁸ Among elements of informed consent defined in federal regulations are "an explanation of the purposes of the research . . ." and "[a] description of any benefits to the subject or to others which may reasonably be expected from the research."¹⁹

Moore's argument is that under these guidelines he was himself the subject of research and, therefore, deserved to be informed of the researchers' purpose and anticipated benefits.²⁰ The researchers' aim was to produce a cell line, and they anticipated that it would be patentable and thus profitable. These particular aims and the anticipated benefits to the researchers were not communicated to Moore in a manner consistent with the above-mentioned codes and guidelines.

It is doubtful that Moore can prevail simply on grounds of breached medical standards. He was not the "subject" of research in a strictly traditional sense, but rather the donor of cells that were themselves the research subject. Moreover, the doctors did elicit his consent for the use of his cells in general research, and it is possible that such consent may be interpreted under these guidelines as a relinquishment of all rights to control the use of those cells.

Professional ethics are helpful in establishing a principle of respect for the patient's dignity and autonomy. Nonetheless, because it is likely that Moore's case will fail under traditional informed consent doctrine, it is necessary to go beyond that inquiry to a discussion of other theories on which a patient's claim to retain control over his or her body may be based.

16. *Id.* at 929-30.

17. 45 C.F.R. § 46 (1983).

18. Levine, Research That Could Yield Marketable Products From Human Materials: The Problem Of Informed Consent, 1 IRB: A Review of Human Subjects Research 6 Jan./Feb. 1986 [hereinafter IRB].

19. *Id.*

20. Brief, *supra* note 1, at 42-44.

B. Common Law and Statutory Rights of Privacy

Even if professional standards do not require a doctor to seek specific consent to use a patient's cells as the basis of a marketable product, common law and statutory rights of privacy may safeguard the patient's right to control the disposition of his or her body parts. The doctors' use of Moore's cells without his specific consent arguably intrudes on his personal life in a manner violative of his right of privacy as it is recognized at common law and embodied in many state statutes.

In a seminal 1890 article entitled "The Right to Privacy,"²¹ Samuel Warren and Louis Brandeis reviewed past cases that had protected a right to privacy without expressly referring to it as such, and concluded that underlying these cases was a broader principle, separate from property or contract law, that deserved independent recognition. The authors found that:

The intense intellectual and emotional life, and the heightening of sensations which came with the advance of civilization, made it clear to men that only a part of the pain, pleasure, and profit of life lay in physical things. Thoughts, emotions, and sensations demanded legal recognition.²²

The right of privacy makes cognizable the individual's right to "decide whether that which is his shall be given to the public."²³ Regardless of their inherent value, certain things are protected from exposure or exploitation merely because exposure would disturb a person's peace of mind. In other words, the right of privacy recognizes a person's right "to be let alone."²⁴

The common law conception of a right of privacy developed out of this need for protection of the individual's feelings.²⁵ According to the Restatement (Second) of Torts, the general principles of this

21. 4 Harv. L. Rev. 193 (1890).

22. *Id.* at 195.

23. *Id.* at 199.

24. Justice Brandeis made one of the most famous statements of the right to privacy in his dissenting opinion in *Olmstead v. United States*, 277 U.S. 438, 478 (1928): "The makers of our constitution . . . sought to protect Americans in their beliefs, their thoughts, their emotions and their sensation. They conferred, as against the government, the right to be let alone—the most comprehensive of rights and the right most valued by civilized men." Although Brandeis cast the privacy right in constitutional terms, the right to be let alone echoes a right he found existing at common law. For an articulation of the common law right to privacy, see, e.g., *Timperley v. Chase Collection Service*, 272 Cal. App. 2d 697, 699, 77 Cal. Rptr. 782 (1969): "The right to privacy has been defined as the right to live one's life in seclusion, without being subjected to unwarranted and undesired publicity; in short, it is the right to be let alone."

25. See, e.g., N.Y. Civ. Rights Law § 50 (McKinney 1986).

common law right of privacy provide that privacy is invaded by "unreasonable intrusion upon the seclusion of another, or . . . unreasonable publicity given to the other's private life . . ." ²⁶ Although related to libel, a privacy claim need not allege injury to character or reputation, but only mental distress. The motivations of the defendant have been held to be unimportant in determining whether there is a cause of action. ²⁷ The right of privacy may be waived through consent. ²⁸ However, "consent may be asserted as a defense only where the consent has not been exceeded; consent which has been exceeded is not a defense." ²⁹

Invasion of the right of privacy usually involves the nonconsensual use of photographs, wiretaps, and the like. "The advance of civilization" to which Warren and Brandeis alluded, however, undoubtedly also includes scientific advancement that has the potential to cause hurt feelings. In this light, it would seem quite reasonable for Moore to claim that the doctors violated his right to be let alone. In asserting such a claim, all he would need to show is that something he considers personal, in this case his cells, has been invaded by another in excess of his specific consent. Because Moore's consent was exceeded, he has a strong claim for damages under this right of privacy doctrine. ³⁰ Moore's hurt may stem also from the fact that his body was commoditized. Not only did the doctors act without Moore's specific consent, but also they made commercial use of his cells—an end that not only goes beyond his consent, but offends his personal integrity. ³¹

C. *The Constitutional Right of Privacy*

The constitutional right of privacy protects certain activities—"zones of privacy"—from state interference. ³² Within these zones a

26. Restatement (Second) Torts § 652A (1977).

27. *Freihofer v. Hearst Corp.*, 65 N.Y.S.2d 135 (1985).

