



Winter 1-1-2004

Ownership of Human Tissue: A Proposal for Federal Recognition of Human Research Participants' Property Rights in Their Biological Material

Donna M. Gitter

Follow this and additional works at: <https://scholarlycommons.law.wlu.edu/wlulr>



Part of the [Health Law and Policy Commons](#), and the [Science and Technology Law Commons](#)

Recommended Citation

Donna M. Gitter, *Ownership of Human Tissue: A Proposal for Federal Recognition of Human Research Participants' Property Rights in Their Biological Material*, 61 Wash. & Lee L. Rev. 257 (2011).

Available at: <https://scholarlycommons.law.wlu.edu/wlulr/vol61/iss1/5>

This Article is brought to you for free and open access by the Washington and Lee Law Review at Washington and Lee University School of Law Scholarly Commons. It has been accepted for inclusion in Washington and Lee Law Review by an authorized editor of Washington and Lee University School of Law Scholarly Commons. For more information, please contact christensena@wlu.edu.

Ownership of Human Tissue: A Proposal for Federal Recognition of Human Research Participants' Property Rights in Their Biological Material

Donna M. Gitter*

Table of Contents

I. Introduction	259
II. The Market-Inalienability Model	270
A. <i>Moore v. Regents of the University of California</i>	270
B. Analysis of the Policy Considerations Underlying the Market-Inalienability Model	278
1. According Research Participants Property Rights in Their Tissue Will Not Impede Investment in the Biotechnology Industry or the Advancement of Public Health.....	278
a. An Analysis of the Economic and Transaction Costs Involved in Compensating Research Participants and the Importance of Compensation in Terms of Stimulating Participation.....	281
b. The Issue of Shared Control over the Products of Biomedical Research.....	292
2. Considerations of Equity Militate in Favor of a	

* Assistant Professor of Legal and Ethical Studies, Fordham University Schools of Business; J.D., University of Pennsylvania Law School; B.A., Cornell University.

I am indebted to two individuals who so graciously shared with me their invaluable work authored in the course of their personal involvement in the case of *Greenberg v. Miami Children's Hospital Research Institute, Inc.* discussed herein: Professor Jon Merz of the Center for Bioethics, University of Pennsylvania School of Medicine, and Laurie A. Rosenow, Esq., Fellow at the Chicago-Kent College of Law Institute of Science, Law and Technology. I am also grateful for the able research assistance of Lisa Brubaker, Dorota Czapinska, Ulrike Tinnefeld, and Roland Wig, as well as the generous support provided by the Fordham University Schools of Business.

System That Compensates Research Participants for Their Involvement in Furthering Biomedicine.....	294
3. Recognition of Property Rights in Human Tissue Would Neither Commodify Human Beings nor Erode Notions of Community.....	298
4. The Doctrines of Informed Consent and Breach of Fiduciary Duty Prove Inadequate to Protect Research Participants' Interests in Dignity and Autonomy.....	304
5. Concerns About Scientists Luring Research Participants with Promises of False Profits and Participants Elevating Financial Concerns over Health Concerns Do Not Furnish Sufficient Reason to Deny Research Participants an Ownership Interest in Their Tissue	310
6. Recognition of Research Participants' Property Rights in Their Tissue Will Neither Erode Appreciably Notions of Community nor Discourage Altruism.....	313
III. The PXE Contractual Property Rights Model.....	315
A. Formation and Terms of the Contract Between PXE International and PXE Researchers.....	316
B. The Advantages of the PXE Contractual Property Rights Approach	319
C. The Drawbacks of the PXE Contractual Property Rights Approach	322
IV. <i>Greenberg v. Miami Children's Hospital Research Institute, Inc.</i>	325
A. The Scientific and Legal Background of the <i>Greenberg</i> Action	325
1. The Research Relating to Canavan Disease	325
2. The Patenting of the Gene Associated with Canavan Disease and the Licensing Process	326
3. The Legal Proceedings in <i>Greenberg v. Miami Children's Hospital Research Institute, Inc.</i>	331
B. Analysis of the <i>Greenberg</i> Decision.....	332
1. Lack of Informed Consent.....	333
2. Breach of Fiduciary Duty.....	335
3. Fraudulent Concealment	336
4. Conversion and Misappropriation of Trade	

Secrets	336
5. Unjust Enrichment	337
V. Proposal for Congressional Enactment of a Hybrid Property Rights/Liability Model Recognizing the Property Interest of Research Participants in Their Body Tissue	338
A. Parameters of the Property Rights/Liability Model	340
B. Advantages of a Property Rights/Liability Model	340
C. An Examination of Alternative Models	342
1. The Harrison Hybrid Donative/Liability Model	342
2. A Gene Trust	343
VI. Conclusion	344

I. Introduction

In the past, one would have expected families afflicted by a degenerative and fatal disease to rejoice at medical researchers' development of reliable carrier and prenatal screening to detect the genetic mutation causing the condition.¹ However, a recent legal action, initiated by families suffering from a rare genetic disorder known as Canavan disease² against the researchers who isolated the gene associated with this condition, illustrates the complexities inherent in the relationships among human research participants and medical

1. See Larry I. Palmer, *Disease Management and Liability in the Human Genome Era*, 47 VILL. L. REV. 1, 10–11 (2002) ("Although we might have expected researchers and disease-specific advocacy groups to be jubilant at the prospect of an effective screening device . . . we are now clearly in a period where the control of significant genetic data is a potential source of economic return.").

2. This neurological disorder, which results from a recessive genetic mutation, is characterized by degeneration of the myelin sheath, the protective insulation for the brain's nerve cells. Individuals born with Canavan disease suffer from a lack of motor coordination, poor vision, and death, usually before their teen years. There is no known cure for Canavan disease, which occurs with particular frequency among people of Eastern European Jewish, or Ashkenazi, descent. See R. Matalon et al., *Canavan Disease: From Spongy Degeneration to Molecular Analysis*, 127 J. PEDIATRICS 511, 511 (1995) (describing Canavan disease as a progressive disease that often leads to death in the first ten years of life and is especially prevalent among Jews of Eastern European descent); see also Matthew Hay Brown, *Hope in a New Treatment for a Fatal Genetic Flaw*, N.Y. TIMES, Oct. 29, 1995, § 13CN, at 1 (stating that Canavan disease is caused by a genetic mutation that prevents production of an enzyme needed to metabolize an acid in the brain that, left unmetabolized, is believed to destroy myelin, the insulation that allows nerves in the brain to function properly); Paul Smaglik, *Tissue Donors Use Their Influence in Deal over Gene Patent Terms*, 407 NATURE 821, 821 (2000) (noting that Canavan disease is a "neurological disorder characterized by the degeneration of the myelin sheath, the protective insulation for the brain's nerve cells").

researchers in our current era of genomic exploration and commercialization. In that case, *Greenberg v. Miami Children's Hospital Research Institute, Inc.*,³ the plaintiffs included a group of parents who gave birth to children afflicted with Canavan disease⁴ and also three nonprofit community groups dedicated to assisting those affected by this condition.⁵ All plaintiffs supplied some combination of tissue, autopsy, blood, urine, and other pathology samples, personal data, funding, and other resources in order to advance medical research of Canavan disease.⁶ The plaintiffs alleged that the defendants, a scientific researcher and a hospital,⁷ breached both their duty of informed consent and their fiduciary duty when they failed to disclose to the plaintiffs their intention to patent the gene and diagnostic test for Canavan disease.⁸ In addition, the plaintiffs asserted that the defendants wrongfully converted the plaintiffs' property by using the plaintiffs' contributions to reap personal economic benefit rather than to promote widely affordable and accessible carrier and prenatal testing for Canavan disease in accordance with the plaintiffs' goals.⁹ According to the plaintiffs, had they known of the defendants' intention to patent the gene associated with Canavan disease, they either would have imposed restrictions on the researchers' use of their genetic material in order to avoid commercialization of the Canavan disease gene or, instead, would have chosen to donate their samples to researchers who pursued objectives compatible with their own.¹⁰ Based upon these same facts, the plaintiffs also asserted claims of unjust enrichment,¹¹ fraudulent concealment,¹²

3. The *Greenberg* plaintiffs originally filed their complaint in the United States District Court for the Northern District of Illinois. Complaint, *Greenberg v. Miami Children's Hosp. Research Inst., Inc.*, 264 F. Supp. 2d 1064, 1068 (S.D. Fla. 2003) (No. 00-C-6779) [hereinafter *Greenberg* Complaint] (on file with the Washington and Lee Law Review). On July 8, 2002, Judge Robert W. Gettleman of that court dismissed the plaintiffs' complaint on the grounds that the court lacked personal jurisdiction and venue over all the defendants, and transferred the action to the United States District Court for the Southern District of Florida, where jurisdiction and venue would be proper. *Greenberg v. Miami Children's Hosp. Research Inst., Inc.*, 208 F. Supp. 2d 918, 928–29 (N.D. Ill. 2002).

4. *Greenberg* Complaint, *supra* note 3, ¶¶ 4–7.

5. *Id.* ¶¶ 8–10; *see also infra* note 288 (listing the various plaintiffs).

6. *Greenberg* Complaint, *supra* note 3, ¶¶ 15–21.

7. *Id.* ¶¶ 12–13.

8. *See id.* ¶¶ 33–45 (stating allegations that defendants breached their fiduciary duty and their duty of informed consent).

9. *See id.* ¶¶ 61–67 (stating allegations of conversion).

10. *Id.* ¶¶ 59–60.

11. *Id.* ¶¶ 46–54.

12. *Id.* ¶¶ 55–60.

and misappropriation of trade secrets.¹³ On May 29, 2003, Judge Federico A. Moreno of the United States District Court for the Southern District of Florida dismissed five of the plaintiffs' six claims pursuant to Federal Rule of Civil Procedure 12(b)(6) for failure to state a claim upon which relief may be granted. He did, however, hold that only the plaintiffs' unjust enrichment cause of action survived the motion.¹⁴

Among the myriad ethical and legal issues raised, but not resolved, by the *Greenberg* action is the optimal means of distribution among biomedical researchers and their research participants¹⁵ of any rights in commercial products and revenues derived from human tissue.¹⁶ In the case that has addressed this question most squarely, *Moore v. Regents of the University of California*,¹⁷ the Supreme Court of California held in 1990 that plaintiff John Moore, a patient undergoing treatment for cancer, did not possess property rights in the commercial products that his physician-researcher developed from

13. *Id.* ¶¶ 68–75.

14. See *Greenberg v. Miami Children's Hosp. Research Inst., Inc.*, 264 F. Supp. 2d 1064, 1077–78 (S.D. Fla. 2003) (dismissing plaintiffs' claims for lack of informed consent, breach of fiduciary duty, fraudulent concealment, conversion, and misappropriation of trade secrets, and denying motion to dismiss plaintiffs' unjust enrichment claim). The parties ultimately reached a confidential settlement agreement effective August 6, 2003. See Press Release, Canavan Foundation, Canavan in the News: Joint Press Release (describing the "highlights" of the confidential settlement agreement), at http://www.canavanfoundation.org/news/09-03_miami.php (Sept. 29, 2003) (on file with the Washington and Lee Law Review); see also *infra* Part IV (discussing the *Greenberg* action).

15. This Article expressly uses the terms "researcher," on the one hand, and "research participant" (or "participant"), on the other, rather than "physician" and "patient," when referring to the parties involved in scientific research. This terminology emphasizes the fact that the Article examines not only the relationships among physicians and the patients whom they are treating for illness or disease, but also focuses more broadly upon the interactions among scientific researchers and the individuals participating in their studies, even in the absence of any therapeutic relationship. Furthermore, this Article consciously avoids the term "research subject," except in verbatim quotes, in order to avoid objectification of the individuals who participate in biomedical research, whether out of entirely eleemosynary motives or to help diagnose and treat a condition affecting them personally, or even unwittingly.

16. Tissue has been defined as follows:

A collection of cells of similar structure organized to carry out one or more particular functions. For example, in animals nervous tissue is specialized to perceive and transmit stimuli. An organ, such as a lung or kidney, contains many different types of tissues.

OXFORD DICTIONARY OF BIOLOGY 592 (Elizabeth Martin & Robert S. Hine eds., 4th ed. 2000). This Article discusses human tissue that is used for biomedical research, as distinguished from: (1) tissue used for therapeutic purposes, such as blood collected for transfusion as well as skin, heart valves, and solid organs provided for transplantation; and (2) tissue used for nonmedical purposes such as manufacturing.

17. *Moore v. Regents of the Univ. of Cal.*, 793 P.2d 479 (Cal. 1990).

his excised tissue.¹⁸ The *Moore* majority based its holding in large measure on its belief that judicial extension of the conversion doctrine would hinder the growth of the fledgling biotechnology¹⁹ industry by making each cell sample "the potential subject matter of a lawsuit."²⁰ The *Moore* majority also found that the plaintiff's rights were protected adequately under the theories of breach of fiduciary duty and lack of informed consent, claims that the court decided in Mr. Moore's favor.²¹ Although *Moore* constitutes binding precedent only in California, this decision is extremely influential in shaping the public policy debate regarding research participants' property rights in their bodily tissue.²² Indeed, the Florida federal court that decided *Greenberg* cited *Moore* for the proposition that the law does not recognize a property interest in excised biological materials for the purposes of a conversion claim.²³

While the judicial precedent established by the *Moore* and *Greenberg* courts seems to suggest that research participants lack property rights in their tissue,²⁴ the experiences of another group of research participants provide striking evidence to the contrary. In 2001, PXE International, a patient group that represents the interests of individuals afflicted with pseudoxanthoma elasticum (PXE), a genetic disease that causes calcification of the connective tissue of the skin, eyes, and arteries,²⁵ successfully negotiated for a share in the patent rights obtained by researchers who identified and filed a patent

18. See *id.* at 497 (holding that Moore failed to state a claim for conversion); see also *infra* Part II.A (discussing in detail the *Moore* proceeding).

19. Biotechnology has been defined as including "any technique that uses living organisms (or parts of organisms) to make or modify products, to improve plants or animals, or to develop micro-organisms for specific uses—including . . . techniques such as gene cloning and cell fusion." UNITED STATES CONGRESS, OFFICE OF TECHNOLOGY ASSESSMENT, OTA-BA-337, NEW DEVELOPMENTS IN BIOTECHNOLOGY: OWNERSHIP OF HUMAN TISSUES AND CELLS—SPECIAL REPORT 24 (1987) [hereinafter OWNERSHIP OF HUMAN TISSUES AND CELLS].

20. *Moore*, 793 P.2d at 495.

21. See *id.* at 494, 497 (stating that liability "based upon existing disclosure obligations . . . protects patients' rights of privacy and autonomy without unnecessarily hindering research"); see also *infra* note 76 and accompanying text (noting that because various defendants in the *Moore* case were not doctors, they owed neither a fiduciary duty nor a duty of informed consent to Moore).

22. See *infra* note 43 and accompanying text (noting that since *Moore*, the medical community has tended to treat those who contribute tissue for research as donors).

23. *Greenberg v. Miami Children's Hosp. Research Inst., Inc.*, 264 F. Supp. 2d 1064, 1074 (S.D. Fla. 2003).

24. The *Greenberg* court did, however, hold that the plaintiffs' claim for unjust enrichment survived the defendants' motion to dismiss. *Id.* at 1072–73; see also *infra* text accompanying note 363 (noting that the plaintiffs did invest significant time and resources in the Canavan research, and deserved compensation for the valuable tissue they donated).

25. Smaglik, *supra* note 2, at 821.

application for the gene associated with the disorder.²⁶ These rights include royalties from any diagnostic test or marketable product resulting from the discovery of the gene, as well as the authority to control licensing of such genetic tests. PXE International negotiated for these rights in exchange for its contributions to the research effort, which included help in identifying and soliciting participation on the part of affected families, setting up a tissue repository, and raising money to support scientific investigation.²⁷ Like the plaintiffs in *Greenberg*, PXE International sought to ensure broad and affordable availability of the test for their disease, as well as any downstream developments.²⁸ Unlike the *Greenberg* plaintiffs, however, PXE International negotiated directly with the scientists to whom they gave research support and materials in exchange for these rights.

Presently, because neither the members of PXE International nor the researchers who identified the gene associated with PXE disease have raised a legal challenge to their agreement, no court has considered the enforceability of this contract. However, the very existence of their agreement invites consideration of how a court would rule if the researchers were to bring a suit alleging that their contract with PXE International is void as against public policy on the grounds that research participants cannot possess property rights in their tissue pursuant to *Moore*. Certainly, it would be surprising if the court were to strike this agreement, which was the product of free and full negotiation among the parties.²⁹ Adherence to a market-

26. *Id.*

27. See Matt Fleischer, *Patent Thyself*, AM. LAW., June 2001, at 84, 86, 98 (stating that Sharon Terry, founder of PXE International, marshaled patients' medical information and gathered blood samples, recruited scientists, and reported the latest developments to scientists); see also Smaglik, *supra* note 2, at 821 ("Researchers wanting to use the samples must agree to the group's terms, which include joint possession of any intellectual property that might result."); Gina Kolata, *Sharing of Profits Is Debated as the Value of Tissue Rises*, N.Y. TIMES, May 15, 2000, at A1 ("Ms. Terry and her husband found 2,000 people with the disease, set up a repository to store tissue samples, and began raising money for research.").

28. See Smaglik, *supra* note 2 (stating that PXE International advocates either free licensing, or, if the researchers insist, a modest fee). PXE International has indicated that it will resist profiteering from its intellectual property should the PXE gene become significant to other researchers, while conceding that any licensing deal would of course have to further the goals of PXE International's members. See Fleischer, *supra* note 27, at 100 (noting that Sharon Terry and her group have said that they will resist patient profiteering, but will seek to enter into deals that maximize PXE patients' access to diagnostic testing and treatment). See *infra* notes 273–75 and accompanying text for a discussion of the potential conflicts of interests arising from control of gene patents by patient groups.

29. It should be noted that this Article's consideration of a potential lawsuit relating to the agreement between PXE International and researchers who identified the gene associated with this disease is entirely hypothetical, and no such case is pending. If, however, such an action were to arise, some support for the enforceability of the agreement might be found in various

inalienability model,³⁰ which posits that human research participants do not possess property rights in their tissue, invites increased scrutiny in an era marked by dramatic commercial gains from biomedicine.

legal decisions upholding contracts governing the disposition of human pre-embryos. See *infra* note 80 for a description of several of these cases. Because courts have honored contracts that control the disposition of pre-embryos, which possess the potential for new human life, one would expect that courts likewise would uphold contracts for the disposition of nonreproductive human cells.

In response to a theoretical argument by the researchers that their agreement with PXE International is void as against public policy, PXE International could argue that the consideration it gave in exchange for patent rights was not a good, meaning the body tissue itself, but rather a service, namely help in locating and contacting tissue donors. Such a contention would seem disingenuous, however, in that the service has no value unaccompanied by the body tissue. Moreover, PXE International does not hold itself out as a tissue broker. See PXE INTERNATIONAL, MISSION STATEMENT ("PXE International, Inc. seeks to further an understanding of pseudoxanthoma elasticum by providing support and education for affected individuals, their families and their physicians. We support and fund medical research."), at http://www.pxe.org/news/1_3.html#doc_begin (Winter 1996) (on file with the Washington and Lee Law Review). As Professor Mahoney has noted in the context of transplantable human organs, although the federal National Organ Transplant Act, see 42 U.S.C. §§ 273–74(g) (2000) (codifying the National Organ Transplant Act), and many state statutes prohibit their sale, transplantable organs essentially become marketable goods once they are sold to patients as part of a package of medical services. See Julia D. Mahoney, *The Market for Human Tissue*, 86 VA. L. REV. 163, 182 (2000) ("One can argue that the organ is not sold, and that patients pay only for medical services, but in fact the services have no value without the organ, and patients have no opportunity to acquire organs in a separate transaction.").

Another potential means of recovery open to PXE International would be a claim for fraudulent misrepresentation. The success of such a claim would depend upon the plaintiff's ability to prove that the researchers entered into the contract with the intention of later initiating legal proceedings to void the agreement.

30. Professor Radin has observed that "[s]ometimes inalienable means nontransferable; sometimes only nonsalable." Margaret Jane Radin, *Market-Inalienability*, 100 HARV. L. REV. 1849, 1849–50 (1987) (footnotes omitted). She coined the term "market-inalienable" to describe a situation in which entitlements may be given away but not sold. *Id.* at 1853 ("In precluding sales but not gifts, market-inalienability places some things outside the marketplace but not outside the realm of social intercourse.").

The *Moore* court clearly accepts the premise that an individual can donate, as opposed to sell, his tissue to researchers. See *Moore v. Regents of the Univ. of Cal.*, 793 P.2d 479, 489 n.20 (Cal. 1990) (citing a California statute that specifies the acceptable methods of disposal of human tissue used for experimentation); see also *id.* at 492 n.34 (citing a California statute that permits all scientific use of human tissue, whether commercial or noncommercial); *id.* at 494–95 (noting that biomedical researchers, including those engaged in commercial exploitation, depend upon cell lines derived from human tissue samples).

It should be further noted that, strictly speaking, the *Moore* court did not reject entirely the notion of property rights in human tissue. The majority emphasized that it did not "purport to hold that excised cells can never be property for any purpose whatsoever." *Id.* at 493. In addition, although Justice Arabian expressed in his concurring opinion profound moral reservations regarding recognition of property rights in human tissue, especially if achieved by judicial fiat, he also suggested that the legislature was the "proper deliberative forum" to create a

A comparison of the *Moore* case, which denied the plaintiff a share in the profits resulting from the commercialization of his bodily tissue, and the PXE agreement, which suggests that research participants are permitted to negotiate for such rights, reveals a fundamental inconsistency. Of course, one key distinction between the *Moore* case and the PXE example is that plaintiff John Moore did not bargain for any ownership interest, while PXE International did negotiate expressly for property rights in order to protect the interests of its members. This distinction fails to justify the disparate treatment accorded to the research participants in these examples, however, when one considers that Mr. Moore's physician engaged in deception by denying his intention to conduct research upon Mr. Moore's tissue.³¹ Certainly, if the courts do

"licensing scheme" that would establish "a fixed rate of profit sharing between researcher and subject." *Id.* at 498 (Arabian, J., concurring). More precisely, the *Moore* court declined to extend the tort of conversion, a strict liability tort, to apply to human tissue used in research. *See infra* notes 77–78 and accompanying text (noting that the *Moore* court declined to extend conversion liability and declared that the legislature is better adapted to determine whether such liability should be extended). Nonetheless, the *Moore* majority opinion did articulate many policy arguments against recognizing a research participant's claim to an ownership interest in his tissue.

Subsequent courts have interpreted *Moore* to preclude a property interest in the right to profit from human tissue, even absent any patient involvement. *See, e.g., Miles, Inc. v. Scripps Clinic & Research Found.*, 810 F. Supp. 1091, 1096–98 (S.D. Cal. 1993) (citing *Moore* in dismissing the conversion action brought by the plaintiff, a pharmaceutical company, against the defendant, a nonprofit research foundation, with respect to the right to commercialize a cell line). *But see United States v. Arora*, 860 F. Supp. 1091, 1099–1101 (D. Md. 1994) (holding that a researcher's intentional destruction of a rival scientist's cell line, which was part of a valuable research project, was a conversion, and awarding both compensatory and punitive damages), *aff'd*, 56 F.3d 62 (4th Cir. 1995). Of course, both *Miles* and *Arora* are distinguishable from *Moore* and *Greenberg* in that they involve property rights in already-developed cell lines, as opposed to the original human biological materials obtained from the research participant.

31. *See Moore v. Regents of the Univ. of Cal.*, 793 P.2d 479, 486 (Cal. 1990) (holding that plaintiff properly alleged that his physician concealed an economic interest in his tissue). While the *Moore* majority seemed to assert that plaintiff had somehow "abandoned" his property interest in his tissue, the court's holding that plaintiff's physician breached the duty of informed consent effectively undermined this argument. *See id.* at 488–89 (stating that "Moore clearly did not expect to retain possession of his cells following their removal"); Laura Ivey, Comment, *Moore v. Regents of the University of California: Insufficient Protection of Patients' Rights in the Biotechnological Market*, 25 GA. L. REV. 489, 518 (1991) ("The court therefore argued inconsistently with its own informed-consent holding when it asserted that Moore could have surrendered possessory rights to his cells while being deceived about why he was surrendering them."); Jeffrey A. Potts, Note, *Moore v. Regents of the University of California: Expanded Disclosure, Limited Property Rights*, 86 NW. U. L. REV. 453, 486 n.210 (1992) ("[A] patient could hardly abandon something to which the patient did not have the opportunity to consent.")

Perhaps the *Moore* court meant rather to express its belief that plaintiff John Moore was not entitled to a share in the *profitable products developed from* his tissue because his corporeal contribution did not aid significantly in their creation, an idea to which the court alluded in

recognize the right of savvy research participants such as the members of PXE International to negotiate for property rights in the commercial products developed from their tissue, it is not only illogical, but also unjust, to deny any property rights whatsoever to the *Moore* and *Greenberg* plaintiffs, from whom researchers withheld critical information about their designs to commercialize their scientific findings.³²

In light of the *Moore* majority's rejection of the plaintiff's conversion claim, other courts likely will hold, in the absence of any contractual provisions to the contrary, that research participants possess no property rights in their body tissue. Clearly, any broad judicial recognition of property rights in human tissue used for research would raise many vexing ethical and policy questions upon which courts generally prefer to defer to the legislature.³³ Thus far,

stating that "Moore does not seek possession of his cells or claim the right to possess them," *Moore*, 793 P.2d at 489 n.20, thereby implicitly suggesting that Mr. Moore himself could not have created value from his own tissue. This notion is separate, however, from an abandonment argument. Moreover, the question is not whether Mr. Moore could himself create a marketable product from his own tissue, but rather whether he could profit by selling it to the highest bidder. See *id.* at 501 (Broussard, J., dissenting in part) (disagreeing with majority's view that a conversion did not take place). In his separate opinion, Justice Broussard stated:

The majority opinion fails to recognize, however, that, in light of the allegations of the present complaint, the pertinent inquiry is not whether a patient generally retains an ownership interest in a body part after its removal from his body, but rather whether a patient has a right to determine, before a body part is removed, the use to which the part will be put after removal.

Id.

By denying Mr. Moore's claim for a share of the profits deriving from the commercial products developed from his tissue, the majority incorrectly assumed that an individual whose tissue is valuable for research would be able only to reject experimentation on his tissue, and would never be able to bargain for consideration in exchange for his tissue. *Id.* at 492-93. The PXE example definitively disproves this assumption.

32. See *id.* at 486 (holding that plaintiff established causes of action for breach of fiduciary duty and lack of informed consent when his physician-researcher concealed his economic interest in plaintiff's bodily tissue); see also *Greenberg v. Miami Children's Hosp. Research Inst., Inc.*, 264 F. Supp. 2d 1064, 1068-72 (S.D. Fla. 2003) (accepting as true plaintiffs' allegations that defendants did not reveal their intent to commercialize their research findings based upon plaintiffs' tissue, though declining to hold this behavior actionable under the theories of lack of informed consent or breach of fiduciary duty).

33. See *Moore*, 793 P.2d at 488 (declining to "'impose [new tort duties] when to do so would involve complex policy decisions,' especially when such decisions are more appropriately the subject of legislative deliberation and resolution"). As noted by Professors Litman and Robertson:

The notion that legislative solutions are preferable to judicial ones is a theme often articulated in cases involving novel questions of property. This is so for reasons of principle and, as well, for practical reasons that go to the disparate abilities of courts and legislatures to resolve complex problems. With regard to principle, the view has often been expressed that it is more appropriate for an institution with a

however, the United States Congress has declined to address this policy debate.³⁴

democratic mandate to resolve fundamental questions of policy. Similarly, there is widespread recognition and acceptance that legislatures are far better equipped to properly resolve complex problems.

Moe Litman & Gerald Robertson, *The Common Law Status of Genetic Material*, in *LEGAL RIGHTS AND HUMAN GENETIC MATERIAL* 51, 76 (Bartha Maria Knoppers et al. eds., 1996) (footnotes omitted).

The judicial disinclination to create judge-made law in the area of human genetics and patent law in particular is evidenced in the order issued by Judge Marilyn Patel, Chief Judge of the Federal District Court for the Northern District of California, who presided over a mock trial held at the California Institute of Technology in November 2001 involving a hypothetical patent infringement action brought by a fictional biotech company against a fictional individual whose genome they patented. See Memorandum and Order, *Nugenera, Inc. v. Salvador Dolly* (No. 019999) (declining to recognize property rights in genetic material without clear legislative action to do so), available at <http://techlaw.ils.edu/events/atc2001/order.pdf>, at 24–29 (2001). For more documents relating to this fascinating mock trial, see CAL. INST. OF TECH., PROG. FOR LAW & TECH., AT THE CROSSROADS OF LAW AND TECHNOLOGY, THIRD ANNUAL CONFERENCE, LAW, TECHNOLOGY & THE HUMAN GENOME, at <http://techlaw.ils.edu/events/atc2001/mock1.html> (2001) (on file with the Washington and Lee Law Review).

