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Recognizing a Quasi-Property Right in Biomaterials

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Recognizing a Quasi-Property Right in Biomaterials

JoAnne Belisle*

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INTRODUCTION

Human cells and tissues are essential in developing and testing new drugs and vaccines.¹ They are also a source of raw material for creating products such as cell lines and diagnostic tests.² The most common source of tissues used in research is from patients undergoing medical treatment.³ Doctors commonly retain samples of blood, tissue, and cells for research after removing them during blood tests, biopsies, operations, and other routine procedures.⁴ After collection, biobanks and tissue repositories store the samples and distribute them to government, university, and commercial researchers for a small fee.⁵

The Research and Development Corporation (RAND Corporation) estimated that in 1999 there were more than 307 million tissue samples from over 178 million individuals stored in biobanks in the United States and that the number of samples is increasing by at least 20 million each year.⁶ Extrapolating this growth rate, there were approximately 527 million samples in 2010.⁷ It is estimated that “most Americans have their tissue on file somewhere.”⁸

Science and technology are rapidly progressing and the market for cells, blood, and biopsied tissue is growing along with it.⁹ These advances in biological and medical research give rise to new legal and ethical dilemmas concerning the problem of allocating rights to cells once they are removed from the body.¹⁰ In

1. Rebecca Skloot, *Taking the Least of You*, N.Y. TIMES MAG., Apr. 16, 2006, at 38, 40; Anthony R. LoBiondo, Note, *Patient Autonomy and Biomedical Research: Judicial Compromise in Moore v. Regents of the University of California*, 1 ALB. L.J. SCI. & TECH. 277, 279 (1991).

2. Dorothy Nelkin & Lori B. Andrews, *Introduction: The Body, Economic Power and Social Control*, 75 CHI.-KENT L. REV. 3, 5 (1999); LoBiondo, *supra* note 1, at 279.

3. See ELISA EISEMAN & SUSANNE B. HAGA, HANDBOOK OF HUMAN TISSUE SOURCES: A NATIONAL RESOURCE OF HUMAN TISSUE SAMPLES 1 (1999); see also Gail Javitt, *Why Not Take All of Me? Reflections on The Immortal Life of Henrietta Lacks and the Status of Participants in Research Using Human Specimens*, 11 MINN. J.L. SCI. & TECH. 713, 722 n.46 (2010).

4. Skloot, *supra* note 1, at 40.

5. See ELISA EISEMAN ET AL., CASE STUDIES OF EXISTING HUMAN TISSUE REPOSITORIES: “BEST PRACTICES” FOR A BIOSPECIMEN RESOURCE FOR THE GENOMIC AND PROTEOMIC ERA 96, 168 (2003); Javitt, *supra* note 3, at 721.

6. EISEMAN & HAGA, *supra* note 3, at 137 app. A; see also Skloot, *supra* note 1, at 40.

7. For reference, in 2010, the U.S. population was 308,745,538. *United States Census 2010: Interactive Population Map*, CENSUS.GOV, <http://www.census.gov/2010census/popmap> (last visited March 27, 2013).

8. Skloot, *supra* note 1, at 40.

9. Michele Goodwin, *Formalism and the Legal Status of Body Parts*, 2006 U. CHI. LEGAL F. 317, 359; Nelkin & Andrews, *supra* note 2, at 5.

10. See EISEMAN & HAGA, *supra* note 3, at 1; see also Lisa Milot, *What Are We—Laborers, Factories, or Spare Parts? The Tax Treatment of Transfers of Human Body Materials*, 67 WASH. & LEE L. REV. 1053, 1088 (2010).

particular, the collection and use of human tissues for use in research raise concerns regarding informed consent and compensation.¹¹ Who owns the cells? Who decides what happens to the cells? Who has rights to the profits derived from the cells? Two distinct, overarching problems arise: the philosophical problem of providing meaning and substance to the autonomy and dignity of the cell donor and the tangible problem of what to do when the research results in a blockbuster medicine earning substantial profits.¹²