28. *Sidis v. F-R Pub. Corp.*, 113 F.2d 806 (2d Cir. 1940), *cert. denied*, 311 U.S. 711 (1940).

29. 62 Am. Jur. 2d *Privacy* § 19 (1972), *citing* *Continental Optical Co. v. Reed*, 119 Ind. App. 643, 86 N.E.2d 306 (1972). *See supra* note 11 and accompanying text.

30. The hurt feelings aspect of Moore's case is present in his claim that he "has suffered mental and emotional distress and will continue to suffer in the future." Complaint, *supra* note 4, at ¶ 15.

31. *See infra* notes 51-54 and accompanying text.

32. The first reference to a right to privacy was made by the Court in *Griswold v. Connecticut*, 381 U.S. 479 (1965): "Specific guarantees in the Bill of Rights have penumbras, formed by emanations from those guarantees that help give them life and substance." The present discussion of privacy issues is not intended to be exhaustive, but only to serve the limited purpose of providing an analogy to the issue presented here.

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person may act free from unwarranted intrusion by the government.³³ Because this privacy right protects the individual from state action, constitutional claims may only be asserted against a government agency or a governmentally funded or subsidized agency.³⁴ Although Moore does not make constitutional arguments, such claims could be raised against the University of California Board of Regents, a state governmental entity.³⁵ Even where the defendant is not a government or governmentally funded entity, however, the constitutional issues are useful in informing the choice of policy. The same values that are cherished and protected from the state by the Constitution deserve respect in all spheres, not only when the government is an actor.

Before the constitutional right of privacy was judicially recognized, several courts upheld a "right" to be free from unwanted intrusion—a right they cast in terms of personal autonomy. In the context of medical care, Judge Benjamin Cardozo wrote for the New York Court of Appeals, "Every human being of adult years and sound mind has a right to determine what shall be done with his body."³⁶ This notion of human autonomy is closely bound to the privacy right. As enunciated by the New York Supreme Court in an opinion upholding a patient's right to reject life-sustaining treatment, "[T]he essence of this [privacy] right is autonomy over matters of personal integrity, including control over one's body"³⁷

With *Griswold v. Connecticut* in 1965,³⁸ the Supreme Court began to etch out certain areas of activity that fall within the protected zone of privacy where state regulation is constitutionally impermissible

33. The Court has applied "strict scrutiny" to laws that interfere with "fundamental rights" guaranteed by the Constitution. This test requires that the state show a "compelling interest" in passing laws that limit personal liberties. See, e.g., L. Tribe, *American Constitutional Law* § 16-6, at 1000 (1978). The Supreme Court has held that the right of privacy is a fundamental right protected by the Constitution and one that requires a showing of compelling state interest when it is limited by legislation. *Roe v. Wade*, 410 U.S. 113 (1973).

34. The constitutional claim against the state is particularly relevant in a case such as Moore's, where one of the defendants, the Board of Regents of the University of California, is a governmental entity that receives government funding. However, even where the defendant is not a government or governmentally funded entity, the constitutional claims bear on the overall discussion of these issues.

35. See Brief, *supra* note 1, at 44, 45 for a discussion of the applicability of federal regulations to the defendants in this case.

36. *Schloendorff v. Society of New York Hospital*, 211 N.Y. 125, 105 N.E. 92, 93 (1914) (finding that although removal of tumor without consent constituted trespass, charitable hospital was not liable), *rev'd on other grounds*, 2 N.Y.2d 665 (1957).

37. *Eichner v. Dillon*, 426 N.Y.S. 2d 517, 538, 73 A.2d 431 (1980), *modified sub nom.*, *In re Storar*, 52 N.Y.2d 263, 420 N.E.2d 64 (1981).

38. 381 U.S. 479 (1965).

unless the state can demonstrate a compelling interest in the regulation.³⁹ Although the Supreme Court has not extended the privacy right to encompass medical decisions,⁴⁰ the abortion decisions tend to pave the way toward this recognition. Justice William Douglas recognized the privacy protection of medical decisions in his concurring opinion in *Doe v. Bolton*,⁴¹ a companion case to *Roe v. Wade*, when he wrote that the right of privacy includes "the freedom to care for one's health and person."⁴² The right of privacy has been invoked by lower courts in certain medical contexts. One example is in *Andrews v. Ballard*,⁴³ where the Texas district court recognized that the constitutional right of privacy protected an individual's decision to obtain or reject medical treatment.

Even more relevant to Moore's claim, the right of privacy has justified a right to refuse medical treatment, as when terminally ill patients refuse life-sustaining treatment.⁴⁴ Moore's right to refuse to be the source of a profitable medical product may be protected by these same constitutional considerations. If a patient has the right to refuse medical treatment, even when such a refusal may damage his or her health, then a patient should have a claim, at least equally as strong, to refuse to be involved in medical procedures beyond those to which he or she consented when that refusal will not cause harm.