34. One commentator noted recently that "[f]ederal laws do not generally forbid the payment of valuable consideration in the acquisition of human research materials," and "[i]n much, if not most of the United States, non-payment for research materials is a norm rather than a mandate." Charlotte H. Harrison, *Neither Moore nor the Market: Alternative Models for Compensating Contributors of Human Tissue*, 28 AM. J.L. & MED. 77, 80 (2002). For example, although Congress prohibits the sale of solid organs for transplant, it does not bar the sale of organs for research use. See National Organ Transplant Act (NOTA), 42 U.S.C. § 274e(a) (2000) (making it unlawful to acquire or transfer any human organ for valuable consideration for the purpose of human transplantation); Radhika Rao, *Property, Privacy, and the Human Body*, 80 B.U.L. REV. 359, 376 (2000) (stating that NOTA "seems to permit" the sale of organs for purposes such as "research or education"). Nor does federal law bar the sale of blood for either transfusion or research. Robert Heidt, *Maintaining Incentives for Bioprospecting: The Occasional Need for a Right to Lie*, 13 BERKELEY TECH. L.J. 667, 673 n.19 (1998) (observing that NOTA may forbid only sales for transplantation, rather than for research purposes); see Mahoney, *supra* note 29, at 171 ("[F]rom about 1917 to the 1970s, a significant percentage of the United States' blood supply was derived from paid human donors.").

While some states have enacted legislation absolutely forbidding commerce in human organs and tissue, including for scientific use, these states generally exempt regenerative human tissue, ostensibly because its removal will not harm appreciably its contributor. See, e.g., MD. HEALTH-GEN. CODE ANN. § 5-408 (Michie 2000) (stating that "[a] person . . . may not sell, buy, or act as a broker for a profit in the transfer of any human organ that[] [i]s removed from a human body that is alive or dead at the time of removal," but excepting from this provision blood and plasma); MICH. COMP. LAWS ANN. § 333.10204 (West 2001) (providing that "a person shall not knowingly acquire, receive, or otherwise transfer a human organ or part of a human organ for valuable consideration for any purpose, including but not limited to transplantation, implantation, infusion, injection, or other medical or scientific purpose," but excepting from this provision "whole blood, blood plasma, blood products, blood derivatives, other self-replicating body fluids, or human hair"); VA. CODE ANN. § 32.1-289.1 (Michie 2001) (barring the sale of "any natural body part for any reason including, but not limited to, medical

This Article proposes that Congress enact legislation permitting and regulating the sale of human tissue used for research purposes,³⁵ and establish a tort of conversion in the event that a scientific researcher wrongfully exercises dominion over a research participant's tissue. Uniform national legislation is essential because scientists typically obtain the tissue upon which they experiment from research participants, tissue banks, and repositories throughout the United States, and from other nations as well.³⁶

In advocating for congressionally mandated recognition of property rights in human tissue used for genetic research, this Article begins in Part II with a critique of the market-inalienability approach. Although the *Moore* court did not advocate strictly for this model,³⁷ the majority decision nonetheless did

and scientific uses such as transplantation, implantation, infusion, or injection," but excepting from this prohibition "hair, ova, blood, and other self-replicating body fluids").

35. This Article treats the sale of human tissue only in the context of scientific experimentation, not the sale of tissue for therapeutic purposes, including transplantation. See *supra* note 16 (describing many different uses of tissue and noting that this Article specifically discusses human tissue that is used for biomedical research). Moreover, the legislative scheme proposed here would apply only to tissue that must be removed from the research participant for medical treatment purposes or the removal of which would not have a permanent deleterious effect upon the participant, as opposed to organs necessary for human health. See Mary Taylor Danforth, *Cells, Sales, and Royalties: The Patient's Right to a Portion of the Profits*, 6 YALE L. & POL'Y REV. 179, 195 (1988) (explaining that "[o]utlawing 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," and noting that "[t]he same justification, however, does not apply to regenerative body fluids" such as "blood, plasma, and semen," because their removal does not threaten significantly the health of the research participant). The topic of the sale of organs and tissue for transplant or other therapeutic purposes is beyond the scope of this Article.

36. In the case of Canavan disease research, for example, scientists relied upon samples provided by over one hundred families from around the world as well as about six thousand stored blood samples furnished by a nonprofit organization. Jon F. Merz, *Discoveries: Are There Limits on What May Be Patented?*, in WHO OWNS LIFE? 99, 102-03 (David Magnus et al. eds., 2002) ("The research drew on tissue samples provided to Matalon by the Greenbergs and over 100 other families from around the world who had been stricken by the disease, as well as blood samples provided by Rabbi Josef Eckstein, Executive Director of Dor Yeshorim Committee for the Prevention of Jewish Genetic Diseases."); see also Bartha Maria Knoppers et al., *Commercialization of Genetic Research and Public Policy*, 286 SCI. 2277, 2278 (1999) (stating that human genetic research and pharmacogenomics are increasingly international in scope).

Congress's authority to regulate the interstate and international transfer of human tissue derives from the Commerce Clause of the United States Constitution. U.S. CONST. art. I, § 8, cl. 3. Congress exercised this power in enacting NOTA. 42 U.S.C. § 274e(a) (2000) ("It shall be 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."). An analysis of the limitations on Congress's power to regulate interstate commerce is beyond the scope of this Article.

37. See *supra* note 30 and accompanying text (explaining that the *Moore* court did not reject entirely the notion of property rights in human tissue).

present the primary policy arguments advanced in support of the normative view that human research participants lack property rights in their tissue. Part II thus begins with a discussion of the facts of the *Moore* case before proceeding to a detailed analysis of the shortcomings of the market-inalienability model. This part also refutes the *Moore* majority's assertion that the doctrines of fiduciary duty and lack of informed consent are sufficient to protect individuals' rights to control the research use of their tissue.

Part III then considers the property model,³⁸ as demonstrated by PXE International, a patient advocacy group that negotiated successfully with scientists for a share in the commercial products developed from its group members' tissue. This Part analyzes both the advantages and drawbacks of this approach to apportioning the profits of biotechnological innovation among scientists and research participants.

Notwithstanding the merits of the property model, it is clear that reliance on a property model alone proves insufficient, in light of the fact that many research participants do not negotiate for property rights in their tissue because they lack (and, indeed, have often been denied by the researchers) significant information, both in terms of the tissue removed from their bodies and the potential value of that material. Part IV examines one such instance, the pending *Greenberg* proceeding, which is the latest legal action to raise the issue of research participants' rights in commercial products developed from their genetic material.

Part V then proposes a hybrid model, which invokes both a property rule and, when necessary, a liability rule³⁹ in the form of an action for conversion. Such an approach is essential because recourse to the property rights model becomes impossible once tissue has been taken and developed into a commercial product.⁴⁰ It is simply inconsistent to recognize research

38. In their classic work, Professor Calabresi and Mr. Melamed categorized the legal rules protecting entitlements as either property rules, liability rules, or rules of inalienability. Property rules provide that no one can "take the entitlement to private property from the holder unless the holder sells it willingly and at the price at which he subjectively values it"; liability rules establish "an external, objective standard of value used to facilitate the transfer of the entitlement"; and inalienability rules prevent the sale of the property altogether. Guido Calabresi & A. Douglas Melamed, *Property Rules, Liability Rules, and Inalienability: One View of the Cathedral*, 85 HARV. L. REV. 1105-06 (1972).

39. *Id.*

40. See Richard A. Epstein, *Symposium: Property Rules, Liability Rules, and Inalienability: A Twenty-Five Year Retrospective: A Clear View of the Cathedral: The Dominance of Property Rules*, 106 YALE L.J. 2091, 2100 (1997) (explaining the need for a liability rule where "restoration to the original owner is not possible," thereby necessitating invocation of the liability rule "by default"). Moreover, a willing research participant frequently neither rues the fact that commercial products were developed from the tissue nor desires return

participants' property rights in their tissue only so long as those rights have been negotiated in advance, but then to deny recovery under a liability rule to other research participants who were denied full information regarding the commercialization of their tissue.

Part V considers some alternative approaches, including a hybrid model combining the donative and liability regimes, as proposed by one commentator. In her article, Charlotte Harrison advocates a ban on private sales of tissue from the original source and instead calls for a statutorily established tribunal or administrative agency to compensate tissue contributors after the fact according to statutory criteria.⁴¹ This model proves inadequate, however, because it denies research participants the opportunity to bargain autonomously, and also threatens to strip power from patient advocacy groups such as PXE International that have been so effective in advancing the rights of their members. Part V also briefly examines the creation of a federal tissue trust, concluding that the implementation of such a system is unlikely, as a practical matter.

II. The Market-Inalienability Model

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

The normative view that research participants possess no property rights in their tissue or the commercial products developed therefrom finds its underpinnings in the 1990 California Supreme Court decision *Moore v. Regents of the University of California*.⁴² Pursuant to the *Moore* market-inalienability model, researchers generally treat their research participants as donors unentitled to any remuneration for their tissue and other bodily material.⁴³ Moreover, as stated by Professor Mahoney, "[a] substantial amount of the tissue used in biotechnology research is extracted in the course of medical treatment" from an individual "who is often—at least at the time of the

of the tissue, but simply wishes for a share in the profits.

41. Harrison, *supra* note 34, at 96–97.

42. See *Moore v. Regents of the Univ. of Cal.*, 793 P.2d 479, 497 (Cal. 1990) (denying Moore's cause of action for conversion).

43. See Harrison, *supra* note 34, at 77–78 ("Since the *Moore* decision, commentators and the medical community have wrestled with the appropriate treatment of tissue sources, whose contributions still tend to be handled as gifts."); see also Mahoney, *supra* note 29, at 191 ("Sources of human cells intended for genetic research are encouraged to make their tissue available without charge to organizations that intend to exercise proprietary rights over the assembled information.").

extraction—unaware that her medical waste carries any potential economic returns."⁴⁴

Plaintiff John Moore was among those individuals from whom scientists harvested tissue for research use without first obtaining informed consent. Mr. Moore first sought treatment at the Medical Center at the University of California at Los Angeles (UCLA Medical Center) in October 1976, shortly after learning that he had hairy-cell leukemia.⁴⁵ Mr. Moore's attending physician, Dr. David W. Golde,⁴⁶ confirmed Mr. Moore's diagnosis and recommended removal of his spleen for therapeutic purposes.⁴⁷ Surgeons at UCLA Medical Center performed the splenectomy in October 1976.⁴⁸

Unbeknownst to Mr. Moore, before his operation, Dr. Golde, his attending physician, and Shirley Quan, a UCLA researcher,⁴⁹ arranged for further scientific study of the spleen tissue removed from Mr. Moore's body.⁵⁰ This tissue particularly interested researchers because its tendency to overproduce certain proteins, called lymphokines, rendered it especially useful in locating the gene responsible for creating those proteins. Some lymphokines possess therapeutic value, and knowledge of the genetic material associated with their production in the body could enable researchers to manufacture large quantities of lymphokines through recombinant DNA techniques.⁵¹ This research had no relation to Mr. Moore's medical care, and neither Dr. Golde nor Ms. Quan ever

44. See Mahoney, *supra* note 29, at 189–90 & n.108 (citing the *Moore* case as well as the exploitation of Henrietta Lacks). In 1951, after Ms. Lacks, a thirty-one-year-old African-American woman of limited financial resources, died of ovarian cancer, researchers took her tissue without the knowledge or consent of her family and "made it into a cell line that is still being sold today." LORI ANDREWS & DOROTHY NELKIN, *BODY BAZAAR: THE MARKET FOR HUMAN TISSUE IN THE BIOTECHNOLOGY AGE* 33 (2001); see also Harrison, *supra* note 34, at 79 ("More often than not, consent forms given to hospital admittees—the primary source of existing tissue samples—have not disclosed the possibility of commercial use for tissue that is initially removed for diagnostic or therapeutic purposes.").

45. *Moore*, 793 P.2d at 481.

46. Dr. Golde was the head of the Hematology-Oncology Department of the UCLA Medical Center when he treated Mr. Moore. Anne T. Corrigan, Note, *A Paper Tiger: Lawsuits Against Doctors for Non-Disclosure of Economic Interests in Patients' Cells, Tissue and Organs*, 42 CASE W. RES. L. REV. 565, 568 n.12 (1992).

47. *Moore*, 793 P.2d at 481.

48. *Id.* The *Moore* majority noted that plaintiff John Moore had signed a written consent form authorizing the procedure, *id.*, which did indeed serve a therapeutic purpose, as "Moore had a grossly enlarged spleen and . . . its excision improved his condition." *Id.* at 486 n.11.

49. *Id.* at 481.

50. See *id.* ("Before the operation, Golde and Quan 'formed the intent and made arrangements' . . . to take [Moore's samples] to a separate research unit.").

51. *Id.* at 481 n.2. Recombinant DNA is "composed of genetic material from more than one individual or species." *Id.* at 490 n.29.

informed Moore of their research plans for this tissue or requested his consent.⁵²

Dr. Golde and Ms. Quan continued their research on Mr. Moore for several years, causing him great inconvenience and expense. Mr. Moore returned to the UCLA Medical Center from his home in Seattle approximately twelve times between 1976 and 1983 at the direction of Dr. Golde, who misled Mr. Moore by misrepresenting to him that such visits were in the interest of his health.⁵³ During these visits, Dr. Golde drew additional samples of blood, blood serum, skin, bone marrow aspirate, and sperm.⁵⁴ Not until 1983, about seven years after the initial surgery and after they had already filed a patent application,⁵⁵ did the researchers inform Mr. Moore that they were engaged in medical experimentation,⁵⁶ and even then the defendants assured him that this research was purely scientific rather than commercial. Mr. Moore further asserted that, despite his express inquiries about the potential financial benefits flowing from their research, defendants repeatedly denied that his biological materials possessed any commercial value.⁵⁷

52. *See id.* at 481 (stating that Moore alleged that the research activities had no relation to his medical care, and that neither Golde nor Quan informed him of their plans to conduct the research nor requested his permission).

53. *See id.* at 485 (alleging that Golde represented that the withdrawals of blood and tissue were essential for Moore's continued medical care); *see also id.* at 513 n.14 (Mosk, J., dissenting) (alleging that Moore was told blood could only be extracted at UCLA, and that such extractions were for the purpose of promoting his health); *The Use of Human Biological Materials in the Development of Biomedical Products: Hearing Before the Subcomm. on Investigations and Oversight of the House Comm. on Science and Technology*, 99th Cong. 241, 241-42 (1985) [hereinafter *House Hearing*] (statement of John Moore) (stating that Moore had returned to the medical center approximately twelve times after his splenectomy).

54. *Moore v. Regents of the Univ. of Cal.*, 793 P.2d 479, 481 (Cal. 1990).

55. *See infra* notes 60-61 and accompanying text (noting that the patent was applied for on January 30, 1981).

56. Mr. Moore stated that the defendants presented him with consent forms during his last two visits with Dr. Golde, on April 11, 1983 and September 20, 1983. *Moore v. Regents of the Univ. of Cal.*, 249 Cal. Rptr. 494, 500-01 (Cal. Ct. App. 1988), *aff'd in part and rev'd in part*, 793 P.2d 479 (Cal. 1990); *see also id.* at 536 n.5 (George, J., dissenting) (stating that Moore's complaint conceded that he signed the consent forms, one in April 1983 and another in September 1983); *House Hearing*, *supra* note 53, at 241-42 (testifying as to the dates that Moore was presented with the consent forms).

57. *See Moore*, 793 P.2d at 485-86 (stating that defendants "repeatedly and affirmatively represented to [Moore] that there was no commercial or financial value to his Blood and Bodily Substances"). Indeed, on the second research consent form presented to him in 1983, the plaintiff expressly declined to relinquish all rights in his cell line or any potential products developed from his tissue or blood. *See Moore*, 249 Cal. Rptr. at 501 (stating that Moore was given a second consent form in September 1983); *supra* note 56 (same); *see also Moore*, 249 Cal. Rptr. at 536 n.5 (George, J., dissenting) (noting that when Moore signed the September consent form, he circled the words "'do not,' preceding a provision relinquishing his 'rights . . .

Notwithstanding their disavowals of any financial interests in Mr. Moore's tissue, Dr. Golde had succeeded, sometime before August 1979, in developing a cell line from it.⁵⁸ On January 30, 1981, the Regents of the University of California (Regents)⁵⁹ applied for a patent on the cell line, and the patent issued on March 20, 1984, naming Dr. Golde and Ms. Quan as the inventors of the cell line and the Regents as the assignee of the patent.⁶⁰ The patent also covered various methods for using the cell line to produce lymphokines.⁶¹ With the Regents' assistance, Dr. Golde negotiated license agreements for commercial development of the cell line and corresponding products with two pharmaceutical firms, Genetics Institute, Inc. and Sandoz Pharmaceuticals Corporation (Sandoz).⁶²

John Moore learned of the patent on the so-called Mo cell line⁶³ only because he had become suspicious of his doctor's insistence upon conducting so many tests after the curative splenectomy, and also of the doctor's refusal to have a doctor in Seattle perform the supposedly necessary tests. An attorney hired by Mr. Moore, Jonathan Zackey, located online a scholarly scientific article in which the coauthors, including Dr. Golde, described their research upon the tissue of an

in any cell line . . . "); *House Hearing*, *supra* note 53, at 242-43 (testifying that Moore refused to circle "I do" on a consent form, which would have relinquished the rights to his cell line).

58. See *Moore*, 793 P.2d at 481 ("Sometime before August 1979, Golde established a cell line from Moore's T-lymphocytes."). Scientists can use human cells to develop a cell line, which is a culture capable of reproducing indefinitely. In contrast, cells taken directly from the human body, known as primary cells, typically reproduce a few times and then die. Thus, cell lines are better suited for research purposes than primary cells. *Id.* at 481 n.2; see *Moore*, 249 Cal. Rptr. at 498 n.3 (briefly describing the genetic engineering techniques used by the *Moore* defendants to create the cell line).

59. The Regents of the University of California is the legal entity that operates UCLA. *Moore*, 249 Cal. Rptr. at 498 n.2.

60. See *Moore v. Regents of the Univ. of Cal.*, 793 P.2d 479, 482 (Cal. 1990) (citing U.S. Patent No. 4,438,032). UCLA policy provided that the Regents, Dr. Golde and Ms. Quan would share in any royalties or profits. *Id.*

61. *Id.*

62. See *id.* (stating that the Genetics Institute was given "exclusive access to materials and research performed," and that Sandoz was later added to the agreement). According to Mr. Moore's complaint, pursuant to these contracts, the Genetics Institute gave Dr. Golde 75,000 shares of stock at a nominal price and also paid Dr. Golde and the Regents \$330,000 over three years, while Sandoz paid Dr. Golde and the Regents another \$110,000. *Id.*

63. The cell line was "named Mo after its unwitting progenitor." *Ivey*, *supra* note 31, at 492 n.27 (citation omitted). The defendants later renamed the cell line "to avoid detection by plaintiff." *Moore v. Regents of the Univ. of Cal.*, 249 Cal. Rptr. 494, 500 (Cal. Ct. App. 1988).

unnamed "37-year-old white male from Seattle, Washington,"⁶⁴ who proved to be John Moore.⁶⁵

In September 1984, Mr. Moore initiated a lawsuit against Dr. Golde, Ms. Quan, the Regents of the University of California, Genetics Institute, and Sandoz, alleging, among other things, conversion,⁶⁶ lack of informed consent, and breach of fiduciary duty.⁶⁷ For his conversion claim, plaintiff's theory of recovery was that the tissue removed from his body was his tangible personal property, at least in the sense that he was entitled to direct its use, and that he never consented to its use in commercial research.⁶⁸ According to this theory, the unauthorized use of his cells constituted conversion, and Mr. Moore therefore claimed a proprietary interest in each of the products that the defendants developed from his cells or the patented cell line.⁶⁹ In his complaint, Mr. Moore sought a share in the proceeds of the products from that cell line, which he estimated at over \$3 billion by 1990.⁷⁰ Even today, the American Type Culture Collection (ATCC)⁷¹ continues to sell Mr. Moore's cells.⁷²

In its five-to-two majority opinion in *Moore*, the Supreme Court of California declined to acknowledge a claim for conversion of Mr. Moore's property under California law.⁷³ In deciding this issue of first impression, the court took the

64. See V.S. Kalyanaraman et al., *A New Subtype of Human T-Cell Leukemia Virus (HTLV-II) Associated with a T-Cell Variant of Hairy Cell Leukemia*, 218 SCIENCE 571, 572 (1982).

65. See ANDREWS & NELKIN, *supra* note 44, at 27–28 ("The co-authors, who included Golde, described a thirty-seven-year-old white male from Seattle whose blood contained unusual and valuable viral anti-bodies. Golde created a special cell-line from Moore's blood, patented it, and named it the Mo-cell line.").

66. The California Supreme Court defined conversion as "interference with possessory and ownership interests in personal property." *Moore v. Regents of the Univ. of Cal.*, 793 P.2d 479, 487 (Cal. 1990).

67. See *Moore v. Regents of the Univ. of Cal.*, 249 Cal. Rptr. 494, 498–99 (Cal. Ct. App. 1988) (alleging causes of action for conversion, lack of informed consent, breach of fiduciary duty, fraud and deceit, and unjust enrichment, among others).

68. *Id.* at 501.

69. *Moore*, 793 P.2d at 487.

70. See *id.* at 482 (alleging a potential market of approximately \$3.01 billion by the year 1990 for a wide range of lymphokines).

71. ATCC describes itself on its web site as "a global nonprofit bioresource center that provides biological products, technical services, and educational programs to private industry, government, and academic organizations around the world." AMERICAN TYPE CULTURE COLLECTION, at <http://www.atcc.org/About/AboutATCC.cfm> (last visited Nov. 4, 2003) (on file with the Washington and Lee Law Review).

72. See ANDREWS & NELKIN, *supra* note 44, at 31 & 192 nn.21–22 ("John Moore's cells are for sale as CRL-8066; a plasmid containing Moore's DNA sequence that codes for colony stimulating factor is sold as ATCC 39754.").

73. See *Moore v. Regents of the Univ. of Cal.*, 793 P.2d 479, 498, 506 (Cal. 1990) (finding by a majority that Moore did not allege a conversion claim; only Justices Broussard and

position that society's need for new medical products must outweigh the interests of research participants, or else the fledgling biotechnology industry would suffer.⁷⁴ Moreover, the court stated that it did not need to expand the tort doctrine of conversion because the legal theories of breach of fiduciary duty and lack of informed consent adequately protected the plaintiff's interests.⁷⁵ Specifically, the court recognized a duty on the part of a physician-researcher to "disclose personal interests unrelated to the patient's health, whether research or economic, that may affect his medical judgment" in connection with procedures he recommends to patients.⁷⁶ Finally, the justices were especially mindful that the conversion theory relied on by Mr. Moore is a strict liability tort, meaning that liability would attach to every party in possession of the cells, even those who had no responsibility for or knowledge of the deception.⁷⁷ The court declared that "[i]f the scientific users of human cells are to be held liable for failing to investigate the consensual pedigree of their raw materials, we believe the Legislature should make that decision."⁷⁸

In fact, the California legislature did not enact legislation invalidating *Moore*,⁷⁹ nor has any other legislature enacted a statute expressly according research

Mosk filed dissenting opinions).

74. *Id.* at 495–96 (warning that "[i]f the use of cells in research is a conversion, then with every cell sample a researcher purchases a ticket in a litigation lottery" and also predicting that "'companies are unlikely to invest heavily in developing, manufacturing, or marketing a product when uncertainty about clear title exists'" (citing OWNERSHIP OF HUMAN TISSUES AND CELLS, *supra* note 19)).

75. *Id.* at 496 ("Any injury to his right to make informed decisions remains actionable through the fiduciary-duty and informed-consent theories.").

76. *Id.* at 485. With respect to the other defendants, however, the court noted that since the Regents, Ms. Quan, Genetic Institute, and Sandoz were not physicians, these defendants owed neither a fiduciary duty nor a duty of informed consent to Mr. Moore. Thus, these four defendants would face liability only through a theory of secondary liability, such as respondeat superior, an issue the court did not reach due to the procedural posture of the case. *Id.* at 485–86.

77. *Id.* at 494 ("Since conversion is a strict liability tort, it would impose liability on all those into whose hands the cells come, whether or not the particular defendant participated in, or knew of, the inadequate disclosures that violated the patient's right to make an informed decision.").

78. *Id.* at 496. The court emphasized that legislatures "have the ability to gather empirical evidence, solicit the advice of experts, and hold hearings at which all interested parties present evidence and express their views." *Id.* (footnote omitted).

79. In 1995, the California Senate considered Senate Bill 1363, which proposed to grant an individual a cause of action for the tort of conversion in cases where physicians or researchers removed or used gametes without that individual's knowledge or informed consent. Kristi Ayala, Note, *The Application of Traditional Criminal Law to Misappropriation of Gametic Materials*, 24 AM. J. CRIM. L. 503, 523–24 (1997). This bill, which was intended by the Senate to overrule *Moore* expressly, at least with respect to gametes, was never enacted. *Id.*

participants the right to sell their tissue for research purposes.⁸⁰ In examining

80. While no state has expressly accorded research participants the right to sell their tissue, all the states have enacted legislation that relies upon a quasi-property rights theory in permitting a decedent to *donate* his body after death for the purposes of transplantation, therapy, research, or education. See Rao, *supra* note 34, at 377–79 (noting that the Uniform Anatomical Gift Act (UAGA), which has been adopted in some form in all fifty states, "appears to regard the bodies and body parts of the deceased as property" because "individuals possess the right to consent to postmortem donation of their bodies and body parts while they are alive or to devise them by means of a will"). The UAGA also permits the following classes of people, in order of priority, to serve as proxies to donate a decedent's organs: the spouse, an adult son or daughter, either parent, an adult sibling, a guardian, and any other person authorized. UNIF. ANATOMICAL GIFT ACT § 2(b) (amended 1987), 8A U.L.A. 99 (1968). However, if either the decedent or a member of the same or prior class opposes the gift, the donee cannot accept it. UNIF. ANATOMICAL GIFT ACT § 2(c) (amended 1987), 8A U.L.A. 99–100 (1968).

U.S. courts have recognized common law rights in the human body that are akin to property rights. For example, in certain circumstances a decedent's relatives possess "property or quasi-property rights" in the decedent's body for the purpose of controlling the disposition of the body after death. See Dorothy Nelkin & Lori Andrews, *Do the Dead Have Interests? Policy Issues for Research After Life*, 24 AM. J. L. & MED. 261, 284–85 & nn.247–48 (1998) (footnotes omitted) (citing a case that described the "quasi- property rights of the survivors" as "the right to custody of the body; to receive it in the condition in which it was left, without mutilation; to have the body treated with decent respect, without outrage or indignity thereto; and to bury or otherwise dispose of the body without interference").

U.S. courts have also recognized a common law ownership interest in human reproductive materials, including sperm and pre-embryos, also called pre-zygotes, which have been defined as "fertilized eggs before they attach to the uterine wall." Philip J. Prygoski, *The Implications of Davis v. Davis for Reproductive Rights Analysis*, 61 TENN. L. REV. 609, 609 n.2 (1994); see also Helen S. Shapo, *Frozen Pre-Embryos and the Right to Change One's Mind*, 12 DUKE J. COMP. & INT'L L. 75, 76 n.3 (2002) (noting that some courts refer to the early-developed fertilized egg as a zygote or pre-zygote, and others use the term pre-embryo); see, e.g., York v. Jones, 717 F. Supp. 421, 426–27 (E.D. Va. 1989) (recognizing that a bailment agreement between plaintiffs, a couple seeking infertility treatment, and defendants, who were fertility doctors and a clinic, granted plaintiffs "property rights" in their cryopreserved embryo, and holding that these rights arose out of the language in the agreement rather than out of state law); Hecht v. Superior Court, 20 Cal. Rptr. 2d 275, 283 (Cal. Ct. App. 1993) (holding that decedent who devised his sperm to his girlfriend after his death "had an interest, in the nature of ownership, to the extent that he had decisionmaking authority as to the use of his sperm for reproduction" and that "such interest is sufficient to constitute 'property'" under California law); Kass v. Kass, 663 N.Y.S.2d 581, 588, 590 (N.Y. App. Div. 1997), *aff'd*, 696 N.E.2d 174 (N.Y. 1998) (affirming an appellate court's enforcement of an agreement whereby a couple provided, before their divorce, that their cryogenically preserved pre-embryos would be retained by their fertility clinic for research if the couple could not reach a joint decision regarding the disposition of the pre-embryos); Davis v. Davis, 842 S.W.2d 588, 597 (Tenn. 1992) (holding, in a dispute over the control of cryogenically preserved pre-embryos, that, although plaintiff progenitors did not, strictly speaking, have "a true property interest" in their pre-embryo, they did possess "an interest in the nature of ownership, to the extent that they have decision-making authority concerning disposition of the pre-embryos"). Likewise, the American Fertility Society has taken the position in its Ethical Statement on In Vitro Fertilization that: "It is understood that the gametes and concepti are the property of the donors. The donors therefore have the right to decide at their sole discretion the disposition of these items, provided such disposition is

whether the United States Congress ought to recognize such a right, it is necessary to consider the policy arguments set forth in *Moore*. As stated previously, the California Supreme Court did not go so far as to declare that human tissue could never be considered property for any purpose whatsoever.⁸¹ Nevertheless, the *Moore* opinion does indeed rely upon the three major arguments proffered by advocates of the market-inalienability model. First, according to this view, granting research participants property rights in their tissue will hinder investment in the biotechnology industry and, concomitantly, the advancement of public health. Second, as a related principle, research participants do not merit property rights because, unlike scientific researchers, they perform no innovative or creative work. Third, the commodification of the human body is immoral and unethical. In addition, commentators concerned about the protection of human health offer two additional arguments, which were not discussed in the *Moore* opinion, in support of the market-inalienability model. They fear that widespread pecuniary compensation for human research participants will permit scientists to lure participants with false or misguided promises of profits and also induce individuals to risk their physical health in exchange for financial gain. Moreover, they assert that the promise of profits will lead to a decline in gratuitous donation of human tissue for research purposes.

within medical and ethical guidelines as outlined herein." ETHICS COMM. OF THE AM. FERTILITY SOC'Y, *ETHICAL CONSIDERATIONS OF THE NEW REPRODUCTIVE TECHNOLOGIES*, 46 *FERTILITY AND STERILITY* 89s (Sept. 1986). Of course, as noted by Professor Shapo, courts are reluctant to classify frozen pre-embryos as property, because of their potential to develop into human beings. Shapo, *supra*, at 77 n.5. Thus, legal actions involving pre-embryos present issues different from cases concerning individuals' rights to exercise control over their nonreproductive tissue.