In answering these questions, courts have not applied any consistent legal construct, but have haphazardly reached decisions on an ad hoc basis, leading to a legal landscape that is messy and inconsistent. Because there is no coherent framework for dealing with allocation of control of human cells and tissues, different courts have reached different conclusions. This has resulted in various doctrines that have led to inconsistent and incorrect results. These decisions often fail to provide meaning and substance to autonomy and neglect to supply an adequate method of compensation to individual donors. Without a framework that completely addresses the allocation of control of biomaterials, individual interests in autonomy and compensation are not adequately protected.

To address these concerns, there needs to be a consistent framework for dealing with cells once they are removed from the body—one way of analyzing and allocating control that can be consistently applied to biomaterials used in research. The contribution of this Note is twofold: first, it provides a taxonomy of approaches to the problems of ownership and control that arise in allocating rights to human cells, and second, it presents a framework that provides meaning and substance to autonomy and leads to a fairer outcome in the case of the blockbuster drug. This Note has three parts. In Part I, I explain the challenges to allocating rights to biomaterials and the problems that exist within the current system because of the unique nature of the cells. In particular, I explore the issues of consent and compensation that arise in the collection of human cells for research. First, I discuss the philosophical dilemma of respecting the autonomy and dignity of the cell donor. Second, I discuss the tangible problem that arises when research on the cells proves valuable—the blockbuster cases—and researchers gain significant profits from the cells; under current law, the donor goes uncompensated. In Part II, I discuss the inconsistent and incorrect approaches that have evolved in current law as legislatures and courts have grappled with these issues. In Part III, I offer solutions to the problems of consent and compensation, providing for a framework that imparts meaning and

11. See EISEMAN & HAGA, *supra* note 3, at xvii, 1.

12. Blockbuster medicine is defined as medicine that generates annual revenues of more than \$1 billion at global levels. *Pharmaceutical Sector Inquiry: Preliminary Report* 17 (European Comm'n DG Competition Staff, Working Paper, Nov. 28, 2008), available at http://ec.europa.eu/competition/sectors/pharmaceuticals/inquiry/preliminary_report.pdf. However, the issue of compensation is apparent with any profitable drug, even those below the \$1 billion threshold.

substance to autonomy and grants fairer outcomes in blockbuster cases. Finally, I conclude with a recommendation of creating a quasi-property right that is tailored to address these issues.

I. PROBLEM

Because of their relationship to the body, biomaterials are “a unique form of ‘property.’”¹³ “The legal definition of property most often refers not to a particular physical object, but rather to the legal bundle of rights recognized in that object”¹⁴ This bundle of rights generally includes the unrestricted right to possess, use, exclude, consume, destroy, sell, modify, lease, and give away the object.¹⁵

Because of the unique nature of human cells and tissues, determining rights to the biomaterials once they have been removed from the body is a challenge. Allocating rights to cells and tissues involves untangling complex issues of ownership and control to determine who owns the cells once they are removed. More specifically, research with biomaterials raises issues of consent and compensation. Must researchers obtain the donor’s consent to conduct research on the tissues? Who has rights to the profits derived from the cells? These questions raise two distinct problems: First, there is the philosophical problem of providing meaning and substance to the personal autonomy and dignity of the cell donor. Second, there is the related, tangible problem of allocating compensation when research on the cells proves valuable, enabling researchers to gain significant profits from the cells, while the cell donor goes uncompensated.