Although the right of privacy has protected individual choice in certain medical areas, the Supreme Court has not defined precisely the contours of this right.⁴⁵ What is clear is that the Constitution protects the individual's right to procreate and the right to terminate pregnancy, the right to choose certain medical treatment, and

39. A partial list of such activities includes the right to procreate, *Skinner v. Oklahoma*, 316 U.S. 535 (1942), the right to use contraceptives, *Griswold v. Connecticut*, 381 U.S. 479 (1965), and the right to obtain an abortion in the first trimester, *Roe v. Wade*, 410 U.S. 113 (1973).

40. *But see* *Winston v. Lee*, 470 U.S. 753 (1985) where the Court held in a fourth amendment context that compelled surgical intrusion into an individual's body for evidence "implicates an expectation of privacy and security of such magnitude that the intrusion may be 'unreasonable' even if likely to produce evidence of a crime." *Id.* at 759.

41. 410 U.S. 179, 213 (1973).

42. 410 U.S. at 213.

43. 498 F.Supp. 1038 (S.D. Tex. 1980) (upholding patient's right to undergo acupuncture).

44. *See, e.g.*, *In re Quinlan*, 70 N.J. 10, 355 A.2d 647 (1976); *Satz v. Perlmutter*, 362 So.2d 160 (Fla. Dist. Ct. App. 1978), *Eichner v. Dillon*, 426 N.Y.S.2d 517, 73 A.2d 431 (1980); *Superintendent of Belchertown State School v. Saikewicz*, 373 Mass. 728, 370 N.E.2d 431 (1977).

45. "The outer limits of . . . privacy have not been marked by the Court." *Carey v. Population Services International*, 431 U.S. 678, 684 (1977).

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the right to refuse medical care. The right to control the use of one's body parts and to prevent nonconsensual use of them is consistent with these other constitutionally protected spheres and should be included within the right of privacy.

However, the right of privacy is not absolute and is limited by assertions of compelling state interest. The state has successfully justified its interference with an individual's medical decision by asserting that it is protecting that person's life;⁴⁶ protecting innocent third parties, either particular individuals⁴⁷ or members of the society at large;⁴⁸ or maintaining the ethical integrity of the medical profession.⁴⁹ None of these limitations, however, seems applicable to Moore's case.

In the cell research context, the state cannot assert that its interference with the patient's personal autonomy is protecting the patient's life; the patient's life was a factor only during the curative stage of treatment, not during the subsequent research stage. Nor is there the interest in protecting an innocent third party, which generally applies to family members of a patient whose refusal of treatment may result in death.⁵⁰ Finally, the concern for the integrity of the medical profession, usually asserted in efforts to continue life-sustaining treatment against the patient's will, may cut in favor of the plaintiff's claim that he continue to consent to whatever use is made of his body. As discussed above, professional ethics support a system of full disclosure of the researchers' aims and expectations to the patient. Assuming that Moore has a right to determine what medical procedures he will undergo—a right protected by the constitutional right of privacy—the state cannot assert a valid interest in overriding that right.

46. See, e.g., *U.S. v. Rutherford*, 442 U.S. 544 (1979); *People v. Privitera*, 153 Cal. Rptr. 431, 591 P.2d 919 (1979) (not permitting access to laetrile a legitimate state interest).

47. See, e.g., *In re Application of Jamaica Hospital*, 128 Misc.2d 1006, 491 N.Y.S.2d 898 (N.Y. Sup. Ct. 1985) (blood transfusion compelled where life of unborn fetus at stake); *Roe v. Wade*, 410 U.S. 113 (1973) (prohibiting abortion of viable fetus).

48. *Jacobson v. Massachusetts*, 197 U.S. 11 (1905) (smallpox vaccination).

49. *John F. Kennedy Memorial Hosp. v. Heston*, 58 N.J. 576, 583, 279 A.2d 670, 673 (1971) ("When the hospital and staff are thus involuntary hosts and their interests are pitted against the belief of the patient, we think it reasonable to resolve the problem by permitting the hospital and its staff to pursue their function [of preserving life] according to their professional standards").

50. Arguably a state could assert an interest in protecting a third party where the cell-based product was essential for curing a particular disease.

D. Moral and Philosophical Arguments

Finally, in exploring the scope of the patient's control, it is necessary to turn to a broader discussion of whether it matters morally or philosophically that Moore was not fully informed, or that he did not fully consent to be the basis for the Mo-cell line. A conception of human dignity lies at the heart of the assertion that the patient has a right to control the disposition of his body parts. Research with human cells that results in significant economic gain for the researcher and no gain for the patient offends the traditional mores of our society in a manner impossible to quantify. Such research tends to treat the human body as a commodity—a means to a profitable end.⁵¹ The dignity and sanctity with which we regard the human whole, body as well as mind and soul, are absent when we allow researchers to further their own interests without the patient's participation by using a patient's cells as the basis for a marketable product. Doctors, like Moore's, who do not get the patient's specific consent yet proceed with their development of a commercial product derived from their patients' bodies are acting contrary to our concept of respect for the human body.