Finally, sales of sperm, blood, and hair are widely accepted under the law based on the rationale that they are renewable and their removal presents little threat to the health of the individual from whom they are removed. See *supra* note 34 (explaining that state laws forbidding sales of organs generally exempt regenerative human tissue); see also *Green v. Commissioner*, 74 T.C. 1229, 1234-35 (1980) (holding that, under the tax code, an individual's sales of her rare blood plasma constituted the "sale of a tangible product").

81. See *supra* note 30 (noting that the *Moore* majority did not reject outright the notion of property rights in human tissue and emphasized that its opinion did not mean that cells can never be property for any purpose).

B. Analysis of the Policy Considerations Underlying the Market-Inalienability Model

1. According Research Participants Property Rights in Their Tissue Will Not Impede Investment in the Biotechnology Industry or the Advancement of Public Health

Absent a clear legislative command, the California Supreme Court in *Moore* declined to extend the tort of conversion so as to grant a research participant property rights in the products derived from his tissue.⁸² The *Moore* majority emphasized that the primary policy reason underlying its decision was the need to facilitate research scientists' access to human tissue, and thereby foster public health.⁸³ Thus, the *Moore* majority embraced the Kaldor-Hicks model of efficiency,⁸⁴ which prescribes that:

[A] proposal for increasing aggregate economic welfare ought to be adopted if, in consequence, gainers could, in concept, have sufficient gain to compensate losers and be left with a net gain. Whether compensation is actually given, however, is not a matter of relevance to the economic analysis of the implementation decision. As Kaldor put it, "this is a political question."⁸⁵

The *Moore* court's application of the Kaldor-Hicks model in this policy area raises the question of whether that court correctly assessed the effects upon the biotechnology industry of according human research participants property rights in their tissue.

Because biomedical research is a costly and financially risky endeavor,⁸⁶

82. See *supra* notes 73–78 and accompanying text (examining the court's finding that *Moore* failed to state a cause of action for conversion).

83. *Moore v. Regents of the Univ. of Cal.*, 793 P.2d 479, 493–97 (Cal. 1990) (explaining the court's preference for the value of socially useful research over a patient's right to make autonomous medical decisions).

84. The seminal essays setting forth the approach that has come to be known as the Kaldor-Hicks test are Nicholas Kaldor, *Welfare Propositions of Economics and Inter-Personal Comparisons of Utility*, 49 *ECON. J.* 549 (1939), and J.R. Hicks, *The Foundations of Welfare Economics*, 49 *ECON. J.* 696 (1939).

85. Denis J. Brion, *Law Making: Utilitarian Reasoning in Judicial Decisionmaking*, 23 *LEGAL STUD. FORUM* 93, 107 (1999) (noting that the *Moore* court applied Kaldor-Hicks reasoning in reaching its holding).

86. According to an industry trade organization, bringing a biotechnology drug or vaccine to market requires on average \$800 million and ten to fifteen years. Of each 5,000 to 10,000 compounds screened, only one product will earn FDA approval. Telephone Interview with Carrie Housman, Communications Coordinator, Biotechnology Industry Organization (Dec. 11, 2002) (on file with author); see also Michael A. Carrier, *Unraveling the Patent-Antitrust Paradox*, 150 *U. PA. L. REV.* 761, 824–25 (2002) (citing numerous sources that present the

Congress must consider carefully whether according human research participants property rights in their tissue will diminish the incentives to invest in this industry. Certainly, if research participants were to enjoy property rights in their tissue, biomedical scientists would face a significant increase in their transaction costs. First, scientists would be obliged to compensate research participants for their genetic material, whether pursuant to a contract negotiated at the inception of the research or pursuant to a liability rule after the fact. This obligation to remunerate research participants presents a particular risk to scientists in the nonprofit sector, who do not necessarily plan to commercialize their findings.⁸⁷ Second, researchers would face significant transaction costs⁸⁸ in locating and then negotiating compensation arrangements with each individual participant involved in a given research effort, and research institutions would incur considerable monitoring and enforcement costs in ensuring the compliance of their staff. Because many biotechnological research studies involve numerous tissue samples from individuals worldwide,⁸⁹ such

significant costs and risks faced by the biopharmaceutical industry). For the year 2001, research and development expenses in the biotech industry totaled \$15.7 billion while product sales equaled \$20.7 billion. See BIOTECHNOLOGY INDUS. ORG., BIOTECHNOLOGY INDUSTRY STATISTICS, at <http://www.bio.org/er/statistics.asp> (last visited Oct. 15, 2003) (citing as the source for its statistics Ernst & Young LLP, annual biotechnology industry reports, 1993–2002) (on file with the Washington and Lee Law Review).

87. As numerous scholars have pointed out, it has become increasingly difficult to distinguish clearly between commercial versus nonprofit research in light of the fact that academic research has become increasingly commercialized since the mid-1980s. See OWNERSHIP OF HUMAN TISSUES AND CELLS, *supra* note 19, at 54 ("The present economic dynamics of research coupled with the proliferation of biotechnology companies have spawned a plethora of university-industry relationships that have made it increasingly difficult to separate the use of human samples in university (or other institution-based) basic research from basic and applied research in commercial settings."); Arti Kaur Rai, *Regulating Scientific Research: Intellectual Property Rights and the Norms of Science*, 94 NW. U. L. REV. 77, 110–11 (1999) (noting the increase in academic-industrial biotech partnerships since the 1980s and citing examples); see also Sheldon Krimsky, *The Profit of Scientific Discovery and Its Normative Implications*, 75 CHI.-KENT L. REV. 15, 15–22 (1999) (describing the trend toward alliances among for-profit and academic researchers). This trend was apparent to the judges deciding *Moore*. See *Moore v. Regents of the Univ. of Cal.*, 249 Cal. Rptr. 494, 536 (Cal. Ct. App. 1988) (George, J., dissenting) ("[I]t should be noted that no perfect dichotomy exists between research and commercial use.").

88. Transaction costs have been defined as "the costs of all resources required to transfer property rights from one economic agent to another. They include the costs of making an exchange (for example, discovering exchange opportunities, negotiating exchange, monitoring, and enforcement), and the costs of maintaining and protecting the institutional structure (for example, judiciary, police, armed forces)." SVETOZAR PEJOVICH, *ECONOMIC ANALYSIS OF INSTITUTIONS AND SYSTEMS* 84 (1995).

89. See *supra* note 36 (noting that thousands of families worldwide provided tissue for Canavan disease research).

negotiations could prove quite complex and protracted. Furthermore, bargaining among scientists and research participants could prove impossible in cases where the identities of these participants are unknown, either because researchers obtained the tissue from another scientist, a tissue bank, or a repository without the tissue's identifying information,⁹⁰ or because the participants remain anonymous.⁹¹ Third, the problems of increased financial and transaction costs reach their apex in the case of the potential holdout who refuses to participate in research unless she is compensated at a very high rate.⁹² Finally, recognizing the research participant's right to share in the revenues may imply some right to control the products of that research; for example, research participants may demand widespread and affordable licensing of the intellectual property developed from their tissue, thereby further decreasing the scientists' profits.⁹³ All of these factors combined would present significant disincentives to researchers, who presumably would encounter these impediments well before they could ascertain the profitability of their research

90. The California Supreme Court noted in *Moore* the frequency with which researchers obtain tissue from repositories and from other scientists. *Moore v. Regents of the Univ. of Cal.*, 793 P.2d 479, 494–95 (Cal. 1990). While the *Moore* majority, writing in 1990, suggested that scientists provided tissue to their colleagues free of charge, in the spirit of professional cooperation, *id.* at 495 & n.39, Justice Mosk contended in his dissent that such sharing was quite limited in light of the commercialization of biotechnology research. *Id.* at 513–14 (Mosk, J., dissenting). In our present day, researchers typically exchange tissue samples in return for valuable consideration as participants in a thriving commercial market. The merchants in this market include hospitals, research centers, private depositories, and numerous public sector bodies, including state public health departments, the U.S. Armed Forces, the U.S. Department of Defense, and the Centers for Disease Control. See ANDREWS & NELKIN, *supra* note 44, at 4–5, 24–41 (describing the extensive commercial market in human tissue).

91. The American Society of Human Genetics explained in its Statement on Informed Consent for Genetic Research that some biomedical research involves anonymous or anonymized biological materials. The former "were originally collected without identifiers and are impossible to link to their sources," while the latter "were initially identified but have been irreversibly stripped of all identifiers and are impossible to link to their sources" although "this process does not preclude linkage with clinical, pathological, and demographic information before the subject identifiers are removed." American Society of Human Genetics, *Statement on Informed Consent for Genetic Research*, 59 AM. J. HUM. GENET. 471, 472 fig. 1 (1996) [hereinafter *Statement on Informed Consent*].

92. For example, a gerontologist in Boston became interested in studying a local family whose members had very long life spans, but the parties were unable to agree upon a level of compensation and negotiations ultimately ceased. Certainly, there is a risk that potential research participants will tend to overvalue their tissue, thereby greatly increasing transaction costs. See generally Kolata, *supra* note 27.

93. See *supra* note 28 (noting that PXE International advocates either free licensing of the intellectual property developed by the researchers with whom they have collaborated, or, if the researchers insist, a modest fee).

enterprise. On the other hand, countervailing arguments support the notion that compensating research participants might stimulate innovation.

a. An Analysis of the Economic and Transaction Costs Involved in Compensating Research Participants and the Importance of Compensation in Terms of Stimulating Participation

While a legal regime that accords research participants property rights in their tissue arguably threatens to increase to some degree the economic and transaction costs facing researchers, thereby negatively affecting scientific innovation, commentators have warned that failure to recognize such rights entails costs of its own. For example, some altruistic individuals who ordinarily would contribute their tissue for biomedical research may decline to participate if they feel exploited because everyone else involved in researching their genes, aside from them, is making a profit.⁹⁴ In addition, less selfless individuals might refuse to undergo the inconvenience, medical risks, loss of privacy, and possibility of genetic discrimination associated with biomedical research without legal protection of their right to remuneration, thereby decreasing the supply of tissue available for research.⁹⁵

What is more, a system that assures compensation for research participants encourages individuals to propose research that scientists might not have conceived on their own, thereby stimulating biotechnological research. For instance, in 1988, Mr. Erich Karl Fuchs, a gay man who had been exposed to the HIV virus on many occasions, began to suspect that he was unusually resistant to it. He continually contacted researchers over a period of six years to

94. See Kolata, *supra* note 27 (quoting Professor Hank Greely of Stanford Law School as stating: "You don't want research subjects to feel cheated and embittered and betrayed In the long run, for research with human subjects to survive, those human subjects have to feel that they've been treated fairly.").

95. Dr. Robert Cook-Deegan, Director of the Center for Genome Ethics, Law and Policy at Duke University, has criticized the tendency to treat research participants as "pure altruists," whereas "everyone else is treated as a pure capitalist." *Id.* As noted by Professor Hoffmaster:

Curiously, . . . when commercialization works to the advantage of scientists, its negative impact on research is less emphasized. The possibility of obtaining patents has already begun to cast a shroud of secrecy around science and has decreased the extent to which research materials and results are freely shared among scientists. Nevertheless, allowing researchers to profit is regarded as a stimulant to science, whereas compensating sources for their materials is regarded as a depressant.

Barry Hoffmaster, *Between the Sacred and the Profane: Bodies, Property, and Patents in the Moore Case*, 7 INTELL. PROP. J. 115, 134 (1992).

suggest that they study his genetic material, and, in 1994, scientists eventually agreed to study Mr. Fuchs and another man exhibiting similar resistance to the virus, Mr. Steve Crohn. Ultimately, researchers were able to isolate the gene responsible for immunity to the HIV virus and to patent a test to identify others with a similar genetic makeup.⁹⁶ As this example illustrates, individuals affected by a medical condition are often among the first to note scientifically significant phenomena within themselves.⁹⁷ On the other hand, potential research participants, motivated by the promise of material gain, might distort the information they provide to researchers in order to increase their value as research participants. Such behavior could detract from the quality of the research results, and even endanger the health of the research participant and others in the study.⁹⁸ Scientists can minimize this problem, however, by

96. Kolata, *supra* note 27.

97. In this particular case, neither Mr. Fuchs nor Mr. Crohn participated in research in return for compensation, although Mr. Fuchs did express the opinion that, while his primary goal was altruism, he believed that he merited some share in the financial rewards from the research. *Id.* (quoting Mr. Fuchs as saying, "I just wanted to do something good. But once money came into the picture, why not have it be shared with me?"). Mr. Fuch's reaction also supports the notion that research participants will feel exploited if others profit from their selflessness. See *supra* note 94 and accompanying text (citing academic support for the proposition that altruistic individuals might feel cheated if others are paid).

Professor Heidt maintains that if the law wishes to stimulate individuals to conduct "self-searching" of their bodies in search of commercially valuable material, it ought to implement a default rule that denies research participants a share in the profits from products developed from their tissue. According to this view, individuals would be more motivated to "self-search" if the only way to realize the value of their cells would be to negotiate for the highest bid. See Heidt, *supra* note 34, at 710–11 & nn.121–22 (describing that "the more the law favors researchers over subjects, the more the law encourages people to self-search and keep all researchers out of the search as much as possible"). This argument neglects, however, to consider the benefits of a system that relies on a property rule combined with a liability rule, see *supra* notes 38–40 and accompanying text (citing scholarship examining the interplay between property and liability rules), invoking the latter in cases where researchers wrongfully deny a research participant full information regarding the commercial nature of their work. Such a system still encourages "self-checking" by individual research participants, who know that they will be more likely to share in the profits of research if they obtain as much information as possible about the value of their tissue in advance and negotiate a contract based upon this knowledge, as opposed to bringing a legal action for conversion after research has begun. Indeed, it is possible that only those individuals who are most likely to possess scientifically significant tissue will engage in self-searching under this hybrid system, since only they will expect to reap from their self-searching financial benefits that outweigh their costs. Those without valuable tissue are more likely simply to rely upon the default liability rule. Thus, this hybrid system has the potential additional benefit of avoiding socially inefficient "defensive" searches, see Heidt, *supra* note 34, at 696 (describing the problems of "defensive" searches), by individuals who do not have particularly valuable tissue (if we assume a direct relationship between the value of an individual's tissue and her likelihood of investigating its worth).

98. See OWNERSHIP OF HUMAN TISSUES AND CELLS, *supra* note 19, at 106 (noting that this behavior could lead to flawed research results and put the subject and others at risk). For a

screening potential research participants to determine whether they meet eligibility criteria before disclosing the possibility of commercial benefits flowing from the study.⁹⁹

While researchers already can choose to encourage participation in biomedical research by voluntarily offering compensation to research participants, assuming that the contractual PXE model withstands judicial scrutiny in the years to come,¹⁰⁰ this model fails to provide a complete solution. Researchers may hesitate to compensate one research participant when others are donating their tissue, lest donors feel exploited and come to expect payment.¹⁰¹ Moreover, the pure property rights approach does not protect research participants against scientists with whom they did not deal directly. Consider, for example, a situation where a research participant permits one researcher to use her tissue for a particular purpose, in exchange for compensation. This researcher then sells the tissue to a second scientist who lacks any contact with the research participant, and this second scientist uses the tissue without the knowledge of its source. Under the current law as set forth in *Moore*, the legal theories available to the research participant, namely the doctrines of breach of informed consent and of fiduciary duty, are most likely ineffective against that second scientist. After all, the second scientist owes the research participant no duties, and therefore would not be liable for the first researcher's wrongful sale of the tissue according to dicta set forth by the *Moore* majority.¹⁰² Faced with this possibility, potential research participants might decline to participate at all. Congressional recognition of property rights in human tissue would encourage the research participant's involvement by offering her a remedy for unauthorized use of her tissue by strangers.

discussion of the converse danger, the possibility that researchers will lure research participants with exaggerated promises of financial gain, see *infra* notes 209–16 and accompanying text (presenting scholarly speculation on the topic).

99. OWNERSHIP OF HUMAN TISSUES AND CELLS, *supra* note 19, at 106.

100. See *supra* notes 24–29 and accompanying text (explaining the PXE International contractual model).

101. See Kolata, *supra* note 27 (quoting a researcher from a Boston medical center who expressed discomfort with paying one family for their tissue when others had donated their tissue).

102. See *Moore v. Regents of the Univ. of Cal.*, 793 P.2d 479, 486–87 (Cal. 1990) (declining to hold any defendant other than Dr. Golde, Mr. Moore's attending physician, liable for breach of fiduciary duty or lack of informed consent absent any "recognized theory of secondary liability, such as respondeat superior"); see also *supra* note 76 and accompanying text (explaining that the *Moore* court declined to ascribe liability to the nonphysician defendants).

Another potential problem raised by recognition of research participants' rights in their tissue, quite apart from the financial costs of compensating them for the tissue itself, is the issue of transaction costs. Indeed, one United States government report stated that "[t]he actual compensation to the human sources of original tissues and cells is unlikely to have a large economic impact on the use of human biological materials, but transaction costs are likely to dwarf the costs of payments to these individuals."¹⁰³ One can argue, however, that pursuant to *Moore*, the duty of informed consent already requires physician-researchers to communicate their financial interests to the research participants with whom they deal directly.¹⁰⁴ This duty must surely extend as well to scientists engaged in primarily research-oriented, as opposed to therapeutic, relationships with their research participants. Courts have held that researchers, as compared to treating physicians, must be held to a higher duty of disclosure vis-à-vis their research participants because research participants stand to reap little or no personal benefit from their involvement in biomedical experimentation.¹⁰⁵ As stated in one government report, "[s]ince greater

103. OWNERSHIP OF HUMAN TISSUES AND CELLS, *supra* note 19, at 13; *see also* Heidt, *supra* note 34, at 712 (stating that "even when negotiations proceed smoothly, the negotiating costs may be substantial compared to their benefits in light of the many patients whose collections researchers may wish to examine and the tiny percent of these negotiated agreements that will ever be used").

104. *See Moore*, 793 P.2d at 483 (holding that in obtaining a patient's consent to a procedure, "a physician must disclose personal interests unrelated to the patient's health, whether research or economic, that may affect the physician's professional judgment" and "a physician's failure to disclose such interests may give rise to a cause of action for performing medical procedures without informed consent or breach of fiduciary duty" (emphasis added)). For a detailed discussion of the limits of the doctrines of informed consent and fiduciary duty in protecting research subjects, *see infra* notes 184–207 and accompanying text.

105. *See Whitlock v. Duke Univ.*, 637 F. Supp. 1463, 1467 (M.D.N.C. 1986) (holding that because the doctrine of informed consent applies "in therapeutic circumstances where the health care provider has as an objective to benefit the patient," a fortiori it applies "in the nontherapeutic context where the researcher does not have as an objective to benefit the subject"), *aff'd*, 829 F.2d 1340 (4th Cir. 1987); *see also* Grimes v. Kennedy Krieger Inst., Inc., 782 A.2d 807, 834–35 (Md. 2001) (holding that "the very nature of nontherapeutic scientific research on human subjects can, and normally will, create special relationships out of which duties arise").

Similarly, in the leading Canadian case on informed consent, *Halushka v. Univ. of Sask.*, [1965] 53 D.L.R. 2d 436, 443–44, the Saskatchewan Court of Appeal imposed upon medical researchers a duty of disclosure toward research participants "as great as, if not greater than, the duty owed by the ordinary physician or surgeon to his patient." *Id.* at 443–44. As noted by one commentator, because *Halushka* is "one of the few cases [dealing with nontherapeutic, experimental research] in North America that has produced a legal judgment, it has set the standard." Daryl Pullman, *Subject Comprehension, Standards of Information Disclosure and Potential Liability in Research*, 9 HEALTH L.J. 113, 115 (2001). United States legal commentators frequently invoke *Halushka* in support of the principle that the doctrine of

disclosure is usually required in a research setting, it would follow that disclosure of potential commercial gain would be required there as well."¹⁰⁶ The report added: "It should not be assumed that all persons, upon learning that they carry a unique cell strain or other type of biological material, will agree to its commercial marketing as a developed cell line. Some people may be opposed to such use"¹⁰⁷

Thus, in light of the generally recognized principle that research scientists who deal directly with a research participant owe a duty of informed consent, which would include the duty to reveal their economic interests in the research,¹⁰⁸ the only scientists who would face an entirely new duty if Congress were to recognize a federal tort of conversion of body tissue would be (1) those who obtain the tissue from other researchers, tissue banks, or repositories¹⁰⁹ and (2) those who conceive of a research use for tissue *after* having obtained it from the research participant.¹¹⁰ Both of these groups presently may be free of any duty of informed consent under federal or state law.¹¹¹ The exemption of such

informed consent may apply more rigorously in the research setting. *See, e.g.*, Richard Delgado & Helen Leskovic, *Informed Consent in Human Experimentation: Bridging the Gap Between Ethical Thought and Current Practice*, 34 UCLA L. REV. 67, 80–81 (1986) (describing the facts and holding of *Halushka*); Jesse A. Goldner, *An Overview of Legal Controls on Human Experimentation and the Regulatory Implications of Taking Professor Katz Seriously*, 38 ST. LOUIS L.J. 63, 78–79 (1993) (same); Richard S. Saver, *Critical Care Research and Informed Consent*, 75 N.C. L. REV. 205, 223 n.61 (1996) (same).

106. OWNERSHIP OF HUMAN TISSUES AND CELLS, *supra* note 19, at 102.

107. *Id.* at 104.

108. *See supra* notes 104–06 and accompanying text (citing case law and commentary to establish researchers' duty to disclose economic interests). *But see* *Greenberg v. Miami Children's Hosp. Research Inst., Inc.*, 264 F. Supp. 2d 1064, 1070 (S.D. Fla. 2003) (acknowledging that "in certain circumstances a medical researcher does have a duty of informed consent," but nonetheless declining "to extend the duty of informed consent to cover a researcher's economic interests in this case").

109. Federal law does not require informed consent for "[r]esearch, involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if these sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects." 45 C.F.R. § 46.101(b)(4) (2002). Similarly, the *Moore* court did not require informed consent where scientists obtained tissue from depositories or other researchers. *See supra* note 102 and accompanying text (noting the *Moore* court's refusal to hold anyone other than the attending physician liable).

110. *See Moore v. Regents of the Univ. of Cal.*, 793 P.2d 479, 484 (Cal. 1990) ("If a physician has no plans to conduct research on a patient's cells at the time he recommends the medical procedure by which they are taken, then the patient's medical interests have not been impaired.").

111. Federal regulations on informed consent apply directly only to research that meets one of the following criteria: the research is federally funded; the research is conducted at an institution that has given the federal government assurances that it will comply with federal

researchers from the requirements of informed consent is quite controversial, and in recent years has generated vigorous debate among, and proposals for reform by, government officials, industry leaders, policy makers, and scholars.¹¹²

In deciding whether to extend the law of informed consent to apply to researchers who obtain tissue from other researchers, tissue banks, or repositories, it is worth noting that, as a practical matter, a system that exempts researchers from obtaining informed consent if they procure tissue from anyone other than the research participant might slow the pace of biomedical research by encouraging scientists to leave the tissue collection to others rather than risk incurring the duty of informed consent. Moreover, "[t]he fundamental principle underlying the need for consent for medical or research purposes is respect for personal autonomy,"¹¹³ and strict adherence to this principle militates against exempting such researchers from the duty of informed consent. Because research participants can refuse involvement altogether,¹¹⁴ they ought to have

regulations; or the research involves an investigational new drug or medical device regulated by the Food and Drug Administration. See Henry T. Greely, *Breaking the Stalemate: A Prospective Regulatory Framework for Unforeseen Research Uses of Human Tissue Samples and Health Information*, 34 WAKE FOREST L. REV. 737, 738-39 (1999); see also 45 C.F.R. § 46.111(a)(4) (2002) (requiring informed consent); 45 C.F.R. § 46.116 (2002) (explaining informed consent). For privately-funded research, the doctrine of informed consent has developed through state common law and, less frequently, state statutory law. See OWNERSHIP OF HUMAN TISSUES AND CELLS, *supra* note 19, at 93-96 (tracing the development of state common law theories of informed consent and noting the paucity of state regulation of this issue); see also *Ketchup v. Howard*, 543 S.E.2d 371, 381-86 (Ga. Ct. App. 2000) (summarizing very briefly the law of informed consent in the fifty states).

112. See generally 1 NAT'L BIOETHICS ADVISORY COMM'N, RESEARCH INVOLVING HUMAN BIOLOGICAL MATERIALS: ETHICAL ISSUES AND POLICY GUIDANCE (1999) (providing recommendations for reform concerning human biological research) [hereinafter RESEARCH INVOLVING HUMAN BIOLOGICAL MATERIALS]; Ellen Wright Clayton et al., *Informed Consent for Genetic Research on Stored Tissue Samples*, 274 JAMA 1786 (1995) (proposing that informed consent is necessary for linkable samples and may be considered for samples being anonymized); Greely, *supra* note 111 (proposing a new regulatory framework for the future collection of human biological materials to be used in research); Bartha Maria Knoppers & Claude M. Laberge, *Research and Stored Tissues: Persons as Sources, Samples as Persons?*, 274 JAMA 1806 (1995) (advocating changes in the law of informed consent for research on human biological materials).

113. OWNERSHIP OF HUMAN TISSUES AND CELLS, *supra* note 19, at 10.

114. The *Moore* court, in holding for the plaintiff on his claims for breach of fiduciary duty and lack of informed consent, effectively acknowledged that he had a right to refuse research participation altogether. Federal law also mandates that participation in federally funded research is voluntary, providing that a research participant shall be furnished with "[a] statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled." 45 C.F.R. § 46.116(a)(8) (2002). In addition, the Nuremberg Code, which was written after World War II by

access to information about all research uses of their tissue.¹¹⁵ This logic applies equally to anonymized tissue samples,¹¹⁶ even though federal regulations do not require informed consent for research on them.¹¹⁷ As stated in a report of the National Bioethics Advisory Commission (NBAC):

[I]t is incorrect to assume that because the sources cannot be identified they cannot be harmed or wronged. Some interests of the sample sources may be harmed even if they are not completely identifiable, and interests of others also may be at risk. For example, there may be group or family interests that could be revealed or placed at risk because of research that is conducted on a class of similar, albeit individually unidentifiable, samples. Individuals have an interest in avoiding uses of their tissues that they regard as morally impermissible or objectionable. Thus, were their materials to be used in research that they would consider objectionable, it is possible that some individuals could be wronged, if not harmed.¹¹⁸

American judges involved in trying Nazi doctors for their crimes, provides that "[t]he voluntary consent of the human subject is absolutely essential." THE NUREMBERG CODE, *reprinted in* THE NAZI DOCTORS AND THE NUREMBERG CODE: HUMAN RIGHTS IN HUMAN EXPERIMENTATION 2, 2 (George J. Annas & Michael A. Grodin eds., 1992). As stated previously, however, the right to refuse research participation is less clear when researchers use existing anonymized tissue specimens, and this issue is currently the subject of much debate. *See supra* notes 109 & 111 and accompanying text (outlining the relevant law and scholarship surrounding the issue).

115. As stated in a report on genetic research by a committee of the National Academy of Sciences: "It is not ethically or legally acceptable to ask research participants to 'consent' to future but yet-unknown uses of their identifiable DNA samples." COMM. ON HUMAN GENOME DIVERSITY, COMM'N ON LIFE SCIENCES, NAT'L RESEARCH COUNCIL, EVALUATING HUMAN GENETIC DIVERSITY 65 (1997); *see also Statement on Informed Consent, supra* note 91, at 473 ("It is inappropriate to ask a subject to grant blanket consent for all future unspecified genetic research projects on any disease or in any area if the samples are identifiable in those subsequent studies.").

116. *See supra* note 91 (defining anonymous and anonymized tissue samples).

117. *See supra* note 109 (describing relevant federal law).

118. RESEARCH INVOLVING HUMAN BIOLOGICAL MATERIALS, *supra* note 112, at 60–61. While acknowledging that "these concerns are valid," the NBAC declined to "find that they are sufficiently substantial to restrict further use of such samples." *Id.* at 61. Of course, informed consent and, by extension, compensation for the research participant's tissue, may prove impossible in cases where tissue specimens are anonymous or anonymized. *See supra* note 91 (defining anonymous and anonymized tissue samples). Any federal legislation ensuring compensation to research participants in exchange for their tissue must include a provision allowing a research participant to waive her right to compensation so long as she understands clearly the implications of the waiver and signs a written waiver agreement. Such a provision would protect researchers from financial liability not only in cases in which a scientist wishes to conduct research on anonymous or anonymized human tissue samples, but also in cases in which a research participant indicates her willingness to make a gratuitous donation of her tissue. As a practical matter, Congress realistically could impose this waiver requirement only for tissue collected after the effective date of such legislation. Federal regulations currently, however, bar research participants from executing voluntary waivers of their rights in their

In order to assist researchers in tracking whether informed consent was given for the use of tissue obtained from tissue banks and repositories, federal legislation could require these institutions to retain informed consent documents and contact information relating to the suppliers of its tissue samples.