13. *Hecht v. Superior Court (Hecht III)*, 59 Cal. Rptr. 2d 222, 226 (Cal. Ct. App. 1996) (depublished) (“[T]he genetic material involved here is a unique form of ‘property.’ It is not subject to division through an agreement among the decedent’s potential beneficiaries which is inconsistent with decedent’s manifest intent about its disposition.”). *Hecht v. Superior Court (Hecht I)*, 20 Cal. Rptr. 2d 275, 283 (Cal. Ct. App. 1993), also refers to sperm as a “unique type of ‘property.’” Note that there are three *Hecht* cases: 1) *Hecht I*, 20 Cal. Rptr. 2d 275; 2) *Kane v. Superior Court (Hecht II)*, 44 Cal. Rptr. 2d 578 (Cal. Ct. App. 1995); and 3) *Hecht III*, 59 Cal. Rptr. 2d 222. Pursuant to an order of the California Supreme Court, *Hecht III* was ordered not to be officially published. The case cannot be “cited or relied on by a court or a party in any other action” or proceeding (except in limited circumstances). CAL. R. CT. 8.1115(a). However, “[a] Supreme Court order to depublish is not an expression of the court’s opinion of the correctness of the result of the decision or of any law stated in the opinion.” CAL. R. CT. 8.1125(d). See Charles M. Jordan, Jr. & Casey J. Price, *First Moore, then Hecht: Isn’t it Time We Recognize a Property Interest in Tissues, Cells, and Gametes?*, 37 REAL PROP. PROB. & TR. J. 151, 176–82 (2002) (explaining the three different *Hecht* cases).

14. 63C AM. JUR. 2D *Property* § 1 (2d ed. 2009) (citing *United States v. Gen. Motors Corp.*, 323 U.S. 373, 377–78 (1945) (“[P]roperty’ . . . denote[s] the group of rights inhering in the citizen’s relation to the physical thing, as the right to possess, use and dispose of it.”) and *Dolan v. City of Tigard*, 512 U.S. 374, 393 (1994) (“[T]his right to exclude others is ‘one of the most essential sticks in the bundle of rights that are commonly characterized as property.’”)).

15. See 63C AM. JUR. 2D, *supra* note 14, § 1; see also *Moore v. Regents of the Univ. of Cal.*, 793 P.2d 479, 509 (Cal. 1990) (Mosk, J., dissenting).

To illustrate these issues, I will provide an example, using the story of Henrietta Lacks. Lacks underwent treatment for cervical cancer at Johns Hopkins Hospital in the 1950s and, unbeknownst to her, launched modern biomedical research. After biopsying her tumor, Lacks's doctor collected a small sample of her cells, which he passed on to a researcher in the hospital. From that sample of cancer cells, the researcher developed a cell line, "the first *immortal* human cells: a continuously dividing line of cells all descended from one original sample, cells that would constantly replenish themselves and never die."¹⁶ This cell line became known as "HeLa."¹⁷

HeLa cells have played a major role in understanding and treating diseases such as cancer, the flu, herpes, leukemia, Parkinson's disease, and HIV/AIDS.¹⁸ They led to the development of the polio vaccine, gave rise to gene mapping and cloning, and have been used to study the effects of zero gravity, atomic radiation, and nuclear bombs on the human body.¹⁹ Since Lacks's death, scientists have cultivated over twenty tons of her cells and obtained nearly 11,000 patents involving the HeLa line.²⁰ Had Henrietta kept the cells, it is possible that no one would have benefitted from them—without the HeLa cell line, scientists may not have achieved some of the greatest accomplishments in biomedical science.

Generally, extracted cells and tissues are little more than medical waste destined for the hazardous-materials bin. But in some rare instances, the cells, like those from Henrietta Lacks, have substantial value and lead to development of a blockbuster drug, vaccination, or test. In these blockbuster cases, the researchers and pharmaceutical makers stand to earn significant profits, reaping the commercial rewards from the results of research with human cells. The individuals who provided the raw materials, on the other hand, go uncompensated for their contributions and do not benefit economically.²¹ For individuals like Lacks, whose tissue proves uniquely useful, this "double standard" is especially exploitative.²² The major medical breakthroughs derived from Lacks's cells have enabled researchers and companies selling HeLa cells to earn billions of dollars in profit,

16. REBECCA SKLOOT, *THE IMMORTAL LIFE OF HENRIETTA LACKS* 30 (2010).

17. Javitt, *supra* note 3, at 717.

18. Dwight Garner, *A Woman's Undying Gift to Science*, N.Y. TIMES, Feb. 3, 2010, at C1; Ron Claiborne & Sidney Wright IV, *How One Woman's Cells Changed Medicine*, ABCNEWS.COM (Jan. 31, 2010), <http://abcnews.go.com/wn/henrietta-lacks-woman-cells-polio-cancer-flu-research-medicine/story?id=9712579>.