This same concept of human dignity and autonomy is at the heart of medical ethics.⁵² One ethicist, John Fletcher, writes of the autonomy issue in medicine:

To be a person, to have moral being, is to have the capacity for intelligent causal action. . . . In Biblical terms it means that man is made in the image of God, and that therefore he is self-conscious, saying 'I am,' and that he is self-determined, saying 'I will'. . . . This is what it means to be a person and not an object to be manipulated either by doctors or medicine or by the impassive operations of physical nature.⁵³

Fletcher's discussion focuses on the notion of self-determination. For Fletcher, the very definition of personhood includes the ability to be responsible for one's actions. While this passage addresses the entire informed consent question, it also applies to the specific question of the nonconsensual use of a cell in a marketable product. When a person like Moore unknowingly becomes the basis for a

51. Kant's first maxim seems to reject such treatment: "Act so as to treat humanity, whether in thine own person or in the person of another, always as an end, never as a means only." I. Kant, *Groundwork of the Metaphysics of Morals* 96 (1964).

52. See, e.g., P. Ramsey, *The Patient as Person* (1970). Ramsey's thesis is that respect for individual human autonomy ought to be central in determining medical priorities and ought to limit the scope of medical procedures in many instances.

53. J. Fletcher, *Morals and Medicine* 218-19 (1954).

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commercial product, he may feel that he has lost some of that self-determination that makes him human.

Thomas Murray, a professor of ethics, has discussed the ethical issues present in Moore's particular case. Murray is interested in how we view human body tissues after they have been removed from the body.

There is something very special about human organs and tissues, even when removed from the body. We do retain moral interests in them, so that at least they are not misused or treated in an undignified manner. . . . We do not let people sell them, nor do we let others profit unduly from them.⁵⁴

This view that the sanctity of the human body lingers even after removal is essential to the discussion of patients' rights here. All legal arguments are dwarfed if we accept the overarching notion that a human's body deserves respect and that using it without the owner's consent to make a commercial product violates that respect.

These moral intuitions are the core of the argument requiring that patients give specific consent to the use of their body parts in marketable products. Only when the patient is informed fully and consents freely to the use of his or her body can the resulting research be consistent with the notion of human self-determination. A patient's consent at one stage to donate parts of his or her body to research does not imply his or her consent to be used as the basis for a saleable product. Informed consent is necessary for every aspect of the research that uses a person's body.

II. The Patient's Claim for Compensation

The above discussion suggests that a patient must give specific consent to be used by researchers for commercial purposes. In the absence of such consent, the patient may make a claim against the researchers that stems from notions of professional ethics, the right of privacy, and moral intuitions. While such an argument would sustain a claim for emotional damages, the claim for compensation becomes even more compelling when it is based not only on the lack of consent, but also on an argument that the researchers have violated the patient's property rights.⁵⁵ The first step toward this as-

54. Murray, *Who Owns the Body? On the Ethics of Using Human Tissue for Commercial Purposes*, 1 IRB at 3.

55. Moore in fact asserts a conversion claim. See Brief, *supra* note 1, at 19-25.

section is to establish that a property right exists in the body.⁵⁶ This concept has been espoused in several broad discussions of the notion of human autonomy.⁵⁷ Common law and state statutes also lend support to the property claim by recognizing exclusive rights to one's own name or likeness;⁵⁸ this exclusivity can be extended to encompass one's own cells. When it is determined that a property right in the body does exist, the proper remedy for a violation of that right is compensation to the owner. In exploring a system of compensation, patent law provides a helpful analogy for the argument that contributors to a product ought to retain ownership rights in the product and continue to benefit from its commercial success.

A. Property Rights in the Body

The patient's claim against researchers who used the patient's cells without permission is strengthened by the argument that he or she has an exclusive property right in the body that if violated warrants compensation. Several ethicists have raised the possibility of viewing the body as property over which we have exclusive ownership. For example, in her discussion of human autonomy, ethicist Judith Thomson focuses on positive and negative property rights, i.e., owning something and preventing others from having access to it. She relates these rights to the human body, believing that, "if we have fairly stringent rights over our property, we have very much more stringent rights over our own persons."⁵⁹ She goes on to say that every person has an exclusive right to sell his or her own knee (if anyone would buy it), damage the knee, and deny anyone else the right to touch it or look at it.⁶⁰ The exclusive dominion one has over inanimate property becomes even more inviolable when ownership is immutable and the thing owned has the sanctity of the human body.

In his article, "An Essay on Rights," Mark Tushnet also discusses control over one's body in terms of property rights. Tushnet grapples with the individual's property-based right to control an organ,

56. For a recent discussion of property rights in the body, see Comment, Toward The Right Of Commerciality: Recognizing Property Rights In The Commercial Value Of Human Tissue, 34 UCLA L. Rev. 208 (1987).

57. See *infra* notes 59-63 and accompanying text.

58. For discussion of the common law, see e.g., Prosser, Privacy, 48 Cal. L.R. 383 (1960). One example of statutory recognition of this right is Cal. Civ. Code § 3344 (West 1988).