In terms of the application of the law of informed consent in cases where later research uses are conceived for previously collected tissue, it is clear that both federal and state law recognize the importance of a continuing duty of informed consent on the part of researchers.¹¹⁹ According to a government report, "[i]t can be argued that the discovery in a subject's body of a unique cell line that may be commercially valuable constitutes a significant new finding" that "could influence a subject in deciding whether or not to continue his role in

tissue. See 45 C.F.R. § 46.116 (2002) ("No informed consent, whether oral or written, may include any exculpatory language through which the subject or the representative is made to waive or appear to waive any of the subject's legal rights, or releases or appears to release the investigator, the sponsor, the institution or its agents from liability for negligence."). Congress must therefore amend federal law to permit research participants to waive their financial interest in their tissue. The legislative language barring participants from waiving their financial interest in their tissue actually was intended to preserve a research participant's right to sue for injuries resulting from his research participation, see *House Hearing*, *supra* note 53, at 233 (statement of Dr. Charles R. McCarthy, Director, Office of Protection From Research Risks, National Institutes of Health), and therefore should not preclude a research participant from waiving his right to compensation for his tissue. See OWNERSHIP OF HUMAN TISSUES AND CELLS, *supra* note 19, at 107–08 (proposing specific changes to the federal law to permit research participants to waive any rights to commercial gain from their tissue); Heidt, *supra* note 34, at 668 n.3 & 709 n.118 (contending that research participants ought to be able to waive their rights to compensation for their tissue).

In any event, most biomedical researchers prefer identifiable, not anonymous or anonymized, tissue samples, so that they can track individual health histories and symptoms, as well as preserve the ability to recontact the individual contributor to gather additional data or provide therapeutic information. See RESEARCH INVOLVING HUMAN BIOLOGICAL MATERIALS, *supra* note 112, at 18 (explaining why a researcher may want to contact the provider of a tissue sample); Fleischer, *supra* note 27, at 100 (citing an analyst with RAND's Science and Technology Policy Institute, who explained that biomedical researchers prefer tissue samples that are linked to an identifiable contributor).

119. Federal statutory law requires disclosure of "significant new findings developed during the course of the research which may relate to the subject's willingness to continue participation." 45 C.F.R. § 46.116(b)(5) (2002). State court decisions likewise have upheld a physician's continuing duty of informed consent in a therapeutic context. See, e.g., *Tresemer v. Barke*, 150 Cal. Rptr. 384, 393–94 (Cal. Ct. App. 1978) (holding that patient stated a cause of action against doctor for failure to contact the former patient and warn of newly discovered risks of intervention); *Taber v. Riordan*, 403 N.E.2d 1349, 1353 (Ill. App. Ct. 1980) (analogizing the duty to inform a patient of certain risks before a medical procedure to the physician's duty to inform the patient that complications have indeed arisen after the procedure).

the research project," and therefore must be disclosed to the research participant.¹²⁰

Another set of transaction costs faced by researchers required to compensate their research participants involves record-keeping. Professor Heidt states that "researchers would need to keep track of patients, cell lines, the patient's contribution to each cell line, [and] the role of each cell line in developing the end products" and that "[s]tudies involving the development of cell lines can takes years to complete and commercial application even longer."¹²¹ There is good reason, however, to require researchers to keep careful track of human tissue, whether used separately or in combination with the tissue of others. The *Moore* majority itself acknowledged the importance of keeping biological materials in safe hands, as the cell line derived from Mr. Moore's body contained genetic material capable of reproducing a harmful virus.¹²² Certainly, the current fear in the United States regarding the possibility of bioterrorism, as demonstrated by recent concern about anthrax, has highlighted the importance of monitoring closely the exchange of potentially hazardous biological materials.¹²³ Such record keeping to track the use of each biological sample surely would not prove unduly burdensome in light of "the meticulous care and planning necessary in serious modern medical research."¹²⁴

Another transaction cost facing researchers obliged to compensate their research participants is the problem of the potential holdout who refuses to supply tissue unless his price is met. Some courts and scholars reject the notion that a research participant is entitled to determine the amount of consideration tendered for his tissue, arguing that such behavior by research participants smacks of inappropriate profiteering by individuals seeking a windfall from the

120. OWNERSHIP OF HUMAN TISSUES AND CELLS, *supra* note 19, at 102.

121. Heidt, *supra* note 34, at 713.

122. *Moore v. Regents of the Univ. of Cal.*, 793 P.2d 479, 491-92 (Cal. 1990). The *Moore* majority invoked this notion in support of an argument contrary to the one advanced here, contending that California statutory law vests in medical practitioners, not patients, the right to dispose of biological materials, and therefore does not recognize patients' property interest in these materials. *Id.* at 492 ("[T]he statute eliminates so many of the rights ordinarily attached to property that one cannot simply assume that what is left amounts to 'property' or 'ownership' for purposes of conversion law.").

123. See Laurie Garrett & Earl Lane, *Scientists Stymied in Anthrax Probe: Spores May Not Be Traceable*, NEWSDAY (New York), Jan. 1, 2002 (Queens Edition), at A8 ("It is difficult to say how many labs might have obtained copies of the reference Ames strain [of anthrax] by informal exchange among scientists before the 1996 federal Centers of Disease Control and Prevention rules on transfer of select agents such as anthrax.").

124. *Moore v. Regents of the Univ. of Cal.*, 249 Cal. Rptr. 494, 508 n.14 (Cal. Ct. App. 1998).

research efforts of others.¹²⁵ On the other hand, the principle of informed consent enshrined in both state and federal law already recognizes the right of research participants to refuse involvement in biomedical research on moral, ethical, religious, health, privacy, or any other personal grounds.¹²⁶ While some may contend that widespread acceptance of the notion that research participants merit compensation will discourage altruism on the part of certain individuals who otherwise would donate their tissue gratuitously, it is already the case that research participants can negotiate with researchers for a share in the profits from commercial products developed from their tissue.¹²⁷ Federal codification of this right would merely ensure that even those research participants denied informed consent would receive compensation, alongside their counterparts who had bargained for remuneration.

As a practical matter, it is difficult for biomedical researchers to determine the terms of compensation for their various research participants in light of the fact that only rarely is the tissue "provided by any single (or very few) individual(s) potentially profit-yielding to the research community because the [tissue] is both commercially useful and rare."¹²⁸ Instead, "[r]esearch results are typically a series of several joint efforts with specimens provided by several individuals,"¹²⁹ and "many laboratory transformations over a long period of time separate the original extraction from the end product."¹³⁰ Ultimately,

125. See *Moore*, 793 P.2d at 493 (stating that it is "inventive effort that patent law rewards, not the discovery of naturally occurring raw materials," so "Moore's allegations that he owns the cell line and the products derived from it are inconsistent with the patent, which constitutes an authoritative determination that the cell line is the product of invention"); see also Heidt, *supra* note 34, at 673 (characterizing a research participant with commercially valuable tissue who seeks to negotiate with the researcher who detected that tissue as "a free rider on the search efforts of the researcher").

126. See *supra* note 114 and accompanying text (noting that there is a general right to refuse participation in research altogether); see also *Schloendorff v. New York Hosp.*, 211 N.Y. 125, 129–30 (1914) (stating, in the context of a surgery performed without informed consent, that "[e]very human being of adult years and sound mind has a right to determine what shall be done with his own body").

127. See *supra* notes 24–29 and accompanying text (examining PXE International's success in contracting for a share of profits from tissue research).

128. OWNERSHIP OF HUMAN TISSUES AND CELLS, *supra* note 19, at 55. Mr. John Moore was unusual in that a highly profitable cell line was developed solely from his tissue. See *supra* Part II.A and accompanying text (describing the unique nature of Moore's tissue).

129. OWNERSHIP OF HUMAN TISSUES AND CELLS, *supra* note 19, at 55; see also *supra* note 36 and accompanying text (noting that Canavan research is an example of scientific experimentation involving thousands of individual specimens).

130. Heidt, *supra* note 34, at 711 (citing OWNERSHIP OF HUMAN TISSUES AND CELLS, *supra* note 19, at 54). Professor Heidt seems to suggest that a research participant is even less entitled to compensation when his tissue did not "constitute any physical part of the end product," but then acknowledges that this approach is rather arbitrary. *Id.* at 711–712. Indeed, any

however, researchers would adapt to a legal regime that accords research participants property rights in their tissue by negotiating with each putative participant in advance,¹³¹ thereby strengthening the law of informed consent.¹³² Furthermore, should judicial calculation of damages prove necessary pursuant to a liability rule, "mere difficulty in ascertaining damages is not a basis for denying them," as explained by a federal court that awarded a researcher both compensatory and punitive damages on his conversion claim after a rival scientist destroyed his cell line, which was part of a valuable research project.¹³³

Speaking purely in terms of economic efficiency, facilitating the ability of research participants to negotiate for compensation in exchange for their tissue

calculation of damages should depend upon the *value* of the research participant's contribution, including educational benefit to the researcher, rather than hinging upon whether such tissue constitutes some part of a physical end product.

131. *Id.* at 712 (theorizing that "measurement problems should diminish in the face of a clear rule recognizing the patient's right to share, because researchers would react to that rule by negotiating the patient's share at the time of the collection," but concluding that transaction costs would nonetheless stifle innovation). While Heidt alludes to the unseemliness of bedside negotiations between doctor and patient, *id.*, which could impair feelings of trust between them, Harrison, *supra* note 34, at 91, it is important to note that a patient is even more likely to feel exploited if everyone else profits from her tissue while she cannot. See *supra* note 94 and accompanying text (citing academic support for the proposition that altruistic individuals might feel cheated if others are paid). Moreover, as explained by one commentator:

The relationship is already a contractual one, however, and not merely a humanitarian one. The physician agrees to treat the patient for a certain fee. If the fee is too high, theoretically the patient will go elsewhere or possibly discuss a fee reduction, which is itself adversarial bargaining. The only added element due to requiring disclosure of research and potential monetary interests is that such face-to-face bargaining is *likely* to occur. This adversarial confrontation does not itself indicate an absence of trust, however, because it is at least forthright. A calculated deception by which the doctor profits secretly from his patient would do much more harm to the trust relationship, when discovered, than would a straightforward bartering session.

Ivey, *supra* note 31, at 511-12.

A diminution of the trust between physician and patient also raises serious public health concerns, because the unspoken fear that the physician plans to profit from the patient's tissue might render the patient less likely place confidence in the physician and heed his medical advice, or might even render the patient reluctant to seek medical care in the first place. Cf. Rochelle Graff Salguero, Note, *Medical Ethics and Competency to Be Executed*, 96 YALE L.J. 167, 183 (1986) ("The state's interest in protecting the public health requires it to ensure both the availability of competent, ethical physicians, and a population with sufficient trust in physicians to avail themselves of medical care.").

132. *Moore v. Regents of the Univ. of Cal.*, 793 P.2d 479, 494 (Cal. 1990) (conceding that "the threat of liability for conversion might help to enforce patients' rights [of informed consent] indirectly").

133. *United States v. Arora*, 860 F. Supp. 1091, 1100 (D. Md. 1994), *aff'd*, 56 F.3d 62 (4th Cir. 1995).

might actually stimulate more productive biomedical research. Our current system, which permits many researchers to obtain biological materials for nominal cost, fails to allocate these materials to the highest bidder, who presumably would put them to their most efficient use.¹³⁴ While Professor Gold argues persuasively that market analysis proves an inappropriate means of valuing human tissue because of the significant nonmarket value inhering in such material from the perspective of the research participant,¹³⁵ this analysis does not settle the question. It is clear that at present the biomedical industry rests firmly upon free market principles,¹³⁶ and that the creation of a nonprofit, nongovernmental organization to control valuable tissue, as envisaged by Professor Gold,¹³⁷ is unlikely.¹³⁸ Thus, in allocating property rights among researchers, it is logical to rely upon the market system in order to ensure that the tissue goes to the user who values it most highly and will, it is hoped, use it most productively.

b. The Issue of Shared Control over the Products of Biomedical Research

Critics of any system that accords research participants property rights in their tissue also fear that research participants will wish to control the licensing of the intellectual property created using their tissue, thereby leading to suboptimal use of the technology. This argument conflates, however, the notions of property rights in human tissue and ownership of the intellectual property developed from that tissue. Pursuant to federal patent law, only the person holding the patent possesses the exclusive right

134. RICHARD A. POSNER, *THE ECONOMICS OF JUSTICE* 71 (1981) (stating that property rights ought to be allocated to those individuals who value them at the highest dollar amount).

135. See Richard Gold, *Owning Our Bodies: An Examination of Property Law and Biotechnology*, 32 *SAN DIEGO L. REV.* 1167, 1242–46 (1995) (examining *Moore* while concluding that property law does not address appropriately the concerns raised by biotechnology issues). The expanded doctrine of informed consent set forth in this Article, *supra* notes 113–20 and accompanying text, respects the wishes of putative research participants who ascribe a very high nonmarket value to their tissue and therefore prefer not to sell it in many or all circumstances.

136. See Mahoney, *supra* note 29, at 166 (stating that "markets in human biological materials not only exist but are for all practical purposes unavoidable"); see also *supra* note 90 (describing the market in human tissue used for research).

137. See Gold, *supra* note 135, at 1246–47 (outlining an alternative to placing the property rights either with the patient or the researchers).

138. See Mahoney, *supra* note 29, at 199–200 (noting the "dearth of serious proposals to remove human tissue from the realm of commercial activity" and contending that "true non-commodification of human biological materials represents a radical position, one with no public supporters").

to make, use, or sell the invention,¹³⁹ or to license that property to others.¹⁴⁰ Implementation of a law according research participants a property interest in their tissue would not ipso facto supplant federal patent law. Indeed, absent any finding of joint inventorship,¹⁴¹ a research participant has no more right to control the intellectual property developed from her tissue than would the person who supplied chemical reagents to the researchers. Rather, federal law would simply recognize the research participant's right to negotiate for compensation for her tissue, and also her right to receive remuneration under a liability rule where she has neither negotiated for nor expressly or impliedly waived her rights to payment. In such liability cases, damages would depend upon the characteristics of the tissue, the profit earned by researchers, and whether the researchers acted in good faith, as opposed to concealing information from the research participant.¹⁴² With respect to the right to *control the intellectual property* developed from human tissue, however, Congress could provide that a research participant must negotiate directly for such rights with her biomedical researchers, as PXE International has done.¹⁴³

Notably, more than one commentator has expressed concern that research participants might condition their consent to research upon scientists' promise that "the patient's cells only be used in research designed to benefit certain races" or social groups.¹⁴⁴ This argument is not compelling, however, because not only research participants, but also

139. 35 U.S.C. § 154(a)(1) (2000).

140. *Id.* § 261.

141. Federal patent law sets forth the basic requirements for joint inventorship. See 35 U.S.C. § 116 (2000) (defining the requirements for joint inventorship). Case law has defined a joint inventor as one who contributes to the "conception of the invention." *Ethicon, Inc. v. United States Surgical Corp.*, 135 F.3d 1456, 1460 (Fed. Cir. 1998). "Conception is the 'formation in the mind of the inventor, of a definite and permanent idea of the complete and operative invention, as it is hereafter to be applied in practice.'" *Hybritech Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 1376 (Fed. Cir. 1986) (quoting 1 ROBINSON ON PATENTS 532 (1890)).

142. Where researchers did not act in good faith, courts could consider, as an equitable remedy in exceptional cases, permitting tissue contributors to participate in the decision-making process with respect to the licensing of the intellectual property developed from their tissue. See *infra* text accompanying note 389 (explaining further this possible approach).

143. See *supra* notes 24–28 and accompanying text (discussing PXE International's contract with researchers).

144. Heidt, *supra* note 34, at 718; see also Children's Hospital's Memorandum in Support of Their Motion to Dismiss Complaint, Case No. 00-C-6779 (N.D. Ill. 2000), at 15 (suggesting that a hypothetical tissue contributor might dictate that a genetic test "be made available only to people whose lifestyle he approved") (on file with the Washington and Lee Law Review) [hereinafter Children's Hospital's Motion to Dismiss].

scientists themselves, might exhibit such prejudices. Moreover, federal antidiscrimination law is the appropriate means for dealing with such issues if they arise, and could be amended, if necessary, for this purpose.

As demonstrated by the foregoing discussion, proponents of the market-inalienability model overestimate the negative impact that recognition of the property rights of human research participants would have on biomedical research. In addition, they fail to consider fully that research participants contribute considerable value to the research process, and therefore merit compensation.

2. Considerations of Equity Militate in Favor of a System That Compensates Research Participants for Their Involvement in Furthering Biomedicine

Another principle underlying the market-inalienability model is the notion that the biotechnology industry is entitled to reap all of the pecuniary rewards flowing from its inventive work, because its endeavors require significant investment of capital, labor, and time, and offer only a small likelihood of success.¹⁴⁵ In *Moore*, for example, the Supreme Court of California held that the plaintiff did not possess any property interest in the patented cell line and the products derived therefrom because the patent awarded by the United States Patent and Trademark Office (PTO) demonstrated that the cell line was the product of invention created by the researchers alone.¹⁴⁶ According to this view, research participants do not merit any share in the wealth because they simply supply the naturally occurring raw materials. By contrast, researchers employ skill and ingenuity to transform these materials into marketable products.

While it is true that research participants do not fit within the definition of a joint inventor,¹⁴⁷ this fact should not operate to deprive them of any property

145. See *supra* note 86 and accompanying text (outlining the costs associated with biotechnology research and development).

146. See *Moore v. Regents of the Univ. of Cal.*, 793 P.2d 479, 493 (Cal. 1990) (noting that it is "inventive effort that patent law rewards, not the discovery of naturally occurring raw materials," and that "Moore's allegations that he owns the cell line and the products derived from it are inconsistent with the patent, which constitutes an authoritative determination that the cell line is the product of invention").

147. See *supra* note 141 (presenting the requirements for joint inventorship); see also OWNERSHIP OF HUMAN TISSUES AND CELLS, *supra* note 19, at 71 (stating that "patients and research subjects who contribute cells to research will not be considered inventors").

rights whatsoever in the valuable raw materials that they supply. As Justice Mosk observed in his vigorous dissent in *Moore*:

[N]o one can question Moore's crucial contribution to the invention—an invention named, ironically, after him: but for the cells of Moore's body taken by defendants, *there would have been no Mo cell line . . .* [F]or all their expertise, defendants do not claim they could have extracted the Mo cell line out of thin air.¹⁴⁸

Because human tissue is just as indispensable in the research process as chemical reagents and other equipment used in scientific research, research participants are no less deserving of compensation than the suppliers of these materials.¹⁴⁹ In fact, researchers' obligation to remunerate their research

148. *Moore*, 793 P.2d at 511 (Mosk, J., dissenting); see also Roy Hardiman, *Toward the Right of Commerciality: Recognizing Property Rights in the Commercial Value of Human Tissue*, 34 UCLA L. Rev. 207, 209 & n.6 (1986) (explaining that "human cells are indispensable to the creation and production of human biologics" and that biotechnologists "must start with a living cell as the raw material").

149. Commentators often analogize human tissue used in biomedical research to natural resources. For example, the appellate court in *Moore* offered the example of a farmer who pays an oil refinery company to remove from his land crude oil that is ruining his crop. According to the court, "the farmer, who would be unable without the refinery's aid to turn the crude oil into a usable commodity, is still entitled to a share of the refinery's profits from his land's product." *Moore v. Regents of the Univ. of Cal.*, 249 Cal. Rptr. 494, 507 n.13 (Cal. Ct. App. 1998) (citing Rorie Sherman, *The Selling of Body Parts*, NAT'L L.J., Dec. 7, 1987, at 1); see also Knoll v. Delta Dev. Co., 218 So. 2d 109, 111 (La. Ct. App. 1969) (holding that willful trespassers who converted timber to their own use were liable to plaintiff for the market value of the converted product, and stating in dicta that even a trespasser in good faith who cuts down timber believing it to be his would be liable to the owner for the stumpage value, but not the value of the converted products).

Professor Heidt has argued that a party who locates natural resources on the land of another has no duty to disclose material information about which it knows the other party is mistaken. See Heidt, *supra* note 34, at 674–75 & n.26 (citing "powerful precedent" for allowing nondisclosure). In support of this proposition he invokes the 1969 decision of the Ontario High Court of Justice in *Leitch Gold Mines Ltd. v. Texas Gulf Sulphur Co.*, [1969] 3 D.L.R. (3d) 161, 184–85 (Ont. H.C.J.) (implying that the defendant mining company, which had purchased land containing mineral deposits for a price far below its true value, was under no common law obligation to disclose to land owners information regarding the value of their land that the company had obtained through aerial surveys). This case proves inapposite, however, when considering whether research participants merit compensation for their tissue used in research. First, the parties in *Leitch* had an arm's length relationship, whereas a fiduciary relationship exists between a researcher and the research participant, at least to the extent that the researcher deals directly with the participant. See *supra* note 76 and accompanying text (describing fiduciary duty as outlined in *Moore*). Second, the defendant in *Leitch* obtained its information as to the value of plaintiff's land via aerial surveys and therefore never encroached upon plaintiff's land, whereas direct physical contact with a research participant's body is necessary in order to obtain human tissue. Finally, unlike the plaintiff in *Leitch*, a research participant often is not even aware that she is conveying anything at all of value to a researcher, and therefore is not in a position to investigate the value of what she provides. See *supra* note 44

participants arises at the moment when the researchers begin to use that tissue, even if a patent is never issued. In the *Moore* case, for example, where researchers put Mr. Moore's tissue to productive use for more than seven years before their patent was issued, the patent should not be understood to "operate retroactively to immunize defendants from accountability for conduct occurring long before the patent was granted."¹⁵⁰ Surely, as stated by Justice Mosk, "a patent is not a license to defraud."¹⁵¹

In cases where a research participant sues for conversion, federal law should provide that the fact-finder consider researchers' skill and efforts in altering and enhancing the value of the tissue in calculating the damages, if any, owed to the plaintiff. This approach is more equitable than denying research participants any share whatsoever in the profits from the commercial products developed from their tissue.¹⁵² Ultimately, the development of a market in human tissue would see the emergence of market prices for various human tissues.

Those who oppose compensation of research participants for their tissue also contend that it is unfair for an individual to enjoy a windfall simply because he happens to possess tissue that is valuable to researchers, especially when the health of all members of society depends upon biomedical innovations developed through the use of such tissue. Property rights already inhere, however, in that which we did not earn. As explained by one commentator:

and accompanying text (noting that many patients are not aware of the potential value of their medical waste).

The further argument that research participants somehow abandon their tissue when researchers remove it from their body is without merit in cases where research participants do not receive informed consent as to the commercial potential of that tissue. *See supra* note 31 and accompanying text (discussing the implications of informed consent in the *Moore* case); *see also* Hardiman, *supra* note 148, at 242–44 (contending that the relationship between a patient and his physician with respect to tissue removed for therapeutic purposes is one of bailment, rather than abandonment). The doctrine of informed consent suggests that there is a presumption against abandonment, and that a research participant should retain rights in his tissue absent an express waiver.

150. *Moore*, 793 P.2d at 511 (Mosk, J., dissenting).

151. *Id.* at 512.

152. *Moore v. Regents of the Univ. of Cal.*, 249 Cal. Rptr. 494, 507 (Cal. Ct. App. 1998) ("The complaint alleges that defendants exploited plaintiff's cells, not just the knowledge gained from them. Without these small indispensable pieces of plaintiff, there could have been no three billion dollar cell-line."); *see also Moore*, 793 P.2d at 503 (Broussard, J., dissenting in part) ("Although the damages which plaintiff may recover in a conversion action may not include the value of the patent and the derivative products, the fact that plaintiff may not be entitled to all of the damages which his complaint seeks does not justify denying his right to maintain any conversion action at all.").

In our present society . . . people can freely exploit their natural beauty, talent or scientific genius, and can even be paid for material contributions to a blood or sperm bank for purposes other than research. Unless current conditions change, an argument based on equality cannot justify denying payment to contributors of tissue samples for research.¹⁵³

Research participants also merit property rights in their genetic material because, like the scientists themselves, participants face risks associated with biomedical research. While the scientists' risks are primarily financial, research participants must contend with the potential for harm resulting from the medical procedures they undergo in the experimentation process, the loss of privacy, the dangers of negative consequences from the release of their medical information, and the risk of learning emotionally disturbing information about their health.¹⁵⁴

While research participants may garner some benefit from their scientific participation, this is not reason enough to exclude them from any share in the profits from products created from their tissue. The notion that research participants merit no compensation other than the chance to consume the diagnostics and therapeutics developed from research on their tissue found expression in the comments of Fima Lifshitz, chief of medical staff at Miami Children's Hospital, who was quoted as declaring, in response to the lawsuit initiated by the *Greenberg* plaintiffs, that "[t]he issue should be quenched [sic] at once because these people are going to derive a great deal of benefit from this. They shouldn't be complaining."¹⁵⁵ The reality, of course, is that research participants often do not derive direct benefit from the experimentation on their tissue, either because such research does not lead to a successful product; because medical advances arrive too late to help individuals who had participated in the research at an earlier stage, as was the case for many of those who contributed tissue to the Canavan research effort; or because the research participants are not directly affected by the disease being studied but, instead, simply wish to assist a research effort for which their tissue could be useful. Moreover, the potential for medical benefit from research is not reason enough to deny any compensation whatsoever to research participants who contribute valuable tissue to medical research. Just as a research scientist might derive both professional prestige and pecuniary gain from a patented product, so might

153. Harrison, *supra* note 34, at 79; see also *supra* note 80 (explaining that sales of sperm, blood, and hair are widely accepted).

154. Harrison, *supra* note 34, at 92 (noting the psychosocial risks associated with being a research subject).

155. Karen Rafinski, *Hospital's Patent Stokes Debate on Human Genes*, MIAMI HERALD, Nov. 14, 1999, at 1A.

a research participant benefit both financially and physically from her research contributions.

The issue of the equitable distribution of the profits from biomedical products developed through the use of human tissue has practical as well as moral consequences. Widespread public perception that the current system is unfair will not only lead to mistrust between patients and doctors¹⁵⁶ and a general decrease in research participation,¹⁵⁷ but could also cause an overall decline in public and, therefore, government, support of such research.¹⁵⁸ Thus, considerations of equity militate in favor of acknowledging a research participant's property rights in her tissue. Nevertheless, such an approach raises complex moral, ethical, and religious questions about commodification of the human body.

3. *Recognition of Property Rights in Human Tissue Would Neither Commodify Human Beings nor Erode Notions of Community*

While the *Moore* majority did not address the moral, ethical, and religious issues raised by a potential property interest in the human body, Justice Arabian did do so in his separate concurring opinion. In rejecting Mr. Moore's claim, Justice Arabian declared:

Plaintiff has asked us to recognize and enforce a right to sell one's own body tissue *for profit*. He entreats us to regard the human vessel—the single most venerated and protected subject in any civilized society—as equal with the basest commercial commodity. He urges us to commingle the sacred with the profane. He asks much.¹⁵⁹

Justice Arabian did not, however, assert that under no circumstances should the law recognize a property right in human tissue. Rather, he even spoke approvingly of a "licensing scheme" establishing "a fixed rate of profit sharing"

156. See *supra* note 131 (contending that deception or a lack of ability to share in profits will lead to research subjects' distrust of doctors).

157. See *supra* note 94 and accompanying text (speculating that research participation would decline if patients began to feel cheated).

158. Cf. Heidt, *supra* note 34, at 697–98 (stating, notwithstanding his support of the right of biomedical researchers searching for valuable cells to deceive research participants in certain situations, that the law's acceptance of such deception could possibly dissuade those who currently support biomedical research both financially and through other volunteer efforts from maintaining such support).

159. *Moore v. Regents of the Univ. of Cal.*, 793 P.2d 479, 497 (Cal. 1990) (Arabian, J., concurring).

between researcher and participant, and suggested that the legislature is the proper forum for consideration of such a regime.¹⁶⁰

Some commentators warn, however, that legislative recognition of the property rights of individual research participants in their tissue would both commercialize and commodify the human body.¹⁶¹ Professors Andrews and Nelkin suggest chilling possibilities, such as a man being denied welfare because of the value of his kidney, or a woman's eggs being harvested to pay for her hospital bill.¹⁶² Professor Radin raises the specter of the government exercising its power of eminent domain to declare certain organs public property.¹⁶³ Congress also has evinced concern about the commercialization of human body parts through enactment of federal legislation prohibiting the purchase and sale of human organs for transplantation.¹⁶⁴

Professor Mahoney responds that such arguments regarding the dangers of commercialization of human tissue fail to consider that "[p]roperty is a flexible

160. *Id.* at 498 (Arabian, J., concurring) (citing with approval a profit-sharing proposal advanced by Danforth, *supra* note 35, at 198–201).

161. *See* Rao, *supra* note 34, at 365 n.15 (citing an extensive listing of scholarly articles advocating against (and also in favor of) recognizing property rights in the human body).

162. *See* ANDREWS & NELKIN, *supra* note 44, at 165 (offering a series of hypothetical scenarios stemming from the concern that if a property right in body tissue is established others might also view that tissue with property value in mind).

163. *See* MARGARET JANE RADIN, REINTERPRETING PROPERTY 156 (1993) (querying "If we conceive of the body as property, can kidneys be condemned for public use?").