19. Garner, *supra* note 18, at C6.

20. Denise M. Watson, *Cancer Cells Killed Henrietta Lacks—Then Made Her Immortal*, PILOTONLINE.COM (May 10, 2010), <http://hamptonroads.com/2010/05/cancer-cells-killed-henrietta-lacks-then-made-her-immortal>.

21. Natalie Ram, *Assigning Rights and Protecting Interests: Constructing Ethical and Efficient Legal Rights in Human Tissue Research*, 23 HARV. J.L. & TECH. 119, 134 (2009).

22. *Id.*

while Lacks's family had very little money.²³ This double standard, which arises in blockbuster cases, highlights the issue of compensation.

When Lacks went to the doctor fifty years ago, research on human cells was uncharted territory. Scientists had not yet found a way to keep human cells alive outside of the body. There was no legal framework in place for the use of human cells in research because there was no reason to develop one. Doctors did not ask for informed consent. Today, there is a doctrine in place for informed consent, but the extent to which it extends to research conducted on cells and tissues once they have been removed from the body is unclear. The doctrine of informed consent is generally limited to the provision of medical services. Thus, research participants often have no cause of action, because the harm they suffer affects their dignity and autonomy, rather than their medical interests.²⁴ Additionally, research on excised cells is largely exempt from regulations governing research on human subjects. Ultimately, informed consent laws do little to protect the autonomy of cell donors and their right to control the use of their cells.²⁵ These issues must be resolved to protect the autonomy of donors.²⁶

Although Henrietta Lacks is probably the best-known blockbuster story, because of the ubiquity of HeLa cells and a best-selling book chronicling her legacy, this is not an isolated instance.²⁷ Within the last few decades, there have been lawsuits emerging as donors have begun asserting rights to their excised cells, tissues, and the information contained in them. Most notably, in California, John Moore sued his physician, researchers, and the research university after they obtained a patent on, and received profits from, a cell line derived from his cells.²⁸ In doing so, Moore became the first person to assert a right to his own cells and the profits arising from them. Research on human cells is becoming even more prevalent, and profitable, today.

A. Ownership: Who Owns the Cells?

The primary issue that arises in research on human cells is one of ownership: a determination of who owns the cells once they are removed. Do the cells belong to the donor whose body produced them? To the doctor who collected samples of the cells? To the researcher using the samples? To the institution storing the samples? Depending on the court, the answers to these questions have varied

23. Claiborne & Wright, *supra* note 18.

24. 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, 307 (2004).

25. *Id.* at 310.

26. See Erin Colleran, Comment, *My Body, His Property?: Prescribing a Framework to Determine Ownership Interests in Directly Donated Human Organs*, 80 TEMP. L. REV. 1203, 1204 (2007).

27. See generally SKLOOT, *supra* note 16 (explaining that Henrietta Lacks's story is not an isolated incident, but an incident that sparked litigation from donors asserting rights to their excised cells and tissues).