59. Thomson, The Right to Privacy, 4 Phil. & Pub. Affairs 295, 303 (1975).

60. *Id.* at 303.

such as a spleen, after its removal from his body.⁶¹ "He can donate it to an organ bank, cook it, or throw it away. It is, after all, *his* spleen."⁶² While he concedes that we recognize such a right, Tushnet admits that the right is "queer," as it is only understandable in terms of the alternatives. The ground for the right, he says, is that it would be outrageous to allow a collection agency to commandeer the spleen for some other person's use or to override the man's decision if it is less than optimal. The property-based right in the body is then most vivid when one imagines the consequences of its not existing.⁶³ The right to determine what happens to one's body parts becomes cognizable when doctors or researchers use it for their own benefit.

The property right in the body ought to be protected against invasion.⁶⁴ Common law already protects the individual's exclusive right to appropriate his or her own name or likeness, a right that is based on a conception of property.⁶⁵ Although cast in terms of privacy, this right is based more on a concept of ownership—what is mine, my name, or my likeness, is mine alone and cannot be exploited by another.⁶⁶ This common law right would need only a slight extension to protect the patient from outsiders' appropriation of cells.

This property-based notion of control over one's name or likeness should be extended to one's body parts. The common law recognizes the individual's exclusive right to use what is inherently personal, and nothing is more personal than one's own genetic material. If a person has exclusive ownership rights in his or her name or image, it follows that he or she has the same exclusive rights in

61. Tushnet, *An Essay on Rights*, 62 Tex L. Rev. 1363, 1366-67 (1984).

62. *Id.* Tushnet does not address whether the patient may sell his or her body part, but the important issue is the exclusive control over the body, rather than its marketability. It is currently illegal to sell body organs; *see infra* notes 68-72 and accompanying text.

63. *Id.*

64. The idea of a property right in the body can also be seen in laws governing the disposition of dead bodies. Most courts in America recognize that a person designated in a will or, where there is none, a family has a "quasi-property" right in a corpse. Chatin, *Property Rights in Dead Bodies*, 71 W. Va. L. Rev. 377 (1969). While this right arises not from a view of the body as property, but from a duty to bury the dead, *id.* at 380, the exclusive right to disposition is the same in this area as in the question of control of one's cells.

65. Restatement (Second) of Torts § 652(c) (1977) ("One who appropriates to his own use or benefit the name or likeness of another is subject to liability to the other for invasion of his privacy.").

66. California has codified the privacy-property interest, making a "personality's" interest in his or her name or likeness devisable at death. Cal. Civ. Code § 990 (West 1988).

his or her own body. Without the owner's consent, no outsider can make a profit from another's property, in this case another's cells.

The monopoly granted to the individual to use his or her own name or likeness recognizes that its use may have commercial value. Therefore, the individual must consent to its use by another, and in the absence of consent, any invader of that monopoly is liable for wrongful appropriation of what is another's private property.⁶⁷ Similarly, in a case like Moore's where researchers have appropriated cells to which he alone has rights, they ought to compensate the owner. When the researchers make use of the patient's body without the patient's consent, the researchers must compensate the patient retroactively. It would be preferable, however, for a patient to agree initially to grant monopoly rights to the researchers and to receive fair compensation from the outset.

The notion of a property right in one's body accords with the present scheme of government regulation of organ procurement and transplantation. In 1984 Congress enacted the National Organ Transplant Act.⁶⁸ In addition to encouraging organ donation and transplantation through the creation of a task force and a nationwide network, the Act makes it:

unlawful for any person to knowingly acquire, receive, or otherwise transfer any human organ for valuable consideration for use in human transplantation if the transfer affects interstate commerce.⁶⁹

The Act defines "human organ" as "the human kidney, liver, heart, lung, pancreas, bone marrow, cornea, eye, bone, and skin, and any other human organ included by the Secretary of Health and Human Services by regulation."⁷⁰ The legislative history makes clear that "[t]he term 'human organ' is not intended to include replenishable tissues such as blood or sperm."⁷¹ In addition to the federal regulation of organ transplantation, several states have enacted their own statutes, which are more explicit than the federal statute by excluding "hair, blood and other self-replicating body fluids" from the

67. See, e.g., *Peay v. Curtis Publishing Co.*, 78 F. Supp. 305 (D.D.C. 1948) (publication of photo was invasion of right to privacy akin to publication of private letters that law forbade as encroachment of property interest); *Zacchini v. Scripps-Howard Broadcasting Co.*, 47 Ohio St.2d 224, 351 N.E.2d 454 (1976) (one who appropriates to his or her own use or benefit the name or likeness of another is subject to liability to the other for invasion of his or her privacy, and the use or benefit need not necessarily be commercial); *Galella v. Onassis*, 353 F. Supp. 196 (S.D.N.Y. 1972).

68. 42 U.S.C. § 274e (Supp. 1985).

69. *Id.*

70. *Id.*

71. S. Rep. No. 382, 98th Cong., 2d Sess. 16-17, reprinted in 1984 U.S. Code Cong. & Admin. News 3975, 3992.

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prohibition of sale.⁷² The existence of these laws suggests that in the absence of such prohibitions, the sale of organs would be legal. The laws thus recognize, in an indirect manner, that a property right in the body part, which includes the exclusive right to sell, vests in its owner.