164. *See* National Organ Transplant Act (NOTA), 42 U.S.C. §§ 273–274e (2000) (criminalizing the transfer of human organs for valuable consideration if that transfer "affects interstate commerce" and the organ is to be used as a transplant); *see also supra* notes 34 & 36 and accompanying text (describing the scope of the NOTA and the role of states in regulation of this area). Of course, there are critical distinctions between the sale of solid human organs for transplantation on the one hand and, on the other hand, the sale for research purposes of human tissue that is either (1) regenerative; (2) not necessary for health; or (3) removed from the research participant for diagnostic or therapeutic purposes. First, while the removal of a solid organ presents significant risks to the donor, excision of the three types of tissue listed immediately above does not, and in the case of the third example is even medically necessary for the health of the tissue contributor. This distinction forms the basis for state laws that bar commerce in transplantable human organs but permit the sale of regenerative human tissue. *See supra* note 34 (observing that state laws generally do not prohibit the sale of blood, regenerative tissue, or other renewable biological materials). Second, because a patient in need of an organ transplant typically faces imminent death, there are obvious ethical reasons for forbidding bargaining in this context, such as the possibility that high-income patients will bid up the prices of human organs beyond the reach of middle- or low-income people. By contrast, the law does not have the same interest in procuring for researchers human tissue samples free of charge. Certainly, society benefits to the extent that research scientists can obtain access to human tissue at low cost, but the relationship between such research and the preservation of life is more attenuated. In the purely research setting, it is justifiable to attach greater weight to the property rights of the tissue contributor.

concept, not an all-or-nothing one,"¹⁶⁵ and that the existence of heavily regulated markets such as the one in securities demonstrates that "the choice is not between a completely unrestricted exchange system on the one hand and a total absence of commercial activity in human tissue on the other."¹⁶⁶ The sale and purchase of human tissue for research would be appropriate for regulation by federal agencies such as the Department of Health and Human Services and Food and Drug Administration. What is more, federal law could be formulated to provide that an individual who declares bankruptcy is entitled to retain his biological property if he chooses, much as the bankruptcy laws in many states permit a debtor to retain his Bible and other family treasure as well as the tools of his trade, in recognition of their uniqueness.¹⁶⁷

Furthermore, warnings about the dangers of recognizing a property interest in human tissue presuppose that such tissue is not yet commodified. It is clear, however, that biomedical advances have already resulted in unprecedented commercialization of the human body, and both researchers and shareholders in biotech firms routinely profit from this process. In the *Moore* case, for example, where the plaintiff alleged that the defendants could expect profits of over three billion dollars from their research on his tissue,¹⁶⁸ the appellate court declared that the researchers' position that "plaintiff cannot own his tissue, but that they can, is fraught with irony."¹⁶⁹ Indeed, human tissue provided gratuitously can be exploited for its financial value once it has been taken from the donor and stored in a secondary repository.¹⁷⁰ In addition, a thriving commercial market already exists in blood and gametes.¹⁷¹

165. Mahoney, *supra* note 29, at 202 (footnote omitted).

166. *Id.* at 204.

167. See G. Marcus Cole, *The Federalist Cost of Bankruptcy Exemption Reform*, 74 AM. BANKR. L.J. 227, 228 (2000) (observing that debtor property exemption statutes generally exclude property from the bankruptcy estate that is "deemed necessary for an individual debtor's normal economic functioning" and "thought necessary for a new beginning").

168. See *supra* note 70 and accompanying text (noting the market potential of the products that were derived from Moore's cell line).

169. *Moore v. Regents of the Univ. of Cal.*, 249 Cal. Rptr. 494, 507 (Cal. Ct. App. 1998).

170. See Mahoney, *supra* note 29, at 175 ("Although the initial transferors (e.g., donors of solid organs, patients who agree to provide tissue to be used in medical research) may be spurred solely by beneficence, subsequent transferors (e.g., transplant programs, pharmaceutical companies) often are not."). See generally ANDREWS & NELKIN, *supra* note 44 (describing the market for human tissue).

171. See *supra* note 80. Scholars have described the U.S. market for gametes as follows:

Payment for sperm and eggs, referred to separately and together as "gametes," is widespread in American clinical infertility programs. A large market for sperm donation has existed for many years, and a market for eggs for IVF [in vitro fertilization] programs is now flourishing. This market involves direct solicitation

In any event, the mere fact that markets do exist for various types of human biological materials does not dictate that market prices are the only measure of their worth. It is possible to place a price tag on something without that price being the only measure of its value. According to Professor Maguire Shultz:

Many things that partake of the monetary economy also involve aspects of life that are deeply revered. We buy a wedding ring or a home but its personal worth is not equated with its price. Doctors deal with the creation, sustenance and termination of life. We do not expect the fees we pay them to capture all of their meaning and importance to us. Neither do we deny them the capacity to get monetary recognition for their work. Similarly, we appraise a couple's ability to sustain the costs of raising a child when we decide whether they are fit adoptive parents. We award child support when a divorce occurs; we assess damages for the costs of raising a child born because of a negligent diagnostic test, or for an untimely death in a wrongful death action. We are not confused about whether these financial representations adequately sum the value of the lives or relationships in question. We simply say that money is one dimension of human interaction and valuing. The critical issue is not whether something involves monetary exchange as one of its aspects, but whether it is treated as reducible solely to its monetary features.¹⁷²

Analogously, life insurance "initially provoked condemnation but has come to enjoy broad social acceptance."¹⁷³ This perspective challenges the Kantian notion that pricelessness is the hallmark of dignity.¹⁷⁴

of women donors through student newspapers and bulletin boards and arranged transactions through egg brokers Sperm donors receive roughly \$50, and egg donors, \$2000 per donation.

Ann Alpers & Bernard Lo, *Commodification and Commercialization in Human Embryo Research: The Absence of National Standards Sets the United States Apart from Other Western Nations*, 6 STAN. L. & POL'Y REV. 39, 41 (1995). Professor Mahoney has explained that, although providers of gametes are termed "donors," they are routinely offered financial compensation for their biological material. See Mahoney, *supra* note 29, at 186 (arguing that donor is a misleading moniker for a person who exchanges gametes for money). She has pointed out that payments to women for their ova have generated far more controversy than payments to men for their sperm because egg donors are expected to harbor altruistic rather than financial motives, notwithstanding the fact that removal of ova is much more invasive than the process by which men provide sperm. See *id.* at 188-89 (noting the current re-examination of payment for sperm donation in light of the negative reaction to payment for egg donation).

172. Marjorie Maguire Shultz, *Reproductive Technology and Intent-Based Parenthood: An Opportunity for Gender Neutrality*, 1990 WIS. L. REV. 297, 336 (1990) (footnote omitted).

173. Mahoney, *supra* note 29, at 212 n.166.

174. See IMMANUEL KANT, *GROUNDWORK OF THE METAPHYSIC OF MORALS* 96 (H.J. Paton trans., Hutchinson & Co. 1972) ("In the kingdom of ends everything has either a *price* or a *dignity*. If it has a price, something else can be put in its place as an equivalent; if it is exalted above all price and so admits of no *equivalent*, then it has a *dignity*."); see also *House Hearing*,

Indeed, fixing a price for human tissue might actually enhance its dignity.¹⁷⁵ As Professor Maguire Shultz stated in advocating for the rights of private parties to contract for maternal surrogacy services:

Efforts sharply to segregate money and values are frequently regressive in effect. "Either/or" thinking rarely captures the complexity or nuance of human reality. Nor does experience suggest that the more we value something, the less we entangle it with money. In fact, there is a strongly competing truism suggesting that that which we reward with money is that which we value.¹⁷⁶

In addition, it is overly simplistic to conceive of the recognition of the property rights of research participants as commodification of the human body. Courts and scholars have noted that the concept of property law actually rests upon the notion of a "bundle of rights," including the rights to "possess, to use, to exclude, to profit, and to dispose."¹⁷⁷ Thus, according to Professors Litman and Robertson, the issue of property rights in human tissue ought to be framed in terms of control:

supra note 53, at 120 (statement of Dr. Thomas H. Murray, Institute for the Medical Humanities, University of Texas Medical Branch) (noting "the deep conviction that the body and its parts are somehow different from other things, central to our dignity as human beings . . . [and] should not be for sale").

175. See Mahoney, *supra* note 29, at 205 ("Indeed, requesting compensation commensurate with one's market 'worth' can be construed as an expression of self-respect.").

176. Maguire Shultz, *supra* note 172, at 336 (footnote omitted). Maguire Shultz cites as an example the fact that, in the marketplace, occupations that society views as altruistic "'women's work' (nursing, child care, teaching, etc.) are paid far lower wages than traditionally male work, even where the skills and required credentials are equal to or higher than those of traditionally masculine jobs." *Id.* at 336 n.117.

177. *Brotherton v. Cleveland*, 923 F.2d 477, 481 (6th Cir. 1991) (holding that removal of decedent's corneas without permission of next-of-kin constitutes deprivation of a constitutionally protected possessory interest); see also *Moore v. Regents of the Univ. of Cal.*, 249 Cal. Rptr. 494, 504 (Cal. Ct. App. 1998) ("As a matter of legal definition, 'property' refers not to a particular material object but to the right and interest or domination rightfully obtained over such object, with the unrestricted right to its use, enjoyment and disposition [T]hus 'property' is nothing more than a collection of rights.") (quoting 63A AM. JUR. 2D *Property* § 1); Litman & Robertson, *supra* note 33, at 62 (defining property as "the bundle of rights, powers, immunities, privileges, and obligations that give specific expression to the right of control . . . includ[ing] the right of possession, the right of exclusion, the power of alienation (including the right to sell, exchange, make gifts etc.), the liberty to use, enjoy, and manage, the right of destruction and injurious use, and the right to the fruits and profits produced by the object of property") (citing Roscoe Pound, *The Law of Property and Recent Juristic Thought*, 25 A.B.A. J. 993, 996 (1939)); STEPHEN R. MUNZER, A THEORY OF PROPERTY 44-56 (1990) (recognizing the "bundle of rights" theory to the extent that rights in the human body should be considered limited property rights rather than full ownership).

[I]f property is viewed more accurately, in terms of control over one's body, these criticisms [regarding commodification of the human body] may be inapt. If property confers exclusive control to people over their own bodies, then their dignity is enhanced, not diminished. Indeed, as a general proposition, the greater the control conferred on individuals in relation to their bodies, the greater the respect that is being accorded to individuals.¹⁷⁸

Justice Broussard emphasized in his separate opinion this right of control, suggesting that the "pertinent inquiry is not whether a patient generally retains an ownership interest in a body part after its removal from his body, but rather whether a patient has a right to determine, before a body part is removed, the use to which the part will be put after removal."¹⁷⁹

Certainly, if we assume that human tissue will generate profit in our society, then our notions of individual autonomy militate in favor of according the individual the power to control what becomes of that tissue. As the lower court emphasized in *Moore*, to decide otherwise "would open the door to a massive invasion of human privacy and dignity in the name of medical progress."¹⁸⁰ This is especially true when the parties possess unequal bargaining power, a circumstance recognized by the courts.¹⁸¹ Biomedical researchers possess scientific information about the value of body tissue and their designs to obtain a patent that their research participants do not possess.

178. Litman & Robertson, *supra* note 33, at 60.

179. *Moore v. Regents of the Univ. of Cal.*, 793 P.2d 479, 501 (Cal. 1990) (Broussard, J., dissenting in part). As explained by Professors Litman and Robertson, "the manner in which the issue is framed can affect the resolution of the issue," Litman & Robertson, *supra* note 33, at 59, and in the California Supreme Court decision in *Moore*, "Justice Arabian's approach is to compare objects," *see supra* note 159 and accompanying text (explaining the intellectual foundation of Justice Arabian's opinion), "whereas Justice Broussard focuses on the question of right of control." Litman & Robertson, *supra* note 33, at 59 n.31.

180. *Moore v. Regents of the Univ. of Cal.*, 249 Cal. Rptr. 494, 508 (Cal. Ct. App. 1998). The lower court analogized a plaintiff's right to control and capitalize upon his tissue to his entitlement to do likewise with his persona, including his name and likeness, *id.*, a right protected under California statutory law. *See CAL. CIV. CODE* § 3344(a) (West 1997) (providing for damages where "[a]ny person . . . knowingly uses another's name, voice, signature, photograph, or likeness, in any manner, on or in products, merchandise, or goods, or for purposes of advertising or selling, or soliciting purchases of, products, merchandise, goods or services, without such person's prior consent"). According to the lower court in *Moore*, "[i]f the courts have found a sufficient proprietary interest in one's persona, how could one not have a right in one's own genetic material, something far more profoundly the essence of one's human uniqueness than a name or face." *Moore*, 249 Cal. Rptr. at 508.

181. *See, e.g., Canterbury v. Spence*, 464 F.2d 772, 780 n.14 (D.C. Cir. 1972) ("Patients ordinarily are persons unlearned in the medical sciences . . . [and] it is only in the unusual case that a court could safely assume that the patient's insights were on a parity with those of the treating physician."); *Moore*, 793 P.2d at 516 (Mosk, J., dissenting) (stating that "the parties are not in equal bargaining positions").

Moreover, research participants are often concerned about a disease affecting themselves or their loved ones and therefore may feel particularly vulnerable during the bargaining process.¹⁸²

Some contend that research participants can receive adequate protection of their dignitary interests under the *Moore* holding, which provides that physician-researchers who take an economic interest in their patients are subject to a duty of informed consent and also a fiduciary duty to disclose this information.¹⁸³ Nevertheless, these common law doctrines prove insufficient in several respects to protect the autonomy and dignity of research participants.

4. *The Doctrines of Informed Consent and Breach of Fiduciary Duty Prove Inadequate to Protect Research Participants' Interests in Dignity and Autonomy*

The doctrines of informed consent and breach of fiduciary duty, as they have been interpreted traditionally and were set forth in *Moore*, prove inadequate in four major respects to protect research participants' interests in their autonomy and dignity. This statement would prove true even if the Supreme Court of California's decision in *Moore*, which is binding precedent only in California, were to be adopted on a national scale.¹⁸⁴

First, the *Moore* court itself undermined its holding by stating that "[i]n some cases, . . . a physician's research interest might play such an insignificant role in the decision to recommend a medically indicated procedure that disclosure should not be required because the interest is not material."¹⁸⁵ As noted by one commentator, this qualification by the *Moore* court "abolishes a

182. For a discussion of the propriety of permitting bedside negotiations between physician and patient/research participant in the first place, see *supra* note 131.

183. See *supra* note 76 and accompanying text (describing the duty the *Moore* court placed on doctors to disclose monetary and nonmonetary interests they might have in a patient's biological material). Professor Krause has noted, however, that the opinion of the Supreme Court of California in *Moore* actually "came at the motion to dismiss stage, and holds only that *Moore* stated a cause of action for breach of the physician's disclosure obligations; it does *not* indicate whether he would have prevailed at trial on this theory." Joan H. Krause, *Reconceptualizing Informed Consent in an Era of Health Care Cost Containment*, 85 IOWA L. REV. 261, 340 (1999). Research revealed no published decision from any such trial.

184. Research did not reveal any state statute or, aside from *Moore*, any judicial decision relating to informed consent or fiduciary duty that held *specifically* that physicians or researchers are obliged to divulge to their research participants their economic interests in research participants' tissue.

185. *Moore v. Regents of the Univ. of Cal.*, 793 P.2d 479, 485 n.9 (Cal. 1990).

uniform standard of disclosure" by introducing an ambiguous "materiality" standard and then fails to specify whose definition of materiality will apply.¹⁸⁶

Second, the doctrines of informed consent and breach of fiduciary duty protect only those research participants involved in a physician-patient relationship with the researchers. As stated by Professors Alpers and Lo:

[T]he *Moore* decision leaves large groups of patients unprotected and large groups of profit-makers unregulated. The doctrines of informed consent and fiduciary obligation operate only within the confines of the physician-patient relationship. While informed consent is required in research on human subjects, the relationship between the researcher and subject is not a fiduciary one. The researcher need not be a physician, and even if he is, he has no fiduciary responsibility if the research subject is not his patient in the clinical sense. Furthermore, the requirements of informed consent and fiduciary responsibility, which infuse the culture of clinicians, have no sway over the activities of corporate entities engaged in biotechnological research. These requirements leave completely unregulated commercial entities which may exploit research materials for a profit.¹⁸⁷

Thus, while the doctrines of informed consent and breach of fiduciary duty required Mr. Moore's treating physician to inform Mr. Moore of the physician's economic interests in his tissue, the researchers and biotech firms with whom Mr. Moore had no therapeutic relationship faced no similar obligation.¹⁸⁸

Third, even in cases involving physician-researchers, the amount of damages available under the theories of lack of informed consent and breach of

186. Potts, *supra* note 31, at 469-70 (arguing that the inclusion of the materiality requirement guts the majority rule of the *Moore* case and hinders its application).

187. Alpers & Lo, *supra* note 171, at 43 (footnote omitted). As an example, Justice Broussard noted in his separate opinion in *Moore* that:

[I]f a patient donated his removed cells to a medical center, reserving the right to approve or disapprove the research projects for which the cells would be used, and if another medical center or a drug manufacturer stole the cells after removal and used them in an unauthorized manner for its own economic gain, no breach-of-fiduciary-duty cause of action would be available and a conversion action would be necessary to vindicate the patient's rights.

Moore, 793 P.2d at 504 (Broussard, J., dissenting in part). In an analogous situation, where a researcher intentionally destroyed a rival scientist's fully developed cell line (rather than mere tissue) which was part of a valuable research project, a federal court has already recognized the tort of conversion. See *United States v. Arora*, 860 F. Supp. 1091, 1099 (D. Md. 1994), *aff'd*, 56 F.3d 62 (4th Cir. 1995). For a discussion of the arguments in support of extending the application of the doctrines of breach of fiduciary duty and informed consent to researchers as well as treating physicians, see *supra* notes 105-06 and accompanying text.

188. See *supra* note 78 and accompanying text (explaining that the *Moore* court left it to the legislature to decide if a duty of informed consent or fiduciary duty traveled with the tissue to subsequent research).

fiduciary duty will not motivate them to disclose their financial interests. As indicated by Justice Mosk in his *Moore* dissent, in order to recover under these doctrines, which sound in negligence rather than battery, the plaintiff must prove a "causal relationship between the physician's failure to inform and the injury to the plaintiff," a connection that arises "only if it is established that had revelation been made consent to treatment would not have been given."¹⁸⁹ The reason for this requirement is that the two doctrines aim to prevent physicians' pecuniary interests from clouding their professional judgment concerning the treatment of their patients, not at protecting patients' dignitary or financial interests or their personal autonomy.¹⁹⁰ The *Moore* majority took care to emphasize this point, declaring that "[a] physician is not the patient's financial adviser," and "the reason why a physician must disclose possible conflicts is not because he has a duty to protect his patient's financial interests, but because certain personal interests may affect his professional judgment."¹⁹¹

Three years after *Moore*, the California Supreme Court clarified in *Arato v. Avedon*¹⁹² its narrow view of the scope of a physician's duty of informed

189. *Moore*, 793 P.2d at 519 (Mosk, J., dissenting) (footnote omitted). Justice Mosk noted in his dissenting opinion in *Moore* that the vast majority of jurisdictions apply an objective standard of consent, requiring the plaintiff to prove that no *reasonably prudent person* would have consented to the proposed procedure if he had been fully informed. The application of the objective standard of consent renders a nondisclosure suit "largely a paper tiger," because few plaintiffs will be able to establish that a reasonable person would decline medical treatment rather than permit commercial exploitation of his tissue. *Id.* at 519–20. Another significant problem with the objective standard, which still represents the majority rule, Krause, *supra* note 183, at 317, is that it impedes an individual's autonomy by foreclosing his ability to make an atypical medical choice. *See id.* at 319 (positing that the objective standard actually hinders a patient's freedom of personal choice in care by weighing his choice against that of a theoretical reasonable patient who might not take the same risks).

190. *See* Susan L. Goldberg, *Medical Advocates: A Call for a New Profession: A Cure for What Ails? Why the Medical Advocate Is Not the Answer to Problems in the Doctor-Patient Relationship*, 1 WIDENER L. SYMP. J. 325, 347 n.97 (1996) (declaring that the *Moore* court "was more concerned that the physicians' interests were clouding their professional judgement concerning treatment, rather than with the patient's financial interests in the sale of the cell line"). Indeed, many commentators have observed that traditionally courts have "den[ie]d recovery for inadequate disclosure in the absence of bodily harm." Alan Meisel, *A "Dignitary Tort" as a Bridge Between the Idea of Informed Consent and the Law of Informed Consent*, 16 LAW, MED. & HEALTH CARE 210, 211 (1988); *see also* Heidt, *supra* note 34, at 703 ("In most states, a violation of the doctrine [of informed consent] only gives rise to an action in negligence for injuries from the treatment."). The *Moore* court acknowledged that "questions about the validity of a patient's consent to a procedure typically arise when the patient alleges that the physician failed to disclose medical risks, as in malpractice cases, and not when the patient alleges that the physician had a personal interest," but then the court declared that "[t]he concept of informed consent . . . is broad enough to encompass the latter." *Moore*, 793 P.2d at 483.

191. *Moore*, 793 P.2d at 485 n.10.

192. *Arato v. Avedon*, 858 P.2d 598, 604–09 (Cal. 1993) (discussing the wide berth the

consent.¹⁹³ In *Arato*, family members brought an informed consent action against the decedent's physicians, alleging that the physicians' failure to disclose statistical mortality information affected the decedent's nonmedical interests. The family contended that, if the physicians had made decedent aware of his short life expectancy, he would have put his business and investment affairs in order.¹⁹⁴ The court rejected this argument, noting that:

[A]lthough an aspect of personal autonomy, the conditions for the exercise of the patient's right of self-decision presuppose a therapeutic focus The fact that a physician has "fiducial obligations" . . . which . . . prohibit misrepresenting the nature of the patient's medical condition, does not mean that he or she is under a duty, the scope of which is undefined, to disclose every contingency that might affect the patient's *nonmedical* "rights and interests."¹⁹⁵

According to Professor Krause, "[b]y focusing exclusively on *medical* interests, the *Arato* court limited *Moore* in a way that may exacerbate the problems inherent in traditional informed consent law: where a patient's health is improved at the expense of his 'non-medical' dignity interests, *Moore* will not provide relief."¹⁹⁶ Thus, the doctrines of lack of informed consent and breach of fiduciary duty are inadequate to protect the interests of research participants facing situations similar to those encountered by Mr. Moore and the *Greenberg* plaintiffs. Arguably, research participants will be left without a remedy, because the harm they suffered affected not their medical interests, but rather their dignity and autonomy.¹⁹⁷

California courts grant to doctors in informing patients and noting that the information need only concern medical issues and not the patient's nonmedical interests).

193. See *id.* at 601–02 (observing that the gravamen of the action was a supposed failure by the physician to convey the life expectancy figures for the disease to the decedent and his family prior to treatment).

194. See *id.* at 602 (relating the plaintiff's assertion that knowledge of the risks of treatment would have convinced the decedent to live out his days with his family preparing for his death and not undertaking treatment).

195. *Id.* at 608–09 (footnotes omitted).

196. Krause, *supra* note 183, at 341; see also Judith F. Daar, *Informed Consent: Defining Limits Through Therapeutic Parameters*, 16 WHITTIER L. REV. 187, 193 (1995) (stating that "the *Arato* court turned *Moore*'s broad disclosure requirement on its head, holding that where a patient's economic interests are concerned, a doctor has no duty to disclose medical information that may be relevant to those considerations because a 'physician is not the patient's financial adviser'").

197. Theoretically, such plaintiffs could recover under the theories of intentional or negligent infliction of emotional distress, because courts in most jurisdictions no longer require the plaintiff to prove physical harm in these cases, as was necessary in the past. See Meredith A. Moore, Note, *South Dakota's Interpretation of Negligent Infliction of Emotional Distress and the "Zone of Danger" Rule in Nielson v. AT&T Corporation: A Dangerous Hybrid*, 45 S.D. L.

In response to Justice Mosk's contention in his dissent in *Moore* that the remedies afforded under the theories of breach of fiduciary duty and lack of informed consent are "largely illusory" and therefore insufficient to protect the interests of research participants,¹⁹⁸ Justice Broussard suggested that, at least in a therapeutic context where treatment is successful, such as the *Moore* case, a plaintiff who did not give informed consent to research "should not be required to establish that he would not have proceeded with the medical treatment in question if his physician had made full disclosure, but only that the doctor's wrongful failure to disclose information proximately caused the plaintiff some type of compensable damage."¹⁹⁹ Thus, because the harm Mr. Moore alleged arose from the use of his cells without his permission and not from his splenectomy itself, the court should require him to prove only that he would have refused research on his tissue, not that he would have declined surgical treatment for his life-threatening leukemia.²⁰⁰ Noting that the *Moore* majority did not identify the damages Mr. Moore could recover in an action for breach of fiduciary duty, Justice Broussard indicated in his separate opinion his belief that "in appropriate circumstances, punitive as well as compensatory damages would clearly be recoverable in such an action."²⁰¹

REV. 379, 381–82 & nn.11–14 (2000) (analyzing the historical development of tort recovery for emotional distress and chronicling the decline of the physical harm test). Even in jurisdictions where the courts now recognize these torts as separate and independent, however, the law compensates only for emotional distress that is "so severe that no reasonable man could be expected to endure it." RESTATEMENT (SECOND) OF TORTS § 46 cmt. j (1965). Where bodily harm is not present, "the courts may perhaps tend to look for more in the way of outrage as a guarantee that the claim is genuine." *Id.* § 46 cmt. k (1965). It is therefore probable that, as with the tort of lack of informed consent, plaintiffs who object to researchers' unrevealed plans for their tissue but who suffer no physical harm will recover little in damages for emotional distress.

198. *Moore v. Regents of the Univ. of Cal.*, 793 P.2d 479, 519–20 (Cal. 1990) (Mosk, J., dissenting) (contending that the standard of proof in breach of fiduciary duty and lack of informed consent cases render these theories ineffective for plaintiffs seeking damages).

199. *Id.* at 500 (Broussard, J., dissenting in part).

200. See Potts, *supra* note 31, at 473–74 (arguing that Mr. Moore's splenectomy and the use of his cells after the surgery should be considered two distinct procedures, so that he need demonstrate "only that he would have refused the use or disposal of his cells," rather than facing the "much higher causation hurdle" of proving that he would have declined the splenectomy). Of course, plaintiffs would have a much more difficult time prevailing in such an action if they were aware from the outset that they were involved in biomedical research, and objected not to that process, but rather to the commercialization of the products of that research.

201. *Moore*, 793 P.2d at 500 (Broussard, J., dissenting in part). Analogously, California's Protection of Human Subjects in Medical Experimentation Act provides a maximum damages award of only \$10,000 for a willful violation that "exposes a subject to a known substantial risk of serious injury, either bodily harm or psychological harm." CAL. HEALTH & SAFETY CODE § 24176(c) (West 1992). The statute further provides that it does not "limit or expand the right of an injured subject to recover damages under any other applicable law." *Id.* § 24176(g).

Nevertheless, it remains doubtful whether courts and juries would award the damages contemplated by Justice Broussard and, if so, fix such damages at a dollar amount high enough to deter physician-researchers from breaching their duty of informed consent and their fiduciary obligation. If not, many physician-researchers simply would make the rational, albeit immoral, economic choice to use human tissue to develop commercially lucrative biotechnology products without first obtaining informed consent, rather than negotiating with research participants in advance. Certainly, without recognition of a property right in human tissue, it would not be surprising if courts and juries awarded relatively low compensatory and punitive damages, particularly when the plaintiff suffered no physical injury.²⁰² In addressing the adequacy of damages in cases such as *Moore*, Professor Bobinski has proposed more explicit reliance on the principle of unjust enrichment enshrined in fiduciary law, explaining:

If the key to the claim is the impermissible benefit to the physician rather than the actualization of risk for the patient, then unjust enrichment principles might supply the measure of damages A breach of fiduciary duty, for example, could be remedied by requiring that the fiduciary disgorge profits from an undisclosed transaction, even if the transaction also presented benefits to the entrustor.²⁰³

A significant shortcoming of this approach, however, is that the plaintiff's damages likely will prove to be quite small if a third party, such as a biotech firm, rather than the research participant's physician-researcher, reaped the bulk

202. As explained by Justice Mosk in his dissent in *Moore*, the damages available under a nondisclosure cause of action would prove limited because this legal theory fails to recognize that research participants possess not only the negative right to refuse to provide their tissue for experimentation, but also the positive right to bargain with researchers. See *Moore*, 793 P.2d at 520 (Mosk, J., dissenting) (explaining that a nondisclosure cause of action "gives the patient only the right to *refuse* consent . . . [but] not the right to *grant* consent to . . . commercialization"). Since the *Moore* decision, patient groups such as PXE International have exercised this latter right by negotiating contracts with the scientists studying the disease affecting their families. See *infra* Part III for a description of this change in patient-researcher bargaining. The measure of damages available to research participants such as the *Greenberg* plaintiffs should reflect this reality. By failing to reveal their intention to commercialize the tissue provided by the *Greenberg* plaintiffs, researchers denied these individuals essential information that would have permitted them to bargain for rights to compensation and control. See *infra* Part IV.B for an analysis of the *Greenberg* action.

203. Mary Anne Bobinski, *Autonomy and Privacy: Protecting Patients from Their Physicians*, 55 U. PITT. L. REV. 291, 374 (1994). It should be noted that the final judicial decision in the *Greenberg* action permitted the plaintiffs' claim for unjust enrichment to proceed. See *Greenberg v. Miami Children's Hosp. Research Inst., Inc.*, 264 F. Supp. 2d 1064, 1072-73 (S.D. Fla. 2003) (denying a motion to dismiss the plaintiffs' unjust enrichment claim under Florida law).

of the profits from the tissue studied. This issue is hardly a purely academic one, because many physician-researchers transfer their patent rights to third parties who then commercialize the patented innovations on a large scale.²⁰⁴ As noted above, these third parties owe no fiduciary duty or duty of informed consent to the research participants.²⁰⁵ Explicit recognition of individuals' property rights in their tissue avoids this problem, and is consistent with society's acceptance of the right of scientists to profit from their research on human tissue.

For the reasons set forth above, the doctrines of lack of informed consent and breach of fiduciary duty are of limited use in protecting research participants' autonomy and right to control the use of their tissue. As stated in one government report, "[t]he propriety of researchers achieving financial success from manipulating human specimens in their research is an issue best handled under other legal theories and principles," including "provisions in research contracts [and] property law."²⁰⁶ Professor Epstein concurs, stating that even though punitive damages could be assessed, thereby assuring plaintiffs in a breach of duty to disclose case damages equal to what they would win in a conversion action, a conversion action is preferable "because it creates cleaner property rights in those cases in which individuals do enter into various kinds of business transactions."²⁰⁷

5. Concerns About Scientists Luring Research Participants with Promises of False Profits and Participants Elevating Financial Concerns over Health Concerns Do Not Furnish Sufficient Reason to Deny Research Participants an Ownership Interest in Their Tissue

Those opposed to recognizing research participants' property rights in their tissue often express concern that scientists will induce research participation with false or misguided promises of profits.²⁰⁸ Professors

204. For example, in the *Moore* case, while Dr. Golde and the Regents were paid over \$400,000 by two biotech firms, one of which also offered Dr. Golde the opportunity to purchase 75,000 stock shares at a nominal price, *see supra* note 62 and accompanying text, Mr. Moore alleged that the biotech industry could expect to earn \$3 billion overall from his tissue. *Supra* note 70 and accompanying text.

205. *See supra* notes 76, 187–88 and accompanying text (noting that because several defendants, including Ms. Quan, Genetics Institute, and Sandoz, were not doctors, they did not owe any fiduciary duty or duty of informed consent to the plaintiff).

206. OWNERSHIP OF HUMAN TISSUES AND CELLS, *supra* note 19, at 107.

207. Richard A. Epstein, *Steady the Course: Property Rights in Genetic Material*, in F. SCOTT KIEFF, PERSPECTIVES ON PROPERTIES OF THE HUMAN GENOME PROJECT 159 (2003).

208. *See Moore v. Regents of the Univ. of Cal.*, 249 Cal. Rptr. 494, 539 (Cal. Ct. App.

Knoppers and Laberge warn that researchers might lure participants with promises of "ultimately fictitious percentages of far-off royalties."²⁰⁹ Individuals with limited education and financial resources are particularly vulnerable to such offers.²¹⁰ Moreover, even those researchers wishing to deal honestly with their research participants might find themselves unable to estimate accurately the potential commercial value of particular tissue specimens, and would therefore offer unintentionally misleading information.²¹¹ However, a legal system that refuses to recognize research participants' property interest in their tissue does not forestall these problems.

First, it is already "common practice for sponsors and even research institutions to compensate subjects for participating in research."²¹² Thus, even without legal recognition of individuals' property rights in their tissue, scientists presently induce research participation with financial remuneration. On the other hand, it is clear that widespread expectation that a research participant can claim financial compensation, whether through a contractual arrangement or a liability rule, could encourage even more research participation by individuals willing to risk their health in the hope of pecuniary gain.

There are several arguments in response to this concern. First, as a practical matter, there is much to recommend in a legal system that increases

1998) (George, J., dissenting) (warning of the "threat of improper motivation in the area of tissue acquisition").

209. Bartha Maria Knoppers & Claude Laberge, *DNA Banking/Collecting: A Canadian "Sample" of Consent Forms*, in *LEGAL RIGHTS AND HUMAN GENETIC MATERIAL*, *supra* note 33, at 33, 49 (arguing that such outlandish promises of future wealth should be banned); *see also* *OWNERSHIP OF HUMAN TISSUES AND CELLS*, *supra* note 19, at 104 ("For researchers to divulge such information could convince subjects to participate in research on the basis of misinformation, unreasonable expectation, or for the sole purpose of financial gain.").

210. Professor Mahoney highlights in particular the international practice of bioprospecting, where "gene prospectors" visit "remote, inbred populations" in the developing world who are "potentially vulnerable to the entreaties of profit-seeking First World organizations." Mahoney, *supra* note 29, at 191 (footnote omitted).

211. *See* *OWNERSHIP OF HUMAN CELLS AND TISSUES*, *supra* note 19, at 104 (noting that researchers would be unable to give participants accurate financial forecasts because the profits are too "vague and speculative at the time the sample is obtained").

212. Michael J. Malinowski, *Conflicts of Interest in Clinical Research: Legal and Ethical Issues: Institutional Conflicts and Responsibilities in an Age of Academic-Industry Alliances*, 8 *WIDENER L. SYMP. J.* 47, 68 n.96 (2001). "Financial incentives are often used in the early phases of investigational drug, biologic, or device development, especially when health benefits to subjects are inconsequential or non-existent." *Id.* (citing PRICEWATERHOUSE COOPERS, LLP, *INSTITUTIONAL REVIEW BOARD (IRB) REFERENCE BOOK* (Michele K. Russell-Einhorn & Thomas Puglisi eds., 2001)).

the supply of human tissue for research.²¹³ Second, while the law must guard against situations where researchers make false or inaccurate promises in order to secure the involvement of research participants or cases where individuals facing financial hardship agree out of desperation to participate in research, the doctrine of informed consent is specifically designed for just this problem.²¹⁴ Indeed, if we deem these participants so vulnerable that they merit protection from unscrupulous researchers, it is illogical to maintain the current system, which denies effective recovery to the most vulnerable research participants of all, those who were not even aware of their research participation or of their researchers' plans to commercialize their tissue.²¹⁵ Third, with respect to the concern that research participants will risk their health for the speculative promise of profit, it is arguably excessively paternalistic to protect potential research participants from their own desire to contribute tissue for scientific experimentation in exchange for valuable consideration. Moreover, as Professor Mahoney emphasized:

[P]reventing excessive risktaking by banning payments, instead of through the regulation of collection procedures and required disclosure of relevant hazards, is a curious strategy. When a conclusion is reached that workers are exposing themselves to excessive risks, the usual response is to alter workplace conditions to reduce the risk, not to forbid payments for the work while suggesting that altruistically minded volunteers perform the work for free.²¹⁶

It should be acknowledged, however, that widespread societal acceptance of the notion that research participants possess a property interest in their tissue will lead individuals to expect compensation for their research participation.²¹⁷ This problem leads many commentators to express concern that such a system would erode notions of community and discourage altruistic donation not just of tissue for research purposes, but also inhibit gratuitous donation of organs and blood.²¹⁸

213. This very notion underlies the opinion of the *Moore* court, which ultimately took a different approach in order to ensure researchers' access to human tissue for experimentation.

214. Depending upon the factual circumstances, a plaintiff may also have recourse to one or more of the doctrines of fraudulent misrepresentation, negligent misrepresentation, duress, undue influence, unconscionability, and professional disciplinary laws.

215. *Supra* notes 31–32 and accompanying text.

216. Mahoney, *supra* note 29, at 213.

217. See *supra* notes 92–93 and accompanying text (noting the increased expectation of some research participants for compensation and control in the research process).

218. See Mahoney, *supra* note 29, at 164 (outlining the arguments against paid tissue donation, including the belief that a market system "may discourage gratuitous transfers").

6. *Recognition of Research Participants' Property Rights in Their Tissue Will Neither Erode Appreciably Notions of Community nor Discourage Altruism*

Denying research participants property rights in their tissue does not necessarily foster notions of community or disseminate widely the fruits of biotech research. Instead, the tissue taken from research participants without compensation is used by researchers and biotech firms to develop commercial products, some of which may be priced beyond the reach of most consumers.²¹⁹ Our legal and economic systems are premised upon the notion that promise of reward for individual effort, not communitarian ideals, will stimulate biomedical research and innovation that will redound to the benefit of society.

Nonetheless, some commentators fear that recognition of property rights in human tissue ultimately will discourage altruism in other areas where it is typically practiced, such as gratuitous donation of organs²²⁰ and blood²²¹ to human recipients. With respect to organ donation in particular, it is important to recall that federal law already prohibits the sale of human organs for transplant.²²² There are several policy reasons why federal law defensibly could continue to encourage altruistic transfer of human organs for transplant but nonetheless recognize property rights in human tissue that is either (1) regenerative; (2) not vital for the healthy functioning of the human body; or (3) required to be removed for purposes of diagnosis or treatment.²²³

219. See *supra* notes 168–71 and accompanying text (describing the current exploitation of human tissue for commercial profit).

220. See, e.g., *Moore v. Regents of the Univ. of Cal.*, 249 Cal. Rptr. 494, 539 (Cal. Ct. App. 1998) (George, J., dissenting) (citing as an argument against recognition of property rights in the human body "the potential for adverse effects on organ donation for transplantation usage" (footnote omitted)).

221. See, e.g., RICHARD M. TITMUS, *THE GIFT RELATIONSHIP: FROM HUMAN BLOOD TO SOCIAL POLICY* 245–46 (1971) (warning that a system of providing financial remuneration to blood donors results in a decrease in the number of charitable donations and also erodes the communitarian and collectivist attitudes necessary for a strong society).

222. See *supra* note 34 (noting that Congress prohibits the sale of solid organs for transplant). It should be recalled, however, that individuals presumably can sell their solid organs for research purposes. *Id.*

223. See *supra* note 164 (observing that these types of tissues do not present the same removal risks as solid organs and that a market in these tissues will not lead to the type of unethical bargaining that one might imagine with organs). This Article does not take a position on whether a market should exist in human organs for transplant, a topic that legal academic literature has treated at great length. Instead, this work advocates for federal legislation according research participants property rights in certain human tissue used in research, and contends that transplantable human organs and other sorts of tissue are sufficiently distinct, for the reasons set forth at note 164 *supra*, that the U.S. Congress could recognize property rights in the latter without reversing long-standing federal legislation barring the sale of the former.

With respect to other types of tissue, where donative and sales regimes exist side by side, such as blood and plasma, there is no evidence that a commercial market decreases charitable donations, as theorized by Richard Titmuss, a leading British social policy analyst.²²⁴ As explained by one commentator, "[t]he legality of a market in blood for transfusion in the United States has far from eliminated the donation of blood for that purpose."²²⁵ Even if one accepts the notion that overall blood donations have declined since the implementation of a commercial regime,²²⁶ it is not clear that a causal relationship exists between these two factors. In response to Professor Titmuss, Professor Kenneth Arrow, an American Nobel Laureate in Economics, has offered an alternative explanation: that the United States instituted a system of monetary compensation for blood in response to the inadequacy of an entirely donative system.²²⁷ Thus, any shortage in the nation's blood supply may result simply from the American public's disinclination to behave altruistically,²²⁸ as opposed to the availability of payment for their blood and plasma.

224. See TITMUSS, *supra* note 221, at 245–46 (positing an inverse relationship between the availability of compensation for blood and the likelihood that donors will give blood voluntarily).

225. Harrison, *supra* note 34, at 93 (footnote omitted).

226. See, e.g., Kenneth Baum, *Golden Eggs: Towards the Rational Regulation of Oocyte Donation*, 2001 BYU L. REV. 107, 138 (2001) (stating that, since the 1971 publication of Titmuss's book, "trends in blood donation have shifted" such that "[c]haritable donations have declined, resulting in a shortage of blood" and "demand now outpaces supply" (footnotes omitted)). But see Anne Reichman Schiff, *Solomonic Decisions in Egg Donation: Unscrambling the Conundrum of Legal Maternity*, 80 IOWA L. REV. 265, 291 n.114 (1995) (arguing that blood donors in the United States have increased their voluntary blood donations over the past few decades). Specifically, Schiff notes that:

The number of altruistic donations has increased substantially over the past twenty years. In 1965–67, only 7% of the blood collected in the United States came from voluntary donors. Over the next several years, however, a marked change occurred in the blood collection system. By 1975, only 18% of the blood supply came from paid donors, and in 1976 this was reduced to 8.6%.

Id.

227. Kenneth J. Arrow, *Gifts and Exchanges*, 1 PHIL. & PUB. AFF. 343, 350 (1972).

228. Mahoney, *supra* note 29, at 217. Mahoney goes on to note:

Efforts to stimulate altruistic transfers of human biological materials have been notable for their failure: The percentage of the population that regularly donates blood remains low and laws requiring hospital personnel to request surviving relatives of eligible cadavers to consent to donate organs have not substantially increased the supply of organs for transplantation.

See also UNITED STATES DEPT. OF HEALTH AND HUMAN SERVS., NEWS RELEASE: HHS SECRETARY THOMPSON ANNOUNCES NEW BLOOD DRIVE INITIATIVE (Nov. 26, 2002) ("Currently 60 percent of the [United States] population is eligible to donate blood, but only 5 percent are regular donors."), available at <http://www.hhs.gov/news/press/2002pres/20021126.html> (on file with the Washington and Lee Law Review).

Because so little is understood about the causes of altruistic behavior,²²⁹ "[i]t is uncertain whether the existence of payments will cause individuals who would have acted altruistically to instead opt to receive compensation."²³⁰ What is clear is that individuals are highly motivated to pursue their self-interest, as demonstrated by the actions of the patient advocacy group PXE International.

III. The PXE Contractual Property Rights Model

While the *Moore* case posits the altruistic donation of tissue by human research participants, patient advocacy groups such as PXE International are contracting around this decision in order to establish property rights in tissue used by researchers, in what this Article will refer to as the contractual property rights model. Specifically, this grassroots group, which represents the interests of individuals afflicted with pseudoxanthoma elasticum (PXE), a genetic disorder causing calcification of elastic tissue, has negotiated directly with researchers for a share in the profits from any gene patent that might arise.²³¹ Sharon Terry, president of PXE International and the mother of two children afflicted with PXE, has indicated that the group is motivated by its desire to ensure affordable and widely available genetic tests for the disorder.²³²

Ms. Terry and her husband began in 1995 to organize families affected by PXE, shortly after her two children were diagnosed with the disease.²³³ After it became clear to them that researchers with whom the Terry family had banked blood were not willing to share it with other scientists, Ms. Terry realized that,

229. See Oded Stark & Ita Falk, *Transfers, Empathy Formation, and Reverse Transfers*, 88 AM. ECON. REV. (PAPERS & PROC.) 271, 271 (1998) ("[T]he questions of how altruism is instilled and what explains its evolution lie at the very frontier of research on preference formation and transfer behavior."); see also Jane Mansbridge, *Starting with Nothing: On the Impossibility of Grounding Norms Solely in Self-Interest*, in ECONOMICS, VALUES AND ORGANIZATIONS 151, 153 (Avner Ben-Ner & Louis Putterman eds., 1998) ("Empirical studies of the innate human tendency to make the good of others our own are in their infancy, but we may expect experimental and developmental psychology, neuroscience, and evolutionary biology to produce more evidence on this score in the near future.").

230. Mahoney, *supra* note 29, at 217 (citing William M. Landes & Richard A. Posner, *Salvors, Finders, Good Samaritans, and Other Rescuers: An Economic Study of Law and Altruism*, 7 J. LEGAL STUD. 83, 95 (1978)).

231. See Smaglik, *supra* note 2, at 821 (observing that PXE International requires an agreement establishing joint ownership over any patent resulting from research using its blood and tissue bank).

232. *Id.*

233. Fleischer, *supra* note 27, at 84.

in her words, "the research community was not set up to work together."²³⁴ Moreover, those scientists studying the disease had located only about four or five families to study, and therefore could not expect to achieve progress as quickly as they would with more research participants.²³⁵ Indeed, PXE International estimates that the disease affects only about one in 25,000 births, and thus qualifies as a so-called orphan disease of little interest to pharmaceutical companies because even a successful treatment would hold little prospect of generating large revenues.²³⁶

A. Formation and Terms of the Contract Between PXE International and PXE Researchers

The Terry family realized that they could steer researchers toward PXE disease by collecting blood and tissue samples and providing funding, and also that they could maintain some control over the research by exchanging this valuable property only in exchange for consideration.²³⁷ Although neither Sharon Terry, an educator, nor her husband, Patrick, a construction manager, had prior experience in organizing a foundation or in directing biotechnological research,²³⁸ within four years of their children's diagnoses they had located "2,000 people with the disease, set up a repository to store tissue samples, and began raising money for research."²³⁹ During that time, Ms. Terry also engaged pro bono legal help to incorporate PXE International, Inc. as a nonprofit organization and to provide counsel about acquiring samples for the bank.²⁴⁰

234. *Id.*; see also Sara Solovitch, *The Citizen Scientists*, WIRED, Sept. 1, 2001, at 146, 148 (quoting Sharon Terry as saying: "Early on we banked our blood with some researchers. They were fine until some other researchers wanted to use the blood. Then they became hostile.").

235. See Kolata, *supra* note 27 (noting that the Terrys found researchers who had briefly studied PXE disease but were not moving forward for lack of research subjects).

236. See Fleischer, *supra* note 27, at 86 (explaining that because PXE affects relatively few people, drug companies would ignore it even if the sufferers were forced to take medication for the rest of their lives).

237. See *id.* at 87 (relating that the Terrys were "building a fence around their property and granting access only in exchange for something of value").

238. See *id.* (concluding that "the Terry's are unlikely players" in the gene patent game because of their inexperience).

239. Kolata, *supra* note 27.

240. See Fleischer, *supra* note 27, at 87 (describing the relationship between PXE International and the law firm of Testa, Hurwitz & Thibault). At present, the Washington, D.C.-based PXE International has grown into a global organization that coordinates and funds a consortium of nineteen research labs, provides patient support and information from more than fifty-two offices worldwide, directs a blood and tissue bank, and maintains a database of thousands of affected individuals. Press Release, Transgenomic Company Press Release,

According to Ms. Terry, because PXE International had done so much of the work of procuring patients and funding, the group had no trouble partnering with many research teams eager to study the organization's collection of samples and willing to agree to the group's terms.²⁴¹ She also noted that, in light of the *Greenberg* action that was filed around this time,²⁴² researchers were particularly concerned about avoiding negative publicity,²⁴³ and, presumably, potential litigation. According to the contract between the researchers and PXE International, the latter was entitled to retain ownership rights in any patent applications arising from the research, thereby enabling the foundation to share in any revenue from the discoveries, to ensure broad and affordable availability of genetic tests, and to influence future licensing of the intellectual property.²⁴⁴ This marked the first time that researchers who isolated a gene had filed a joint patent application with a patient advocacy group.²⁴⁵

In February 2000, University of Hawaii pathobiologist Charles Boyd isolated the gene associated with PXE.²⁴⁶ While Dr. Boyd listed Ms. Terry on the patent applications as part of the research team²⁴⁷ and also signed the

Transgenomic Signs Collaboration Agreement with Lay Advocacy Group PXE International (Oct. 17, 2002), at <http://www.pxe.org/research/transgenomic.html> (on file with the Washington and Lee Law Review).

241. See Kolata, *supra* note 27 (quoting Sharon Terry as saying that the researchers "are so delighted that we will do all the grant work").

242. See *supra* notes 3–14 and accompanying text (describing the claims and contents of the *Greenberg* complaint); see also *infra* Part IV (examining the *Greenberg* action).

243. See Fleischer, *supra* note 27, at 87 (noting that few have challenged the intellectual property conditions imposed by PXE International for fear of receiving bad press).

244. See Kolata, *supra* note 27 (describing the terms of the contract between PXE International and the individual research teams working on finding the gene associated with PXE disease). The patent for this gene was still pending as of late December 2002. See Helen Altonn, *UH Makes Gene Patent History*, at <http://starbulletin.com/2002/12/23/news/story7.html> (Dec. 23, 2002) (observing that the patent had been filed about one year previously and "is expected to be issued shortly") (on file with the Washington and Lee Law Review).

245. Smaglik, *supra* note 2, at 821.

246. Fleischer, *supra* note 27, at 87, 98.

247. In a break with tradition, Dr. Boyd listed Ms. Terry as a co-inventor based on her success in securing patient participation, recruiting researchers, and alerting researchers of scientific developments published in journals and presented at conferences. See Fleischer, *supra* note 27, at 98 (explaining how the patent was filed and marketed). Moreover, Ms. Terry is credited with achieving "molecular-level insights that accelerated gene discovery." *Id.* at 85.

Where inventorship is contested, federal law sets forth the criteria for joint inventorship. See *supra* note 140 and accompanying text (outlining the statutes and case law that define the requirements for joint inventorship). For example, a federal court has held that an individual who identified an animal virus and provided tissue for researchers to study was not a joint inventor where a patent "claim[ed] isolation and substantial purification of the virus, as well as methods for diagnosing the virus," as opposed to discovery of the virus itself. *Brown v. Regents*

standard PXE International contract, his agreement with the University of Hawaii actually granted the university the rights to his inventions.²⁴⁸ Although the university had not focused on these conflicting contracts at the time when Dr. Boyd began working with PXE International in the mid-1990s, because the prospect of licensing seemed unlikely for a disease as rare as PXE,²⁴⁹ this had changed by the time Dr. Boyd had isolated the gene associated with PXE in 2000. The university balked at giving total control over the licensing rights to PXE International, since the foundation's goals were incompatible with its own. While the University of Hawaii sought lucrative licensing arrangements, PXE International's aim was to ensure that any available medications would be affordable for its members. Ultimately, the parties reached an agreement in 2001.²⁵⁰ The university accorded to PXE International the right to make the licensing decisions, and the parties agreed to split equally the royalties deriving from any diagnostic test or marketable product.²⁵¹

While PXE International's contract with researchers is unprecedented, commentators expect others patient groups to follow suit. This trend has already been observed by executives with Genetic Alliance, a Washington, D.C.-based advocacy group that assisted PXE International in drafting its contract with researchers.²⁵² Patient groups such as Cure Autism Now and the Juvenile Diabetes Research Foundation International have pooled members'

of the Univ. of Cal., 866 F. Supp. 439, 445 (N.D. Cal. 1994).

248. See Fleischer, *supra* note 27, at 98 (describing the negotiation of an agreement between PXE International and the University of Hawaii in order to resolve the conflicting contracts to which Dr. Boyd was a party).

249. See Matt Fleischer, *Seeking Rights to Crucial Gene, Parents of Children with PXE Took Steps to Control Samples Used in Research for a Cure*, NAT'L L.J., June 25, 2001, at C1 (noting that only "an estimated 10,000 to 15,000 people in the United States have PXE, far too few customers to intrigue a big-league drug company").

250. E-mail from Sharon Terry, Executive Director, PXE International, to Donna M. Gitter, Assistant Professor of Legal and Ethical Studies, Fordham University Schools of Business (Mar. 21, 2003, 10:30:17 EST) (on file with author).

251. Fleischer, *supra* note 27, at 98. Thus far, PXE International is collaborating with Transgenomic, Inc., a global company based in Omaha that creates research tools for the life sciences industry, to develop a diagnostic test for the disease. Press Release, Transgenomic Inc., Transgenomic Signs Collaboration Agreement with Lay Advocacy Group PXE International (Oct. 17, 2002), at <http://www.pxe.org/research/transgenomic.html> (last visited Oct. 22, 2003) (on file with the Washington and Lee Law Review).

252. Kolata, *supra* note 27. The Genetic Alliance defines itself as "an international coalition comprised of millions of individuals with genetic conditions and more than 600 advocacy, research and health care organizations that represent their interests" that is dedicated to forming "partnerships to promote healthy lives for all those living with genetic conditions." GENETIC ALLIANCE, ABOUT THE GENETIC ALLIANCE, at <http://www.geneticalliance.org/members/aboutus.html> (last modified Jan. 13, 2003) (on file with the Washington and Lee Law Review).

specimens to create biorepositories, and one Genetic Alliance vice president has indicated that these groups inform her that the terms for access to these repositories would address intellectual property considerations.²⁵³ These patient groups are likely to be able to exert a great deal of leverage, since researchers will prefer tissue from these biorepositories, which comes replete with individual health histories and symptom descriptions, to the millions of specimens already stored in the U.S.²⁵⁴

The necessity of collaboration among research participants, patient advocacy groups, and scientists has been recognized by organizations such as the American Society of Human Genetics (ASHG), a professional association of human geneticists, including researchers, academicians, clinicians, laboratory practice professionals, genetic counselors, and nurses.²⁵⁵ The ASHG emphasizes that these patient groups contribute to biomedical research by encouraging the participation of their members and creating blood and tissue banks, raising funds, educating research participants and scientists about the nature and expectations of the research, as well as the consent process, and bridging cultural gaps between researchers and participants.²⁵⁶ In light of the importance of these groups, it is critical to examine the ramifications of the contractual property rights model they are embracing.

B. The Advantages of the PXE Contractual Property Rights Approach

One of the main benefits flowing from patient groups' claims to property rights in the tissue of their members is the potential for enhanced public access to diagnostic tests and therapeutics for the treatment of disease, to the extent that these groups demand some control over the licensing of the products developed from such tissue. Many scholars have written extensively about the problems that arise when researchers who obtain patents on human genes enter into exclusive licensing agreements, license their intellectual property to a very

253. Fleischer, *supra* note 27, at 100.

254. *See id.* (citing an analyst with RAND's Science and Technology Policy Institute).

255. *See* AM. SOC'Y OF HUMAN GENETICS, ABOUT ASHG, at <http://www.ashg.org/genetics/ashg/menu-about.shtml> (last visited Oct. 15, 2003) (noting that one of the primary objectives of ASHG is to facilitate "interactions between geneticists and patient" public advocacy groups) (on file with the Washington and Lee Law Review).

256. *See generally* AM. SOC'Y OF HUMAN GENETICS, AM. SOC'Y OF HUMAN GENETICS AD HOC COMM. ON CONSUMER ISSUES COMM. REPORT: GENETIC LAY ADVOCACY GROUPS: SIGNIFICANT OTHERS IN THE CONDUCT OF HUMAN GENETICS RESEARCH (Oct. 1999), at <http://www.ashg.org/genetics/ashg/pubs/policy/pol-46.pdf> (last revised Oct. 18, 2001) (on file with the Washington and Lee Law Review).

limited number of downstream users, or charge particularly high fees for these products. These practices maximize the profits enjoyed by scientists, the institutions that employ them, and biotechnology firms, while simultaneously limiting consumers' access to diagnostic tests and therapeutic treatments.²⁵⁷ While the promise of profits is of course necessary to foster innovation, patient advocacy groups can help to balance the need to stimulate profits with the goal of promoting public health. Indeed, PXE International has emphasized repeatedly that its aim is to promote access to diagnostics and therapeutics, not only for its own members, but also for others suffering from disease.²⁵⁸

257. See Lori B. Andrews, *The Gene Patent Dilemma: Balancing Commercial Incentives with Health Needs*, 2002 HOUS. J. HEALTH L. & POL'Y 65, 91 (2002) ("In some situations, the very people whose genes were patented may not be able to afford the test that was created using their bodily material, or may find that a company has decided to quash entirely a test related to their condition."); Donna M. Gitter, *International Conflicts over Patenting Human DNA Sequences in the United States and the European Union: An Argument for Compulsory Licensing and a Fair-Use Exemption*, 76 N.Y.U. L. REV. 1623, 1650-51 (2001) (describing the high royalty fees that Myriad Genetics imposed on medical practitioners conducting genetic tests for two genes linked to breast cancer, BRCA1 and BRCA2, after Myriad had "gained exclusive patent rights to the genetic tests that screen for mutations in these genes, as well as patent rights in the genes themselves"); Merz, *supra* note 36, at 101 (stating that disease gene patents "are often being exclusively licensed to for-profit laboratories by academic medical centers where the basic biomedical science was performed," and that these "exclusive arrangements allow patent holders to enforce their patents in ways that infringe on the practice of medicine, restrict clinical observation and formal research, reduce access, and increase the costs of clinical testing services") (footnotes omitted).

Sometimes the opposite problem occurs, and a patent holder refuses to exploit its intellectual property altogether, because the market for products developed from the patented invention is too small to pursue. See Jeff Donn, *Rush to Patent Disease-Causing Genes Is Under Way*, DESERET NEWS (Salt Lake City), Aug. 23, 2001, at A30 (suggesting that a patent-holding corporation might ignore a market as small as the PXE community because the disease strikes fewer than one in 25,000 people).

258. See Fleischer, *supra* note 27, at 100 (quoting PXE International President Sharon Terry's statement that her group seeks not only to facilitate access to a future PXE diagnostic test or treatment, but also to afford individuals suffering from other diseases access to any diagnostics or therapeutics in which PXE International might hold rights). *But see infra* notes 274-75 and accompanying text (noting that although the group seeks to represent any disease sufferer, PXE International is pursuing licensing contracts that maximize access to PXE treatments and testing).

Like the members of PXE International, the plaintiffs in the *Greenberg* action emphasized that their primary goals in participating in Canavan research were to ensure affordable and accessible carrier and prenatal testing and to "promote the discovery of more effective prevention techniques and treatments and, eventually, to effectuate a cure for Canavan disease." *Greenberg* Complaint, *supra* note 3, ¶ 22. Unlike the members of PXE International, however, the *Greenberg* plaintiffs expected the research results from experimentation on their tissue to remain in the public domain. *Id.*

Patient advocacy groups also contribute to the advancement of research in various ways. These groups help to identify and recruit research participants,²⁵⁹ formulate informed consent policies,²⁶⁰ engage in efforts to increase public awareness of their disease and funding for medical research,²⁶¹ and even become so knowledgeable about their disease that they offer researchers significant medical insights.²⁶²

Furthermore, assuming that it becomes more common for patient advocacy groups to negotiate for property rights in their members' tissue,²⁶³ these groups avoid some of the practical and ethical problems raised by this practice. First, these groups overcome the fact that "individual sources are rarely substantially responsible for products of commercial value."²⁶⁴ For example, Professor Greely suggests:

[I]n research conducted with users of the Veterans Administration system, some share of any commercial value could be dedicated to improving the lives of those in Veterans Administration hospitals. Similar kinds of collective benefits could be foreseen when doing research with members of

259. See CTR. FOR BIOETHICS, UNIV. OF PA. SCH. OF MED., *ETHICS AND INTELLECTUAL PROPERTY: TOWARD AN UNDERSTANDING OF BENEFIT SHARING: BACKGROUND AND SIGNIFICANCE* (2003) (observing that close relationships between patient groups and researchers "greatly facilitate targeted research by . . . giving highly motivated assistance in identifying and soliciting potential participants from these communities, lending credibility to the researchers that can increase trust and participation, and sharing the costs of recruitment"), at <http://www.med.upenn.edu/bioethic/programs/benefit/a1.shtml> (last visited Oct. 23, 2003) (on file with the Washington and Lee Law Review).