Outlawing organ sales is generally thought of as a public policy measure that protects people from acting against their own best interests in the pursuit of financial gain. The same justification, however, does not apply to regenerative body fluids. Blood, plasma, and semen are legally sold in the United States. Because the extraction of these materials does not have permanent effects on the donor, the state does not have the same interest in prohibiting their sale to protect the donor's health.

Cells fall into the category of regenerative—and thus saleable—body material. Unlike kidneys, livers, hearts, and other organs, cells do regenerate;⁷³ they are not irreplaceable and their removal does not have a detrimental effect on the donor's health. As cells are not covered explicitly in any statute that prohibits organ sales, they may be sold under the current legal system. Since cells fall into the same category as blood, plasma, and semen, not only is it legal for Moore to sell his leukemia cells, but also it is reasonable for him to auction his rare cells to the highest bidder. In essence, that is Moore's claim—that had he known his cells were worth something, he would have struck a bargain with the doctors.

B. Patent Law as a Model for Compensation

Principles derived from property and privacy rights, as well as moral notions, support the argument that patients must consent to the use of their cells for research that yields a valuable product. Patent law reinforces this argument. Patent laws are designed to encourage innovation by ensuring that the fruits of an invention flow to the inventor, while at the same time making new products available to the public.⁷⁴ Although patent law is only roughly analogous to the current problem in biogenetic development, the reasoning behind the system helps to crystallize some of the issues involved

72. See, e.g., Va. Code Ann. § 32.1-289.1 (Michie 1985); Cal. Pen. Code § 367f (West 1987).

73. This discussion is only directly relevant to regenerative cells. Non-regenerative cells are more likely to be considered in the same category as organs.

74. See, e.g., Kitch, Patents: Monopolies or Property Rights?, 8 Res. in L. & Econ. 31, 32 (1986).

here.⁷⁵ The policy reasons for granting patents to inventors, encouraging them to make public their innovations through a system of financial reward, may also apply to cell contributors; those whose contributions are essential to a product's development ought to benefit from the fruits of their contribution.

Patent law issues are not new to the biotechnology industry. More than 6,000 patent applications are pending for biotech-related products.⁷⁶ The industry is developing rapidly, yet remains in the hands of only a few firms using basically the same scientific methods, increasing the likelihood of overlapping scientific efforts.⁷⁷ According to one *New York Times* article, "One far-reaching issue that arises in several cases is how to compensate a scientist whose work has been taken a step further by another scientist."⁷⁸ To what degree does one product differ from the other? How much of a change results from the subsequent work?

Frequently, the problem of delineating scientists' contributions and rewarding all of the relevant participants is met by granting the patent to joint inventors. Although the patent is not an "inventor," it can be argued that he or she is a type of joint player in the enterprise. Federal law defines joint ownership: "When an invention is made by two or more persons jointly, they shall apply for patent jointly and each sign the application and make the required oath"⁷⁹ In *Monsanto Company v. Kamp*,⁸⁰ the District of Columbia district court construed this statutory definition:

A joint invention is the product of collaboration of the inventive endeavors of two or more persons working toward the same end and producing an invention by their aggregate efforts. . . . It is not necessary that the entire inventive concept should occur to each of the joint inventors, or that the two should physically work on the project together. . . . The fact that each of the inventors plays a different role and that the contribution of one may not be as great as that of another, does not detract from the fact that the invention is joint, if each makes some original contribution, though partial, to the final solution of the problem.⁸¹

75. For an interesting discussion of notions of justice in the context of contributing to a marketable product, see Murray, *supra* note 54.

76. N.Y. Times, Mar. 9, 1986, at D5, col. 3.

77. *Id.*

78. *Id.*

79. 35 U.S.C. § 116 (1987).

80. 269 F. Supp. 818 (D.D.C. 1967).

81. 268 F. Supp. at 824. It is only fair to note that in its definition of a joint inventor, the court states that, "To constitute a joint invention, it is necessary that each of the inventors work on the same subject matter and make some contribution to the inventive

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The joint invention provision guarantees that all who contribute in a substantial way to a product's development benefit from the reward that the product brings.⁸² Thus, the protection of joint inventors encourages scientists to cooperate with each other and ensures that each contributor is rewarded fairly.

Although a patient who donates cells does not fit squarely within the definition of a joint inventor, the policy reasons that inform joint inventor patents should also apply to cell donors. Neither John Moore nor any other patient whose cells become the basis for a patentable cell line qualifies as a "joint inventor" because he or she did not further the development of the product in any intellectual or conceptual sense. Nor does the status of patients as sole owners of a component part make them deserving of joint inventorship status. What the patients did do, knowingly or unknowingly, is collaborate with the researchers by donating their body tissue. As stated in *Monsanto*, the collaboration need not be equal to warrant joint inventorship status. By providing the researchers with unique raw materials, without which the resulting product could not exist, the donors become necessary contributors to the product.⁸³ Concededly, the patent is not granted for the cell as it is found in nature, but for the modified biogenetic product. However, the uniqueness of the product that gives rise to its patentability stems from the uniqueness of the original cell. A patient's claim to share in the profits flowing from a patent would be analogous to that of an inventor whose collaboration was essential to the success of a resulting product. The patient was not a coequal, but was a necessary contributor to the cell line.

thought and to the final result." Moore and other patient/donors do not contribute to the thought or scientific effort that produces the patentable product. Even so, the language in *Monsanto* is helpful in its recognition of the role of unequal contributors to an invention.