260. See Smaglik, *supra* note 2, at 821 (stating that the National Human Genome Research Institute advised PXE International on informed consent and drew up guidelines limiting how researchers could use the tissue).

261. See, e.g., Andy Coghlan, *Head to Head: People with Inherited Diseases Are Ready to Challenge Pro-Lifers over the Future of Medical Research*, *NEW SCIENTIST*, Feb. 24, 2001, at 4, 4-5 (describing a biotechnology meeting in Lyon, France where delegates from groups representing patients with rare diseases, including PXE International, met to form a global alliance).

262. See *supra* note 247 (stating that Sharon Terry, executive director of PXE International, has been credited with accelerating the gene discovery as a result of her insights and success in recruiting researchers and patients; she is also listed as co-inventor on the patent application); see also Solovitch, *supra* note 234, at 148 (quoting Uta Francke, president of the International Federation of Human Genetics Societies and professor of genetics and pediatrics at Stanford University School of Medicine, as stating that parents of children afflicted with genetic disorders "often know more about certain diseases than the health care providers they interact with" and "want to be involved in the research").

263. See *supra* notes 252-56 and accompanying text (discussing the leverage of patient groups that have asserted property rights in their biorepositories).

264. Greely, *supra* note 111, at 757-58; see also *supra* notes 128-30 and accompanying text (noting that the commercial value of tissue samples results from collecting specimens from several patients, not from individual samples).

other kinds of health systems, such as health maintenance organizations, or in geographically or culturally-defined communities.²⁶⁵

Second, as noted by Professor Greely, patient advocacy groups also overcome the problem that the prospect of a share in the profits might "operate as an undue inducement to someone to participate in research,"²⁶⁶ because the profits would flow to the group rather than the individual research participants. Moreover, group ownership of the commercial profits flowing from the tissue, vested in the foundation, would avoid the appearance of profiting from one's disease, which strikes some as unseemly,²⁶⁷ and also strengthens notions of community so highly prized by scholars such as Titmuss.²⁶⁸

C. *The Drawbacks of the PXE Contractual Property Rights Approach*

Notwithstanding the many advantages offered by the patient advocacy groups, it is clear that they do not provide the only or even the best means of protecting the rights of research participants. For this reason, it is essential that the United States Congress recognize the right of each individual research participant to claim a property interest in his tissue.

Among the most obvious limitations of the group rights approach is that not all patients will locate a patient advocacy group or have easy access to such a group even if one exists. Some individuals may prefer not to participate in such groups, either because they suffer a negative psychological impact from associating with others with their disease or they may fear genetic discrimination if they are linked with such a group.²⁶⁹ Moreover, some patient groups may not represent individual patients as they would

265. Greely, *supra* note 111, at 758. Professor Greely does not seem to favor arm's length negotiations between scientists and research participants; he states that researchers should instead donate a share of their revenues, perhaps ten percent, to organizations that represent the research participants. *Id.*

266. *Id.*; see also *supra* notes 208–11 and accompanying text (examining the concern that researchers may induce participation by fake or misguided promises of compensation).

267. See *supra* note 153 and accompanying text (examining the argument that it would be unfair for an individual to profit from possessing tissue that happens to be valuable to scientists).

268. See *supra* note 221 and accompanying text (discussing the drawbacks associated with financially compensating blood donors).

269. "The fact that genetic diseases are sometimes closely associated with discrete ethnic or racial groups such as African Americans, Ashkenazi Jews, or Armenians compounds the potential for invidious discrimination." Larry Gostin, *Genetic Discrimination: The Use of Genetically Based Diagnostic and Prognostic Tests by Employers and Insurers*, 17 AM. J.L. & MED. 109, 111 (1991).

prefer.²⁷⁰ Thus, individuals should enjoy the legal right to negotiate on their own behalf with biomedical researchers.

Even for a patient with access to and the desire to join an advocacy group, it is not clear that such groups always advance scientific research. Professor Eisenberg has warned that the presence of more parties at the bargaining table hinders the ability of pharmaceutical firms to negotiate the licensing agreements necessary to pursue planned drug development initiatives.²⁷¹ Moreover, a patient group that exerts control over scientists' research agendas because of its ownership of scientifically valuable tissue may choose to pursue research strategies of dubious scientific merit, thereby slowing the pace of biotechnological progress.²⁷²

Even if a patient group ultimately does negotiate successfully with researchers for the implementation of scientifically sound research projects, there is some concern that the group might exercise control over the discoveries in such a way as to maximize the group's profits, while simultaneously limiting access to people afflicted by other diseases. For example, there is evidence that the gene associated with PXE might also relate to hypertension and cardiovascular disease research. As president of PXE International, Ms. Terry has asserted that her group will resist bettering their own fortunes at the expense of other disease sufferers, stating that although "[i]t's been suggested that we could make a killing because who cares if we're making the costs of cardiovascular treatment huge," PXE International does not "just represent people with PXE, we represent anybody who has anything."²⁷³ As a practical matter, of course, she acknowledges that the group would insist upon licensing deals that would maximize the access of PXE patients to a future diagnostic test or treatment.²⁷⁴ Third parties could hardly fault PXE International for protecting its members above all, in light

270. For example, one commentator has noted that an informed consent form used by PXE International at one time neglected to mention that a patent application had been filed by the group. See Anne Nichols Hill, Note, *One Man's Trash Is Another Man's Treasure, Bioprospecting: Protecting the Rights and Interests of Human Donors of Genetic Material*, 5 J. HEALTH CARE L. & POL'Y 259, 279 & nn.153-54 (quoting the PXE International, Inc. informed consent form for blood donors).

271. See Matt Fleischer, *Pitfalls of Pro Se Patenting*, AM. LAW., June 2001, at 87, 87 (citing Professor Eisenberg's concerns that PXE International's humanitarian demands might complicate and delay the otherwise profit-driven drug development process).

272. See *id.* (noting a health policy researcher's concerns that powerful patient groups might degrade scientific research).

273. Fleischer, *supra* note 27, at 100.

274. See *id.* (outlining the goals of PXE International and noting that the group expresses its desire to avoid profiteering).

of the fact that these members incurred the inconvenience and risk of research participation. What is more, it is quite rational for PXE International to guard its discoveries closely and to optimize its profits from them, given that orphan diseases such as PXE garner little direct federal funding.²⁷⁵

If profits from biotechnological products were to flow to the individual members of a disease advocacy group, as opposed to the foundation as a whole, however, this would belie the notion that patient advocacy groups are necessarily communitarian in perspective. Clearly, the existence of a foundation does not preclude the possibility of personal profit, as noted by the attorney who drafted the patent application for PXE International and PXE researchers. He stated that: "[T]he awards of group ownership could include dividends from royalties, despite risking the appearance of getting paid for their disease. After all, . . . the costs of a lifetime of treating a chronic disease add up."²⁷⁶ The payment of such dividends undoubtedly would provoke an outcry from commentators who accept commercialization by a community group, but not by an individual.²⁷⁷

Even those who support the property rights model, however, acknowledge that this approach is insufficient to protect the rights of research participants who did not negotiate with their researchers, such as those involved in the *Greenberg* litigation discussed immediately above. For reasons that will be examined below, it is critical that federal law mandate that research participants in this predicament have recourse to a liability model.

275. See John A. Robertson et al., *Pharmacogenetic Challenges for the Health Care System: Genetically Based Drug Prescribing Could Decrease Overall Health Costs and Fuel New Drug Development*, HEALTH AFF., July/Aug. 2002, at 155, 165 (discussing competition for research funds). As Robertson described the situation:

Given the competition among disease groups for research funding, it may be hard for smaller, genotypically segmented groups to lobby effectively for direct research subsidies. If the population of such groups is less than 200,000, they would still qualify for the tax credits, clinical testing subsidies, and seven-year sales monopolies now provided under the 1982 federal Orphan Drug Act.

Id.

276. Fleischer, *supra* note 27, at 100.

277. Professor Bartha Maria Knoppers is among those who reject the inducement of research participants through "payment for the voluntary transfer of DNA" or "promises of individual percentages of future royalties," while acknowledging, at the international level, the value of "some sharing of eventual profits for humanitarian purposes with the contributing communities and populations." Bartha Maria Knoppers, *Conclusion: Human Genetic Material—Commodity or Gift?*, in LEGAL RIGHTS AND HUMAN GENETIC MATERIAL, *supra* note 33, at 171, 176–77.

IV. *Greenberg v. Miami Children's Hospital Research Institute, Inc.*

The recent action, *Greenberg v. Miami Children's Hospital Research Institute, Inc.*,²⁷⁸ represents the dangers of relying solely upon either the present market-inalienability or the pure property rights model. It is critical to resolve this issue because we can expect lawsuits such as *Greenberg* to prove more common in light of scientists' enhanced ability to locate the genetic markers for various diseases. Ultimately, individuals will tend to refuse to participate in scientific studies if they perceive the law as unfair to the plaintiff research participants.

A. *The Scientific and Legal Background of the Greenberg Action*²⁷⁹

1. *The Research Relating to Canavan Disease*

In 1981, Chicago residents Daniel and Debbie Greenberg gave birth to their first child, Jonathan.²⁸⁰ While Jonathan seemed normal at birth, his parents observed problems with his motor skills during his first year, and a neurologist ultimately diagnosed the child with Canavan disease.²⁸¹ Tragically, the Greenberg's second child, Amy, born in 1983, also suffered from the disease.²⁸² In 1987, Daniel Greenberg approached a medical researcher, Dr. Reuben Matalon, who had never previously studied Canavan, and requested his involvement in such research. At that time, Dr. Matalon directed a laboratory that performed clinical testing and research of phenylketonuria (PKU) and other familial disorders at the University of Illinois in Chicago.²⁸³

Dr. Matalon's research proceeded in two major stages. First, by 1988, he and his team determined that the deficiency of a certain enzyme, aspartoacylase, caused Canavan disease. Dr. Matalon achieved this insight by using blood, urine, and tissue samples provided by the Greenbergs and one other family, as well as money provided by a nonprofit organization. Armed with knowledge of

278. *Greenberg v. Miami Children's Hosp. Research Inst., Inc.*, 264 F. Supp. 2d 1064 (S.D. Fla. 2003).

279. The history of the *Greenberg* action is described in great detail by Professor Jon Merz of the Center for Bioethics, University of Pennsylvania School of Medicine, who has worked closely with the individuals involved in this action. See generally Merz, *supra* note 36.

280. *Greenberg* Complaint, *supra* note 3, ¶ 4; Merz, *supra* note 36, at 102.

281. Kolata, *supra* note 27; see also *supra* note 2 (briefly describing Canavan disease).

282. Merz, *supra* note 36, at 102.

283. *Id.*

the cause of Canavan disease, Dr. Matalon and his team were able to design a prenatal screening test. From 1988 to 1990, at least twenty couples, including the Greenbergs, benefited from prenatal testing developed by Dr. Matalon's lab.²⁸⁴

In the second stage of his research, Dr. Matalon began to search for the gene associated with Canavan disease, both in order to develop a more reliable prenatal test and to perform carrier screening.²⁸⁵ By this time, Dr. Matalon was conducting his research in Miami, where he had been recruited by Miami Children's Hospital (MCH) to establish and direct a center for research on genetic diseases, the Miami Children's Hospital Research Institute (MCH Research Institute).²⁸⁶ This phase of the research relied upon the contributions of thousands of individual research participants.²⁸⁷ As asserted in the *Greenberg* Complaint, the plaintiffs²⁸⁸ provided the researchers with a combination of blood, tissue, autopsy, and other samples, confidential medical information, and funding.²⁸⁹ By early 1993, a graduate student on Dr. Matalon's team succeeded in cloning the gene associated with Canavan disease.²⁹⁰

2. *The Patenting of the Gene Associated with Canavan Disease and the Licensing Process*

Shortly after researchers isolated the gene associated with Canavan disease, the Canavan Foundation and the National Tay-Sachs and Allied Diseases Association (NTSAD) began working with local and national groups to promote Canavan disease testing. The plaintiffs viewed their collaboration with researchers as a "partnership," and alleged in their complaint that, "[c]onsistent with their understanding that affordable and accessible testing was

284. *Id.*

285. *See id.* (stating that the gene provided "the only reliable method for prenatal testing as well as carrier screening").

286. Kolata, *supra* note 27.

287. Merz, *supra* note 36, at 102-03 (noting that Rabbi Josef Ekstein of Dor Yeshorim Committee for the Prevention of Jewish Genetic Diseases in Brooklyn, New York provided to Matalon approximately 6,000 blood samples).

288. The *Greenberg* plaintiffs included several families affected by Canavan disease, as well as three nonprofit community groups incorporated in New York State: the Canavan Foundation, Dor Yeshorim, and the National Tay-Sachs and Allied Diseases Association, Inc. *Greenberg* Complaint, *supra* note 3, ¶¶ 4-10; *see also* Eliot Marshall, *Families Sue Hospital, Scientist for Control of Canavan Gene*, 290 SCIENCE 1062, 1062 (2000).

289. *Greenberg* Complaint, *supra* note 3, ¶¶ 16-21.

290. Merz, *supra* note 36, at 102.

a 'partnership' goal," in spring 1996 the Canavan Foundation had established a free testing program at Mount Sinai Hospital in New York City.²⁹¹ By November 1998, the plaintiffs Canavan Foundation and NTSAD had persuaded the American College of Obstetricians and Gynecologists to issue guidelines recommending carrier screening of Ashkenazi couples.²⁹²

Unbeknownst to plaintiffs, however, MCH Research Institute had filed a patent application for the gene associated with Canavan disease and related applications, including carrier and prenatal testing, in September 1994.²⁹³ The United States Patent and Trademark Office issued U.S. Patent No. 5,679,635 to the MCH Research Institute in October 1997.²⁹⁴ As plaintiffs explained in their complaint:

Through patenting, Defendants acquired the ability to restrict any activity related to the Canavan disease gene, including without limitation: carrier and prenatal testing, gene therapy and other treatments for Canavan disease and research involving the gene and its mutations. The patent enabled Defendants to prevent doctors from testing or examining patients for the Canavan disease gene, even though the doctors could do so using traditional medical practices and such testing or examination would not require the use of any product or device invented by Defendants.²⁹⁵

291. *Greenberg* Complaint, *supra* note 3, ¶ 27.

292. *Id.* ¶ 27; *see also* Merz, *supra* note 36, at 103 (describing the work of advocates from the Canavan Foundation and NTSAD to promote testing for the disease).

293. *Greenberg* Complaint, *supra* note 3, ¶ 28. Dr. Matalon does not hold patent rights in the Canavan gene, as his contract with MCH required him to cede to MCH any marketable intellectual property that he developed in return for \$1 million of research funding annually. Marshall, *supra* note 288, at 1062.

294. Merz, *supra* note 36, at 103. Professor Merz stated that, as of December 2002, this is the only patent owned by Miami Children's Hospital or its research institute. *Id.*

295. *Greenberg* Complaint, *supra* note 3, ¶ 28. Numerous scholars and medical professionals have criticized the patenting of human genes in the United States because it often diminishes health care consumers' access to diagnostic tests and therapeutics. *See, e.g.,* George J. Annas, Lori B. Andrews & Rosario M. Isasi, *Protecting the Endangered Human: Toward an International Treaty Prohibiting Cloning and Inheritable Alterations*, 28 AM. J.L. & MED. 151, 155-56 n.10 (2002) (proposing an international treaty provision that would prohibit human gene patents due to the danger that the patents might impede the development of, and access to, diagnostic tests and treatment); Merz, *supra* note 36, at 99-101 (arguing that disease gene patents violate the product of nature doctrine and criticizing exclusive arrangements between academic medical centers and for-profit laboratories); COLL. OF AM. PATHOLOGISTS, GENE PATENTS DETRIMENTAL TO CARE, TRAINING, RESEARCH (July 5, 2000) (stating that "gene patents pose a serious threat to medical advancement, medical education, and patient care"), available at http://www.cap.org/apps/docs/advocacy/advocacy_issues/Issue_Genepat.html. Nonetheless, such patenting is the norm in the United States, and in other jurisdictions as well. *See generally* Gitter, *supra* note 257 (discussing the arguments surrounding the patentability of human DNA sequences in the United States and the European Union).

The plaintiffs allege that it was around 1994 that the defendants first presented them with a written consent form, at the plaintiffs' suggestion.²⁹⁶ They contend that this form was inadequate, for its description of the defendants' purpose as "identify[ing] mutations in the Canavan gene which may lead to carrier detection within my family" was woefully incomplete in that it failed to reveal the researchers' commercial aims.²⁹⁷

Shortly after their 1997 receipt of the patent, of which the plaintiffs remained unaware, MCH began working with a patent consultant on a marketing plan.²⁹⁸ In late 1998, MCH and MCH Research Institute began sending letters to clinical laboratories engaged in Canavan testing and to the plaintiffs, informing them of the patent and the hospital's plans for commercializing the test.²⁹⁹ These letters indicated the defendants' intent "to enforce vigorously [their] intellectual property rights relating to carrier and patient DNA tests for Canavan Disease mutations."³⁰⁰ Through these letters, the plaintiffs learned for the first time, indirectly, of the defendants' patent and their concomitant ability to earn royalties from the research in which the plaintiffs had participated with the goal of ensuring affordable and accessible carrier and prenatal screening and, ultimately, contributing to a treatment or cure for Canavan disease.³⁰¹

The parties differ in their views of MCH's marketing plan. According to Professor Merz, whose involvement the plaintiffs requested in their negotiations with MCH,³⁰² there were to be two stages of licensing.³⁰³ First, "a

296. *Greenberg* Complaint, *supra* note 3, ¶ 37; Merz, *supra* note 36, at 108.

297. *Greenberg* Complaint, *supra* note 3, ¶ 37. Dr. Matalon has stated that all of his research was approved by MCH's Institutional Review Board (IRB), which ostensibly waived any requirement of informed consent. Professor Merz has criticized the IRB, stating that he sees "no justification for a waiver of fully informed consent to the prospective collection of blood and other tissue samples for genetic studies." Merz, *supra* note 36, at 108. He has added that Dr. Matalon's research team submitted several proposals for NIH funding of their research, which were denied. "IRB approval and compliance with the federal Common Rule, 45 C.F.R. Part 46, would have been strictly required before such funding was provided." *Id.* at n.29. The federal Common Rule provides for informed consent. *See supra* note 111. Thus, federal funding of the Canavan research likely would have ensured the Canavan plaintiffs the protection they lacked.

298. Merz, *supra* note 36, at 103.

299. *Id.*; *Greenberg* Complaint, *supra* note 3, ¶ 30.

300. *Greenberg* Complaint, *supra* note 3, ¶ 30 (referring to Exhibit A of the Complaint).

301. *See id.* (alleging that the plaintiffs first learned of MCH's patent of the gene and the screening test from the enforcement letters to testing centers).

302. *See Merz*, *supra* note 36, at 104 (noting that the Canavan Disease Screening Consortium invited Professor Merz to discuss the ethical concerns regarding MCH's restrictive licensing scheme).

303. *Id.* at 103.

limited number of academic laboratories (likely to be a subset of the many already performing the testing) would be granted nonexclusive licenses to perform an annually limited number of tests" for a "fixed \$12.50 per test royalty."³⁰⁴ During the second phase, "a large commercial laboratory would be licensed as a 'market leader' with what would be, in effect, an exclusive license to the remainder of the testing volume."³⁰⁵

Professor Merz sharply criticizes both the substance of MCH's negotiation demands and its negotiation strategy. With respect to the substance, he refutes what he terms MCH's "justification" for exclusive licensing, namely that "a large reference laboratory would be able to spend the resources for outreach and education needed to ensure screening and testing of all couples at risk."³⁰⁶ Professor Merz notes that testing for Tay-Sachs disease is widespread even though testing methods "have never been restricted," and attributes this success to community groups such as NTSAD and Dor Yeshorim, which "stand as testaments to the ability of community-based organizations to develop and carry out population education and screening."³⁰⁷ With respect to MCH's negotiation strategy, Professor Merz contends that the hospital unfairly established a set of rules that imposed a gag on participants to the negotiation, and acted vengefully by prohibiting physicians at his institution, the University of Pennsylvania School of Medicine (Penn), from sending samples to any licensed lab for Canavan disease testing so long as MCH and Penn were unable to reach a licensing agreement.³⁰⁸ What is more, once MCH refused to license Penn, the hospital callously disregarded human health in its pursuit of profits, according to Professor Merz, by withholding information from physicians at Penn as to

304. *Id.*; see also *Greenberg Complaint*, *supra* note 3, ¶ 31 ("MCH . . . restricted public accessibility to testing through 'volume caps' that limited the number of tests to be performed by licensed laboratories and by requiring all such laboratories to pay royalty and licensing fees to MCH.").

305. Merz, *supra* note 36, at 103; see also *Greenberg Complaint*, *supra* note 3, ¶ 31 ("Defendants MCHRI and MCH . . . sought to substantially restrict the number of laboratories authorized to conduct Canavan disease testing through exclusive licensing agreements."). An exclusive licensing arrangement permits the licensee to charge a monopolistic price, thereby increasing the overall royalty payments flowing to the patent holder. See *Gene Patents and Other Genomic Inventions: Hearing Before the Subcomm. on Courts and Intellectual Property of the House Comm. on the Judiciary*, 106th Cong. 79 (2000) (statement of Jon F. Merz, assistant professor of bioethics, Center for Bioethics, University of Pennsylvania School of Medicine) (reporting on survey results showing that "14 of a sample of 27 disease gene patents . . . had been licensed as of the date of our survey . . . [and] all licenses were exclusive").

306. Merz, *supra* note 36, at 103.

307. *Id.* at 104.

308. See *id.* at 104–06 (describing MCH's actions as retributive and contrary to notions of common decency).

which labs were licensed to perform the testing, simply because MCH intended soon to grant one exclusive license and terminate the limited licenses it had granted to academic labs.³⁰⁹

MCH maintains that, while it had initially "considered donating the gene patent to the public and forgoing royalties on any test," it eventually declined to do so out of fear that, because "there were so few people who needed the test that laboratories would not bother to publicize it."³¹⁰ Thus, according to MCH, after months of deliberations and negotiations with academic and commercial laboratories, MCH decided to charge a royalty fee of \$12.50 per test.³¹¹ This money would be used to defray MCH's costs in funding Dr. Matalon's research, and some of it would be devoted to publicizing the test.³¹²

In April 2000, MCH offered the plaintiffs approximately \$20,000 per year of the estimated \$375,000 in annual royalties, with such funds intended to educate the public about Canavan disease and to subsidize the cost of testing for qualifying families.³¹³ MCH also abandoned its plans to implement exclusive licensing.³¹⁴ Nonetheless, the parties failed to reach an agreement, in large part because MCH's offer of funding was conditioned upon the plaintiffs' promise that they would cease public criticism of the hospital's licensing program and royalty fees, a requirement that the plaintiffs refused to accept.³¹⁵

309. See *id.* at 104–06 (outlining the negotiations between MCH and the Penn laboratory).

310. See Kolata, *supra* note 27 (describing the explanation offered by MCH's patent marketing consultant).

311. The *Greenberg* plaintiffs contest the reasonableness of the \$12.50 fee for a diagnostic test for Canavan disease. According to Judith Tsipis, vice president of the NTSAD: "If we go to testing people for 25, 50, and eventually maybe 100 genes, and each one carries a \$12.50 fee, then the cost of testing becomes prohibitive—or only the rich will get tested." Donn, *supra* note 257. In response, a hospital spokeswoman claims that MCH ultimately will lose money on its Canavan research, since MCH will enjoy a limited monopoly under patent law only for twenty years. *Id.*

312. See Kolata, *supra* note 27 (describing the explanation offered by MCH's patent marketing consultant).

313. Merz, *supra* note 36, at 106.

314. See *id.* (noting that MCH stopped searching for a "market leader" laboratory).

315. See *id.* (stating that the consortium "welcomed the financial help," but declined to accept the conditions set forth by MCH).

3. *The Legal Proceedings in Greenberg v. Miami Children's Hospital Research Institute, Inc.*

In October 2002, Daniel Greenberg, along with his coplaintiffs,³¹⁶ filed a lawsuit in the United States District Court for the Northern District of Illinois against defendants MCH, MCH Research Institute, and Dr. Reuben Matalon.³¹⁷ The six counts of the complaint included lack of informed consent,³¹⁸ breach of fiduciary duty,³¹⁹ unjust enrichment,³²⁰ fraudulent concealment,³²¹ conversion,³²² and misappropriation of trade secrets.³²³

The gravamen of the *Greenberg* plaintiffs' complaint was that they were not informed of, and did not consent to, the patenting of the gene associated with Canavan disease and the commercialization of carrier and prenatal tests.³²⁴ When they furnished researchers with tissue, autopsy, blood, urine, and other pathology samples, as well as personal familial data and funding, the plaintiffs expected Canavan research to remain in the public domain in order to facilitate the development of a cure for the disease, and they also intended for carrier and prenatal testing to be affordable and accessible to as many families as possible.³²⁵ According to

316. See *supra* note 288 (noting that the *Greenberg* plaintiffs were families affected by Canavan disease as well as three nonprofit community groups).

317. See generally *Greenberg* Complaint, *supra* note 3. The Illinois court transferred the case to United States District Court for the Southern District of Florida, on the grounds that the Illinois court lacked jurisdiction and venue over all of the defendants. *Supra* note 3.

318. *Greenberg* Complaint, *supra* note 3, ¶¶ 33–39.

319. *Id.* ¶¶ 40–45.

320. *Id.* ¶¶ 46–54.

321. *Id.* ¶¶ 55–60.

322. *Id.* ¶¶ 61–67.

323. *Id.* ¶¶ 68–75.

324. *Id.* ¶¶ 21–22, 34–36. The plaintiffs alleged that Dr. Matalon first presented them with informed consent forms in 1994, several years after the research had begun, and that these forms were deficient in that they failed to reveal the defendants' financial interest in the research, *id.* ¶ 37, as required under *Moore*. See *supra* note 76 and accompanying text (describing physician-researchers' duty to disclose personal economic interests that may affect their medical judgment).

325. *Greenberg* Complaint, *supra* note 3, ¶¶ 21–22. The plaintiffs' belief that Canavan research would remain in the public domain stemmed in large part from their knowledge that the patent for the gene associated with Tay-Sachs disease, a condition that is also particularly prevalent among Jews of Eastern European descent, is in the public domain. *Id.* In the case of the Tay-Sachs gene, the patent holder is the United States government. See *Palmer*, *supra* note 1, at 12 (noting that the United States government owns the patent because a National Institute of Health researcher identified the gene and diagnostic test). As stated by Professor Palmer, "[t]he federal government's ownership of the patent helps guarantee that the Tay-Sachs disease test is both inexpensive and widely available." *Id.* at 12–13 (footnote omitted).

the plaintiffs, they would have refused to participate in the research had they known of the defendants' "true intentions to commercialize their genetic material through patenting and restrictive licensing,"³²⁶ or else would have "imposed conditions . . . to avoid commercialization of the Canavan disease gene or opted to donate their samples to other researchers who shared their common goals of accessible and affordable testing."³²⁷

The plaintiffs also alleged conversion, claiming a "property interest in their blood, tissue, urine and autopsy samples and those of their minor children, and in the genetic information contained therein,"³²⁸ as well as in the "Canavan Registry," a compendium of contact information and medical data about families worldwide afflicted with Canavan Disease compiled by Daniel Greenberg in conjunction with the NTSAD.³²⁹ Plaintiffs contended that their purpose in contributing their bodily materials was to promote the "good of the public at large,"³³⁰ and that the defendants wrongfully converted their plaintiffs' property for "their exclusive economic benefit."³³¹

B. Analysis of the Greenberg Decision

Given the parallels between the *Greenberg* and *Moore* actions, the court alluded to the latter case when deciding the former, though declining to follow it in some respects.³³² Ultimately, the *Greenberg* court dismissed with prejudice five of the six claims brought by the plaintiffs, permitting

326. *Greenberg* Complaint, *supra* note 3, ¶ 38.

327. *Id.* ¶ 59.

328. *Id.* ¶ 62.

329. *Id.* ¶ 63. The plaintiffs also alleged that the defendants' misuse of the Canavan Registry gave rise to a cause of action for misappropriation of trade secrets. *Id.* ¶¶ 68–75.

330. *Id.* ¶ 67.

331. *Id.* ¶ 66.

332. See *Greenberg v. Miami Children's Hosp. Research Inst., Inc.*, 264 F. Supp. 2d 1064, 1070–71 (S.D. Fla. 2003) (rejecting the *Greenberg* plaintiffs' claim for lack of informed consent on the grounds that the action is distinguishable from *Moore*, where the researcher and the plaintiff had a therapeutic relationship). The *Greenberg* plaintiffs ultimately filed a motion to amend their complaint to allege a "doctor-patient relationship and/or . . . confidential relationship" between the plaintiffs and the defendants, see Motion for Leave to File Amended Complaint, Case No. 02-22244-CIV-Moreno (S.D. Fla., 2003), a motion denied by Judge Moreno on July 22, 2003. Pacer, Civil Docket for Case # 02-CV-22244, *Greenberg, et al v. Miami Children's Hospital*, at <http://pacer.flsd.uscourts.gov/dc/cgi-bin/pacer740.pl> (Sept. 26, 2003) (on file with the Washington and Lee Law Review).

only the unjust enrichment cause of action to survive.³³³ Although the court considered the issues in the context of a Rule 12(b)(6) motion to dismiss for failure to state a claim upon which relief may be granted,³³⁴ as opposed to a full trial on the merits, the *Greenberg* holding provides a telling example of how courts will adjudicate cases involving research participants. This decision clearly demonstrates the necessity for a federally recognized property right inhering in research participants with respect to their tissue.