82. The requirement of collaboration for one who claims joint inventor status is not met where one party's invention has been incorporated in another party's invention. Thus, in *S. W. Farber Inc. v. Texas Instruments, Inc.*, 211 F. Supp. 686, 690-91 (D. Del. 1962), the court denied the claim that a patent granted for a detachable temperature regulating connector that used a pre-existing cartridge-type thermostat was the product of a joint invention. The court found no evidence of collaboration between the inventor of the connector and the inventor of the thermostat.

83. See *supra* note 3 and accompanying text. Moore's cells themselves, while extremely rare, may not be the only cells that could have served the doctors' needs. However, every cell is unique in its genetic makeup. Even if uniqueness or rarity were not an issue, the contribution is necessary to the success of the product, and arguments for compensating the contributor remain the same.

III. *A Profit-Sharing Proposal*

Patients have valid claims to control the disposition of their body parts—claims based on moral intuitions, statutory analogies, and constitutional guarantees. Voluntary or involuntary relinquishment of that right warrants patients' claims to compensation. As biotechnology advances and becomes more profitable, more patients will bring these kinds of claims against researchers. Such litigation could slow the pace of research and development in this area.

Assuming that medical research is a good, policymakers ought to act to prevent future lawsuits similar to Moore's. Among the possible legislative solutions is the development of a form waiving a patient's claim to resulting profits. Alternatively, Congress may decide not to regulate at all, but rather to leave the issue to the researcher and patient to resolve in a free market setting. A third and more equitable solution would be to establish a system whereby researchers and patients routinely share in the profits from the cell-based product. Such a licensing system would address both patient consent and patient compensation.

The benefits of a licensing system can best be seen in comparison to the weaknesses of both the informed consent/waiver of profits and the free market solutions. Informed consent would include a waiver of the patient's rights to future claims to any profits resulting from work with his or her body parts.⁸⁴ If a patient were presented with such a waiver at the same time that he or she was consenting to initial treatment, the coercive force would be clear; physicians would seemingly be linking the provision of treatment to the patient's willingness to give up future rights to profits. Even if a patient found the prospect of a doctor's profiting from him or her objectionable, he or she might feel obliged to sign the waiver in order to receive the initial treatment. The enforceability of informed consent waivers is also uncertain. Neither the doctor nor the patient can be certain that a waiver to future profits would be upheld in court.⁸⁵ Finally, under the informed consent/waiver solution the patient gives up his or her rights to be rewarded for the donation. In light

84. For a discussion of informed consent as a response to this issue, see, e.g., Levine, *supra* note 18, at 7, 8; Sun, *Whose Cells are They, Anyway?*, Wash. Post, July 2, 1986 (Health), at 18. See also *supra* note 12 and accompanying text.

85. According to Patricia King, a lawyer and faculty member at Georgetown University, waivers do not afford good protection against future lawsuits. She predicts that in the area of cell development, "[t]he courts are going to bend over backwards to see if patients were adequately informed." Sun, *supra* note 84.

of the arguments developed above, a more just solution provides for at least some compensation to flow to the patient-donor.⁸⁶

A free market system of buying and selling body parts is also far from ideal. A free market that would allow doctors and patients to strike a bargain in any given case would require separate contractual agreements in every situation where the researcher had reason to predict that some profit might come from research with the patient's body parts. In order to ensure that the patient had given his or her consent, the deal would have to take place before the actual product was produced. Both the doctor and patient would be burdened by this negotiation and frequently the patient's hopes would be unrealistic. In reaching an agreement, the bargaining power of a treating doctor would far outweigh that of the ailing patient, making it unlikely that the patient would be able to realize his or her true contribution.⁸⁷ Finally, a market system would place a price on the actual body part; a researcher could, with one payment, become the owner of the patient's cells, with no interest retained by the patient.

A fixed rate of profit-sharing satisfactorily resolves each of these problems.⁸⁸ First, a license guarantees that the patient receive some reward for his or her contribution. Unlike a waiver to future profits included in the initial informed consent/waiver, the license agreement may be separated from the treatment stage of the doctor/patient relationship and therefore is less likely to coerce the patient. The patient may still be required to sign an initial informed consent waiver to give the doctor the right to use the patient's cells in research, but only later when the research process leading to potential profits begins will the patient be presented with the license agreement.⁸⁹ An appropriate time to disclose to the subject the market value of the product is at the "stage of inevitability, the stage in applied research at which the development of a product that

86. It is possible that a patient could waive his or her right to be compensated, but only after being fully informed of his or her option to partake in the profits.

87. See Levine, *supra* note 18, for a discussion of different bargaining powers according to the rarity of the patient's cells.