1. Lack of Informed Consent

The *Greenberg* court dismissed the plaintiffs' first claim, lack of informed consent, based on several grounds.³³⁵ First, the court questioned whether researchers who lack a therapeutic relationship with the research participant even owe that individual a duty of informed consent.³³⁶ Assuming *arguendo* that researchers do owe such a duty,³³⁷ the court declined in the instant action to extend this obligation to include disclosure of a researcher's economic interests, stating that this requirement "has no support in established law, and more ominously, . . . would have pernicious effects over medical research, as it would give each donor complete control over how medical research is used and who benefits from that research."³³⁸ The court emphasized, in response to plaintiffs' citations of cases that support the notion that a researcher must disclose economic interests, such as *Moore*³³⁹ and *Grimes v. Kennedy Krieger Institute, Inc.*,³⁴⁰ that those

333. *Greenberg*, 264 F. Supp. 2d at 1077-78. As noted above, the parties to this action have reached a confidential settlement agreement. *Supra* note 14.

334. *Greenberg*, 264 F. Supp. 2d at 1068.

335. *Id.* at 1070-71 (declining to extend the duty of informed consent to the disclosure of researchers' economic interests).

336. *Id.* at 1070 (stating that Florida law regarding a duty of informed consent for research subjects is "unsettled and fact-specific").

337. The *Greenberg* court was persuaded by the fact that the defendants had conceded at oral argument the existence of some level of duty to the research participant, a situation not present in every proceeding. *Id.* at 1070.

338. *Id.* at 1070 (agreeing with the defendants' argument against extending the duty of informed consent).

339. See *Moore v. Regents of the Univ. of Cal.*, 793 P.2d 479, 485 (Cal. 1990) (recognizing a duty on the part of the physician-researcher to disclose to research participants any personal interests that might affect the physician's medical judgment).

340. See *Grimes v. Kennedy Krieger Inst., Inc.*, 782 A.2d 807, 834-35 (Md. 2001) (holding that "the very nature of nontherapeutic scientific research on human subjects can, and

cases from other jurisdictions were not controlling authority in Florida.³⁴¹ Most of all, the court was persuaded by "the practical implications of retroactively imposing a duty" of informed consent, namely that such an obligation would "chill medical research as it would mandate that researchers constantly evaluate whether a discloseable event has occurred" and would give research participants too much control over medical research.³⁴²

There are several significant critiques of the *Greenberg* court's rejection of plaintiffs' claim of lack of informed consent. First, as explained above, courts have recognized that, even more so than a treating physician, a researcher owes a duty of informed consent to a research participant.³⁴³ Second, given the fact that most scientific research is commercial in nature,³⁴⁴ it is critical to extend this duty of informed consent to include researchers' economic interests, in order to preserve the autonomy of research participants.³⁴⁵ As the plaintiffs noted, the defendants, in failing to reveal their commercial interests, treated the research participants like "treasure troves."³⁴⁶ Third, the court drew a specious distinction between Mr. Moore, who was an unwitting research participant, and the *Greenberg* plaintiffs, who were aware

normally will, create special relationships out of which duties arise").

341. *Greenberg v. Miami Children's Hosp. Research Inst.*, 264 F. Supp. 2d 1064, 1070 (S.D. Fla. 2003). The court also emphasized the lack of a therapeutic relationship between the defendants and the plaintiffs in *Greenberg*. *But see supra* note 332 (noting that the *Greenberg* plaintiffs ultimately filed a motion to amend their complaint to allege a confidential relationship between the plaintiffs and the defendants, a motion ultimately denied by the court).

342. *Id.* at 1070-71.

343. *See supra* notes 103-07 and accompanying text (advocating that researchers should be held to a higher duty of disclosure because the research participants receive little personal benefit from their involvement). The *Greenberg* plaintiffs also maintained that, like a researcher, a hospital participating in a scientific study owes the research participant the duty of informed consent and the fiduciary duty. Plaintiffs' Consolidated Response to Defendants' Motions to Dismiss and Transfer Venue, Case No. 00-C-6779 (N.D. Ill., 2000), at 23 [hereinafter Plaintiffs' Response to Defendants' Motions to Dismiss] (on file with the Washington and Lee Law Review). What is more, the *Greenberg* plaintiffs emphasized that MCH dealt directly with them by requesting their consent to research in 1994. *Id.* at 27.

344. *See supra* note 87 (giving examples of scholarship that notes the trend of academic research becoming increasingly commercialized).

345. The court noted that the American Medical Association Code of Ethics has provided, since 1994, that "[p]otential commercial applications must be disclosed to the patient before a profit is realized on products developed from biological materials" and "[h]uman tissue and its products may not be used for commercial purposes without the informed consent of the patient who provided the original cellular material." *Greenberg*, 264 F. Supp. 2d at 1070 n.2 (quoting AMA CODE OF MEDICAL ETHICS § E-2.08(2)-(3) (American Medical Association's Council on Ethical and Judicial Affairs 2001)).

346. Plaintiffs' Response to Defendants' Motions to Dismiss, *supra* note 343, at 3.

that they were participating in research. By classifying the latter plaintiffs as willing donors, the court misses an important point: A research participant can be a voluntary donor for one purpose (that is, noncommercial research), but not for another (that is, commercial research). To hold otherwise would be to encourage scientific researchers to overstep the bounds of their described research agenda to conduct upon research participants additional experiments to which they had not consented.

2. Breach of Fiduciary Duty

The *Greenberg* court also dismissed the plaintiffs' second cause of action, breach of fiduciary duty, on two grounds. First, just as the court had declined to find a duty of informed consent between the researcher and the research participant with respect to disclosure of the researcher's economic interests,³⁴⁷ the court held that "[t]here is no automatic fiduciary relationship that attaches when a researcher accepts medical donations."³⁴⁸ Second, the court held that the plaintiffs must allege not only that they placed trust in the defendants, but also that the defendants accepted that trust, and that the *Greenberg* plaintiffs had failed to plead this second element.³⁴⁹ According to the court, "the acceptance of trust . . . cannot be assumed once a donation is given."³⁵⁰

The problem with the court's approach, however, is that it departs from the accepted notion that physicians owe their patients a fiduciary duty.³⁵¹ As a practical matter, research participants perceive their researchers as fiduciaries, even in the absence of a therapeutic relationship, and will tend to repose trust in them. Indeed, without such a relationship of trust and confidence, the scientific collaboration could not proceed. If researchers are not required to honor this trust, the situation is ripe for exploitation of the research participants.

347. See *supra* notes 335–42 and accompanying text (discussing the court's finding that such disclosure would give "each donor complete control over how medical research is used and who benefits from that research").

348. *Greenberg v. Miami Children's Hosp. Research Inst., Inc.*, 264 F. Supp. 2d 1064, 1072 (S.D. Fla. 2003).

349. *Id.*

350. *Id.*

351. See *Moore v. Regents of the Univ. of Cal.*, 793 P.2d 479, 484–85 & n.10 (Cal. 1990) (holding that a physician owes a fiduciary duty to a patient to "disclose all facts material to the patient's decision"). But see *supra* notes 195–97 and accompanying text (explaining how the California Supreme Court placed significant limitations on this concept of fiduciary duty, thereby diminishing its effectiveness in protecting research participants).

3. *Fraudulent Concealment*

In light of its holding that the defendants owed no fiduciary duty to the plaintiffs, the *Greenberg* court also rejected the plaintiffs' claim for fraudulent concealment, stating that there existed "no special relationship that gives rise to a duty to speak."³⁵² Indeed, the court placed the onus on the plaintiffs to uncover facts about the issuance of the patent, stating that "if they were so concerned about a possible intent to patent then a simple phone inquiry to the Defendants would have uncovered the fact."³⁵³ This holding clearly decreases protection for the research participant, requiring him to inquire about the possibility of a patent, despite the fact that it is the researcher, not the tissue contributor, who is most knowledgeable about potential plans to commercialize the scientific findings resulting from the research.

4. *Conversion and Misappropriation of Trade Secrets*

Although the *Greenberg* court noted, in its analysis of the plaintiffs' claim of lack of informed consent, that *Moore* did not represent controlling authority in Florida,³⁵⁴ the court nonetheless invoked *Moore* in deciding the conversion claim. The court cited *Moore* for the proposition that the "[p]laintiffs have no cognizable property interest in body tissue and genetic matter donated for research under a theory of conversion."³⁵⁵ The court also emphasized that, under Florida law, a research participant cedes property rights in blood and tissue samples once the sample is voluntarily given to a third party.³⁵⁶ Furthermore, the court held that a property right inheres in *the information contained in the plaintiffs' tissue, not the tissue itself*, and that this information was developed through the efforts of the defendants, not the plaintiffs.³⁵⁷ According to the court, "[i]f adopted, the expansive theory championed by

352. See *Greenberg*, 264 F. Supp. 2d at 1073 (stating that "[a]llegations of fraudulent concealment by silence must be accompanied by allegations of a special relationship" that give rise to such a duty).

353. *Id.* at 1074.

354. *Id.* at 1070.

355. *Id.* at 1074.

356. See *id.* at 1075 (stating that "limits to the property right that attach to body tissue have been recognized in Florida state courts" and that "the property rights in blood and tissue samples also evaporates once the sample is voluntarily given to a third party").

357. See *id.* (citing *Pioneer Hi-Bred Int'l, Inc. v. Holden Found. Seeds, Inc.*, 1987 WL 341211 (S.D. Iowa 1987), *aff'd*, 35 F.3d 1226 (8th Cir. 1994)) (supporting the proposition that defendants' efforts in gathering and arranging the genetic information entitled them, and not the plaintiffs, to property rights therein).

Plaintiffs would cripple medical research as it would bestow a continuing right for donors to possess the results of any research conducted by the hospital."³⁵⁸

The court's ruling on the conversion cause of action invites several challenges. First, although the court relied upon the notion of voluntary donation by the plaintiffs, this justification proves to be entirely fictional when one considers that the plaintiffs were unaware of the true use of their tissue, largely because they did not have the benefit of informed consent. Second, the court conflated the notion of property rights in human tissue and ownership of the patented invention developed from it.³⁵⁹ The law must distinguish between the two, recognizing a research participant's property rights in the tissue itself, even if patented invention ultimately belongs to another. The commercial profits from the invention, along with the characteristics of the tissue and the behavior of the researchers, should be considered in calculating the damages due to the research participants.³⁶⁰

The court also rejected the plaintiffs' claim of misappropriation of trade secrets in connection with the Canavan Registry, holding that the complaint proved inadequate in two respects. First, the plaintiffs failed to allege that the economic value of the registry derived from its confidentiality.³⁶¹ Second, the plaintiffs failed to demonstrate reasonable efforts on their part to maintain the secrecy of the registry.³⁶²

5. Unjust Enrichment

Only the plaintiffs' unjust enrichment cause of action survived the defendants' motion to dismiss. The court recognized "a continuing research collaboration that involved Plaintiffs also investing time and significant resources in the race to isolate the Canavan gene."³⁶³ For the purposes of this claim, the court recognized that the defendants' patent did not relieve them of responsibility to compensate the plaintiffs for the valuable tissue they furnished

358. *Id.* at 1076.

359. *See supra* notes 139–43 and accompanying text (discussing how a federal law according research participants a property interest in their tissue need not necessarily grant them the right to control the intellectual property developed from the tissue, absent a finding of joint inventorship).

360. *Id.*

361. *Greenberg v. Miami Children's Hosp. Research Inst., Inc.*, 264 F. Supp. 2d 1064, 1072 (S.D. Fla. 2003).

362. *Id.*

363. *Id.* at 1072–73.

to researchers.³⁶⁴ This approach is too ad hoc, however, to be relied upon for future research participants.

Had the *Greenberg* plaintiffs negotiated expressly with their researchers, as PXE International has done, it is likely that they would have been able to enforce their contractual rights. Reliance upon a property rights model alone, however, fails to protect those research participants who remain unaware of their researchers' commercial agenda. This situation arises often, as demonstrated by the *Moore* and *Greenberg* actions. Indeed, the decisions in these cases increase the likelihood that scientists will not divulge their economic interests to research participants, in light of the *Moore* court's holding that a physician-researcher is not a patient's financial advisor³⁶⁵ and the *Greenberg* court's decision exempting researchers who lack a therapeutic relationship with their research participants from the law of informed consent and fiduciary duty.³⁶⁶ Thus, Congress should recognize explicitly research participants' property rights in their tissue through a hybrid property rights/liability model. This approach would safeguard the rights of entities such as PXE International that choose to negotiate with researchers, and also ensure that individuals facing the same situation as the *Greenberg* plaintiffs in the future will recover damages when researchers deprive them of information that would allow them to bargain effectively for rights in their tissue.

V. Proposal for Congressional Enactment of a Hybrid Property Rights/Liability Model Recognizing the Property Interest of Research Participants in Their Body Tissue

Current United States policy regarding research participants' rights in their tissue lacks transparency, consistency, and equity. As one commentator stated:

The current state of affairs presents some of the least attractive features of a new and uncivilized frontier. Information is poorly distributed, if not concealed, and the failure to develop a social policy for the many is mitigated only by the self-help of the few—in particular, those few who are fittest for bargaining or litigation. When problems emerge in an activity so central to biomedical research, there is a public interest in promoting

364. *Id.*

365. *See supra* note 191 and accompanying text (discussing the *Moore* court's holding that a researcher does not have a duty to protect the financial interests of a research participant).

366. *See supra* Parts IV.B.1–2 and accompanying text (noting the *Greenberg* court's reliance on the practical implications of such duties and its concern that such obligations would hinder medical research and give research participants too much control).

transparency and developing a rationally articulated policy for social, economic and professional responsibility.³⁶⁷

As discussed above, this leads to an anomalous situation in which research participants such as the members of PXE International enjoy property rights in their tissue, on the one hand, whereas the *Moore* and *Greenberg* plaintiffs do not, even though the only significant difference between their research participation is that the members of PXE International were aware that they were participating in commercially motivated research, while the others were not.³⁶⁸

Commentators suggest that "legislatures may be in the best position to design and institute appropriate remedies" for this problem,³⁶⁹ a view shared by the *Moore* majority, which emphasized that "[l]egislatures . . . have the ability to gather empirical evidence, solicit the advice of experts, and hold hearings at which all interested parties present evidence and express their views."³⁷⁰ This Article proposes that Congress implement a hybrid property rights/liability model that: (1) recognizes that individuals possess property rights in their tissue and therefore have the right to exchange it for valuable consideration, or to waive such rights if they prefer to make a gratuitous donation;³⁷¹ and (2) permits individual research participants to maintain an action for conversion of their tissue in the event that: (a) they were not informed that researchers were using their tissue for commercial purposes; or (b) they did enter into an agreement regarding the use of the tissue that is voidable under the doctrines of fraud, duress, undue influence, or mutual mistake.

There is ample precedent for federal regulation of property rights in human tissue. First, federal law already prescribes certain rules concerning the treatment of human research participants involved in federally-sponsored research,³⁷² and FDA regulations apply to research involving

367. Harrison, *supra* note 34, at 81.

368. See *supra* notes 31–32 and accompanying text (discussing the different situations of the members of PXE International and the plaintiffs in *Moore*).

369. Harrison, *supra* note 34, at 83 (citing James E. Krier & Stewart J. Schwab, *Property Rules and Liability Rules: The Cathedral in Another Light*, 70 N.Y.U. L. REV. 440, 477 (1995)).

370. *Moore v. Regents of the Univ. of Cal.*, 793 P.2d 479, 496 (Cal. 1990) (citing *Foley v. Interactive Data Corp.*, 47 Cal. 3d 654, 694 n.31 (1988)); see also *supra* note 33 (discussing the suitability of the legislature for addressing broad issues of public policy).

371. See *supra* note 118 (suggesting that a research participant ought to manifest her waiver of her rights in writing, just as she typically indicates her informed consent).

372. See 45 C.F.R. §§ 46.101–124 (2002) (describing the Department of Health and Human Services' basic policy for protection of human research participants).

experimental drugs, biological products, and medical devices that are subject to FDA approval.³⁷³ In addition, Congress recognizes property rights in intangible intellectual property created by human ingenuity, in part to stimulate such innovation,³⁷⁴ and can similarly create an incentive to supply tissue by affording research participants a property interest therein.³⁷⁵

A. Parameters of the Property Rights/Liability Model

In order for the property rights/liability model to operate, research participants ought to be able negotiate mutually satisfactory agreements with their researchers, fully informed as to all the risks associated with the research and the scientists' economic interests.³⁷⁶ In addition, research participants should possess the right to initiate an action for conversion, a strict liability tort, against any researcher who uses their tissue without informed consent. In conversion cases, researchers' participants would be entitled to compensation only if the researchers earned a profit from commercializing their tissue, as the research participants essentially would be functioning as investors who donate capital and stand to lose the value of their investment. Despite fears about a proliferation of conversion actions, research participants likely would file lawsuits only if they were sufficiently aggrieved, and could expect a rather small damage awards if their tissue were not unique.

B. Advantages of a Property Rights/Liability Model

A property rights/liability model promises to stimulate biomedical research in many ways. First, the promise of compensation encourages research

373. See 21 C.F.R. §§ 50.1, 56.101 (2002) (describing the scope of the regulations).

374. See 15 U.S.C. §§ 1051–1129 (2000) (setting forth the federal trademark statute); 17 U.S.C. §§ 101–1332 (2000) (setting forth the federal copyright statute); 35 U.S.C. §§ 1–376 (2000) (setting forth the federal patent statute).

375. See *supra* note 95 and accompanying text (explaining that research participants might be less likely to undergo the risks associated with biomedical research without a legally protected right to compensation).

376. Another issue to be considered is whether individuals ought to be able to sell their entire body to researchers after their death, with the proceeds either enjoyed by them before death or flowing to their estate. On one hand, acceptance of this practice might decrease the number of individuals who make charitable donations of their bodies upon their death. On the other hand, the promise of profit, while decreasing gratuitous donations, may increase overall the number of people who permit scientists to conduct research on their bodies after death.

participation by individuals who might otherwise decline to behave altruistically while others profit, and, what is more, who face the inconvenience, medical risks, loss of privacy, and possibility of genetic discrimination inherent in such participation.³⁷⁷ Second, the promise of profits also fosters self-checking by individuals who will initiate significant research by informing biomedical researchers of the value and uniqueness of their tissue.³⁷⁸ Third, the possibility of a liability action creates even greater incentive for researchers to provide informed consent,³⁷⁹ especially because the monetary damages will prove great enough to serve a deterrent effect.³⁸⁰ Fourth, this model's recognition of research participants' right to bargain with researchers will help to ensure that the tissue ends up in the hands of the highest bidder, who, it is hoped, will put the tissue to its most valuable use.³⁸¹ Fifth, and just as important, notions of equity militate that research participants, who supply useful scientific raw materials,³⁸² and encounter risks through their participation,³⁸³ are entitled to compensation, in light of researchers' own pecuniary gain. Any other approach threatens to lead to a decrease in public support of such research,³⁸⁴ lest the public perceive that researchers obtain scientific inputs from them for free and then charge them for the commercial outputs.

377. See *supra* notes 94–95 and accompanying text (discussing the benefits of compensating research participants). As noted above, a research participant who prefers to make a gratuitous donation would be free to waive the right to share in the profits of biomedical research. See *supra* note 118 (stating that such a provision would protect researchers from financial liability in cases where a research participant expresses a desire to make a gratuitous donation).

378. See *supra* notes 96–97 and accompanying text (noting that medically affected individuals are often among the first to recognize scientifically significant phenomena within themselves).

379. See *supra* note 132 and accompanying text (citing *Moore v. Regents of the Univ. of Cal.*, 793 P.2d 479, 494 (Cal. 1990), in support of the proposition that the threat of a conversion claim may help enforce a patient's right of informed consent).

380. See *supra* notes 189–205 and accompanying text (discussing the likelihood that plaintiffs will recover very little in damages under only the theories of lack of informed consent and breach of fiduciary duty).

381. See *supra* notes 134–38 and accompanying text (noting the advantages of the market system, which puts tissue in the hands of the researcher likely to use it most productively).

382. See *supra* notes 147–52 and accompanying text (explaining that human tissue is just as important a part of the research process as the chemical reagents or other equipment used).

383. See *supra* note 154 and accompanying text (noting examples of the potential harm research participants may encounter due to their involvement in scientific research, including the loss of privacy, the dangers of negative consequences from the release of their medical information, and the risk of learning emotionally disturbing information about their health).

384. See *supra* note 158 and accompanying text (stating that if general public support for biomedical research declines, so too will government support).

C. An Examination of Alternative Models

1. The Harrison Hybrid Donative/Liability Model

In an extremely thoughtful article considering the issue of compensation for human research participants, one commentator, Ms. Charlotte Harrison, a former Fellow in Medical Ethics at Harvard Medical School during the 2000–2001 academic year, proposed retention of the general rule of tissue donation (premised, of course, upon the research participant's consent), along with implementation of an objective, nonmarket mechanism for compensating research participants after scientists have commercialized their research results. She advocates remuneration of the research participants only in those rare cases where the tissue proves of significant commercial value, and considers various objective third parties that could reach this determination, including an administrative agency, an arbitration panel, or a tribunal. In cases where tissue donors cannot be tracked, or do not wish to receive compensation, the companies would be required to dedicate the adjudicated sum to a charitable purpose, thereby discouraging biotech firms from intentionally losing linking information or from dissuading research participants from claiming their share of the proceeds.³⁸⁵ Ms. Harrison highlights the significant advantages of the proposed system, including that it would "enable the acquisition and study of tissue to go forward without the delays, commodifying tendencies and other disadvantages of up-front negotiations;" "would operate evenhandedly after the fact of use;"³⁸⁶ and "could be applied uniformly . . . to the full range of tissues collected in hospitals anywhere in the world."³⁸⁷

385. Harrison, *supra* note 34, at 93–100.

386. *Id.* at 99. While this proposed donative/liability model offers the advantage that the research participant's compensation is calculated after the value of the biomedical product developed from her tissue is known, the property rights/liability model advocated in this Article achieves the same purpose in cases where plaintiffs institute litigation after the commercialization of products made from their tissue. In other cases, the parties can avoid the need for the involvement of a third party by negotiating in advance to establish the consideration to be exchanged for the tissue.

While the donative/liability model also offers the advantage of a predictable, consistent pricing scheme, the development of a sophisticated market will eventually serve the same purpose, with the parties closest to the issue, research firms and research participants, setting the prices. The government certainly could institute regulation, as it has in markets such as those for securities and energy. Nonetheless, the existence of a market can help to deliver tissue to the user who will value it most highly. See *supra* note 134 and accompanying text (explaining that the current system fails to allocate human tissue used in research to the highest bidder, and that a change in the system could help to put the material to its most productive use).

387. Harrison, *supra* note 34, at 99; see also *id.* at 100–03 (explaining that one of the major advantages of her approach is that it is compatible with Western Europe's traditional

While the Harrison donative/liability model does address many of the deficiencies of our current system, it is marked by two significant flaws. First, this model does not take into account that relationships between scientists and research participants are increasingly governed by private arrangements negotiated by the parties, as in the case of PXE International. As a related matter, Ms. Harrison's model does not address research participants' noneconomic interests, in particular the right to participate in licensing decisions,³⁸⁸ an issue of fundamental importance to those afflicted by disease, as demonstrated by the degree to which the members of PXE International and the *Greenberg* plaintiffs devoted their efforts toward ensuring availability of the commercial products developed from their tissue. The model proposed in this Article offers scientists and research participants the opportunity to negotiate agreements regarding the licensing of intellectual property developed from human tissue. As noted above, in those instances where researchers did not act in good faith, courts could consider, as an equitable remedy, permitting tissue contributors to participate in the decision-making with respect to the licensing of the intellectual property developed from their tissue.³⁸⁹

2. A Gene Trust

Some commentators also have proposed the establishment of a human genome trust, to prevent ownership by private entities.³⁹⁰ According to this

objection to the commodification of the human body and the prevailing view in that region that research participants' donation of their tissue furthers the goal of improved public health, a view that naturally holds more sway in countries with nationalized health care systems than in the United States).

388. See *id.* at 83 n.39 (acknowledging that the proposal does not address issues of "ownership and control"); see also *id.* at 87 ("[T]he extent of protection afforded to a tissue contributor's non-economic interests is a public policy question that goes beyond the scope of this article.").

389. See *supra* text accompanying note 142 (describing factors to be considered when a research participant has neither negotiated for, nor expressly or impliedly waived, her right to payment).

390. See, e.g., Patricia A. Lacy, Comment, *Gene Patenting: Universal Heritage vs. Reward for Human Effort*, 77 OR. L. REV. 783, 804-05 (1998) ("Promoting proper dissemination of genetic information, protecting intellectual property rights, and implementing regulatory guidance for genetic research could best be served by the establishment of an international body to hold in trust the human genome as it is discovered."); Barbara Looney, Note, *Should Genes Be Patented? The Gene Patenting Controversy: Legal, Ethical, and Policy Foundations of an International Agreement*, 26 LAW & POL'Y INT'L BUS. 231, 268-69 (1994) (stating that an international body holding the Human Genome in trust would address the "ethical, legal, and policy interests at stake in the gene patenting controversy"); see also Gold, *supra* note 135, at 1246-47 (suggesting that ownership of cell lines should vest in a nonprofit,

view, "[t]o ensure proper dissemination of genetic information, protection of intellectual property rights, and regulatory guidance for genetic research, an international body should be established to hold in trust the Human Genome as it is discovered, granting rights for continuing research that may culminate in" patentable inventions.³⁹¹ In addition, such a system acknowledges the growing globalization of science,³⁹² as it renders United States law compatible with widespread European opposition to commercialization of the human genome.³⁹³ Creation of such an institution would be difficult to achieve, however, in light of the need for widespread international cooperation and financial support.³⁹⁴ Most importantly, as noted previously, the creation of a nonprofit, non-governmental organization to control valuable tissue is unlikely,³⁹⁵ as private ownership of human DNA sequences is already firmly entrenched in both the United States and throughout Western Europe.³⁹⁶ For this reason, a hybrid property rights/liability model proves a superior solution.

VI. Conclusion

The *Greenberg* litigation illustrates the inadequacies of our current system of apportioning property rights among the participants in biomedical research on human tissue. Although the *Greenberg* plaintiffs remained unaware during their participation in research on Canavan disease that researchers aimed to commercialize the results of these experiments, the *Moore* holding serves to deny the plaintiffs relief under the theories of lack of informed consent and breach of fiduciary duty. The *Greenberg* court interpreted *Moore* to oblige

nongovernmental organization such as the Red Cross).

391. Looney, *supra* note 390, at 268.

392. *Id.* at 271–72 (noting the lack of international consensus regarding patenting of the human genome).

393. For a discussion of the opposition to commercialization of the genome prevalent throughout the European Union, see Gitter, *supra* note 257, at 1656–59.

394. See David Keays, *Patenting DNA and Amino Acid Sequences—An Australian Perspective*, 7 HEALTH L.J. 69, 87 (1999) (noting that "creation of a Human Genome trust would require a major collaborative effort on an international level," and cautioning that "one is likely to encounter political tension, imbalances of power and bureaucratic waste"); see also Looney, *supra* note 390, at 269 (noting the political tension inherent in the establishment of a single international genome policy).

395. See *supra* notes 136–38 and accompanying text (observing that the biomedical research industry rests firmly upon free market principles, at least insofar as it concerns the exchange of materials among researchers).

396. See Gitter, *supra* note 257, at 1660–61 (setting forth reasons why private ownership of human DNA sequences is likely to continue in the United States and Western Europe).

only physicians who have a therapeutic relationship with the research participant, not pure researchers, to honor these duties. What is more, the *Moore* court declined to extend the strict liability tort of conversion to apply to human tissue, out of concern that every tissue sample would become the subject matter of a lawsuit.

Had the *Greenberg* plaintiffs negotiated in advance with their researchers, as the patient advocacy group PXE International has done, it is possible, though hardly assured, that they would have enjoyed the right to control the use of their tissue. No court has yet ruled on the legitimacy of such agreements, which seem to conflict with legal precedent and some scholarly opinion that suggest that it is inappropriate to recognize a market in human tissue. Nevertheless, it is clear that researchers, tissue banks, and tissue brokers, as well as patients themselves, already buy and sell human biological material, including blood and gametes.

In light of the fact that a market in human tissue already exists, this Article advocates for congressional enactment of a hybrid approach to property rights in human tissue. The law should entitle plaintiffs to invoke a property rule where they negotiated in advance for rights in their tissue, and, when necessary, to invoke a liability rule in the form of an action for conversion when researchers withheld from them vital information that would have facilitated their ability to bargain for such rights. As noted above, it is inequitable to deny relief to the *Greenberg* plaintiffs, who contributed valuable tissue to research just like the members of PXE International, yet were not informed of their researchers' goal of commercialization. While the *Greenberg* court's apparent acceptance of the plaintiffs' unjust enrichment argument is promising, such an approach is too ad hoc to lend certainty to this pressing issue.

The hybrid property rights/liability approach proposed in this Article will create an incentive for individuals to participate in research, compensate them equitably for their contribution, and also enable them to make decisions that will foster the availability and affordability of diagnostic and therapeutic biomedical products to other consumers. What is more, under this system, it is more likely that tissue will end up in the hands of researchers who will use it most productively, as evidenced by their willingness to pay valuable consideration for it. Congressional enactment of legislation implementing this model offers the opportunity to advance biotechnological innovation, enhance the public accountability of researchers, and foster citizen involvement in pressing public health decisions, all while ensuring honorable and equitable treatment of research participants.