88. The typical license in the patent context is issued from a patent holder to a corporation on the condition that the licensee pay a set fee and a percentage of the royalties to the licensor. The licensor retains a property interest in the patent. Analogously, the patient retains a property interest in the body part that he or she licenses to the scientist on the condition that he or she receive some percentage of the profits derived from the product.

89. It would be possible to divide the informed consent into two stages, one at the curative and one at the research stage. However, such a practice does not solve the original problem of providing compensation to the patient.

could have market value becomes inevitable," as Levine suggests.⁹⁰ Waiting until this point separates therapy and consent to conduct research from consent to develop a saleable product, eliminating the element of coercion. Disclosure at this point does not prematurely raise the patient's expectations of profiting from his or her contribution. Finally, a license system stands on more certain legal footing than would an informed consent waiver, as it would be defined by statute rather than being judge-made.

Congress should determine an appropriate rate of compensation, eliminating the need for separate determinations in each case and the confusion of varying state compensation schemes. Government rate setting will equalize the bargaining power between doctor and patient, as both will enter the deal on terms set by a third party. Finally, a profit-sharing plan relieves the perception that patients are "selling" their body parts. The free market system sets a price on the body part itself, whereas the license agreement focuses on the profits made from the product.⁹¹ Rather than having a market in which the researcher buys out the patient's interest in his or her body, the license option moves toward establishing a continuous partnership between the researcher and patient.

The license allows the researchers to use the patient's body and derive profit from it on the condition that a percentage above a statutorily determined minimum be returned to the donor. The exact figures would be determined by Congress,⁹² perhaps with the advice of the AMA. The drafters should consider what percentage of the profits would be high enough to encourage patients to agree to the terms while low enough to allow researchers to make profits sufficient to provide an incentive for biotechnological research. It should also provide a large enough return that researchers are not tempted to work around the license system by failing to seek a licensing agreement in the hope that the patient will remain unaware that his or her body cells could yield a profit. Additionally, the license should require researchers to get the patient's consent if they

90. Levine, *supra* note 18, at 7. Levine goes on to recommend that if the patient chooses to accept the product development, he or she would, at this point, be required to waive any right to a share in the profits.

91. For an insightful discussion of the societal interest in not pricing body parts, see G. Calabresi, *Tragic Choices* (1978).

92. One appropriate entity for examining these issues is the Biomedical Ethics Board, which consists of members of the House and Senate. The Board appoints an advisory committee to conduct studies and reports on "ethical issues arising from the delivery of health care and biomedical and behavioral research, including the protection of human subjects of such research and developments in genetic engineering . . ." 42 U.S.C.A. § 275 (Supp. 1987).

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wish to sell the product or patent to a third party and to assure the patient that they will sell it at fair market value with the patient receiving a set percentage of the sale price.⁹³ The AMA might also help to foster compliance by including in its ethical guidelines a requirement that doctors engaging in research using patients' body parts present the statutory licensing agreement to the patient at the appropriate time. Failure to propose a license would be punishable by fine and/or professional sanction, and the license itself would be enforceable in contract.

The licensing agreement proposed here resolves many of the issues raised by biogenetic research. The license ensures that the patient consent to the development of his or her cells into a saleable product. Requiring notice and consent protects the patient's right of privacy by protecting his or her right to determine what is done with the cells. This self-determination is necessary if biogenetic research is to comply with notions of human dignity. The license also accords with property law principles, as it is based on the idea that the patient remains the owner of the cell and only agrees to allow the scientists to use it while continuing to share in the resulting profits. The profit-sharing arrangement fairly compensates the contributor just as joint inventors are compensated in patent law.

A licensing arrangement is not perfect. Doctors still retain significant bargaining power over patients; the requirement that a doctor offer a license must be strictly enforced for patients to receive fair compensation.

Conclusion

A license agreement ensures both that the patient has consented to the use of his or her body in the development of a marketable product and that the patient has been compensated for his or her contribution. The above discussion shows that this kind of insurance ought to be required in the bioengineering field. The patient's consent is mandated by professional medical standards. Researchers must also receive a patient's consent in an effort to respect his or her right to privacy—a right that exists as a matter of common law, state statutes, and constitutional law. A patient's property interest in his or her body further strengthens the claim to maintain control over the disposition of that which is exclusively his or hers. When

93. Like other property rights, the license should be devisable. This is particularly appropriate where, as here, the property owners are generally in poor health.

any of these rights is violated, the patient must be justly compensated.

A system of compensation that is structured as a "joint venture," rather than as a retroactive payment following a violation, is more respectful of the patient as a participant in the development of the product that incorporates his or her body. It is this sense of respect that is at the heart of the patient's claim to a share of the profits. Both the consent and compensation requirements are, at their base, efforts to treat the patient as fully autonomous — as able to control what is done with his or her body and to partake in any financial benefits derived from it.

A standard profit-sharing arrangement strikes a balance between concern for the patient's dignity and autonomy and concern for the progress of biogenetic research. Such a balance should not be arrived at through litigation, but through a coherent policy that respects the values and rights of patients and recognizes the benefits of medical progress.