28. *Moore v. Regents of the Univ. of Cal.*, 793 P.2d 479, 481–82 (Cal. 1990).

wildly. Some courts have held that researchers own the samples they use,²⁹ others have held that institutions own the samples they store,³⁰ and in some limited instances, courts have recognized that individual donors have a limited property right in the cells removed from their bodies.³¹

Much of the confusion stems from the fact that extracted human cells are unique from other forms of property. Excised cells are not clearly property, nor are they clearly part of the person. Although excised cells are physically separate from the body, the line is blurred as to whether they are also legally distinct. To use an example provided by Robin Feldman,

[S]uppose a man severs his finger while sawing wood in his backyard. . . . [H]e has the right to ask that the finger be reattached, as opposed to any other potential uses or modes of disposition, including use for research. . . . The man would claim the finger . . . because it is *his*.³²

Unlike the severed finger, ownership of excised cells is not so clear-cut. Courts have been reluctant to grant individuals carte blanche ownership over their excised cells and tissues.

This confusion is further exacerbated because these extricated parts of our bodies are not readily susceptible to analogy with anything else.³³ Eventually, as technology expands, judges and lawyers will be analogizing to cells. However, courts have not yet analyzed whether cells fit into the framework of property law. Until such analysis is conducted, courts cannot reach the correct result. For now, researchers, doctors, individuals, and judges are left trying to sort out the issues of contribution and consent that arise when human tissues are separated from the body.

B. Consent: Who Decides What Happens to the Cells?

The question of ownership raises further questions regarding consent: a determination of who has the right to decide what can be done with the cells once they are removed. Is it up to the researchers to decide what extricated cells may be used for? Do cell donors need to consent to research on cells removed from their bodies? Consent entails the power to make decisions about how the cells may be

29. *Id.* at 488–93 (holding that biomaterials removed from a patient by a physician during the course of the treatment belonged to the doctor, not the patient).

30. *Wash. Univ. v. Catalona*, 437 F. Supp. 2d 985, 1002 (E.D. Mo. 2006) (finding that biomaterials that were collected for research purposes were owned by the university where they were stored rather than by the individuals from whom they were collected or by the doctor who collected the samples for research).

31. *Hecht v. Superior Court (Hecht I)*, 20 Cal. Rptr. 2d 275, 283–84 (Cal. Ct. App. 1993) (holding that a sperm donor had a testamentary right to leave his sperm in his will).

32. Robin Feldman, *Whose Body is it Anyway? Human Cells and the Strange Effects of Property and Intellectual Property Law*, 63 STAN. L. REV. 1377, 1383 (2011).

33. Lori Andrews, *Who Owns Your Body? A Study in Literature and Law*, 84 CHI.-KENT L. REV. 3, 9–10 (2009).

used. Generally, property cannot be used without the owner's consent; thus, whoever owns the cells has the right to decide what may be done with them. The issue of consent revolves around philosophical concerns over the personal autonomy and dignity of the cell donor. Indeed, the main drive behind requiring consent for medical or research procedures is to ensure "respect for personal autonomy."³⁴

A significant number of cell donors are unaware that their samples may be used for research or commercial activity at the time of removal.³⁵ Henrietta Lacks, for example, never knew that her cells had become famous or that drug companies had become wealthy from using her cells; her family did not learn about the legacy of HeLa until two decades after Lacks' death.³⁶ Similarly, John Moore was unaware that researchers were profiting from his cells until several years after the university had patented his cell line.

The current system where tissue is obtained without donors' consent "is an affront to human dignity and autonomy."³⁷ When an individual like Lacks or Moore "unknowingly becomes the basis for a commercial product, he may feel that he has lost some of that self-determination that makes him human."³⁸ Upon discovering the patent, Moore "felt that his integrity had been violated, his body exploited, and his tissue turned into a product."³⁹ Describing the researchers who patented his cells without his knowledge, Moore said, "They viewed me as a mine from which to extract biological material. I was harvested."⁴⁰

Personal autonomy and bodily integrity are generally held to be fundamental to personhood and integral to what it means to be human. Respect for personal autonomy is a "concept, fundamental in American jurisprudence."⁴¹ It is well recognized that "[e]very human being of adult years and sound mind has a right to determine what shall be done with his own body."⁴² The importance of autonomy

34. Gitter, *supra* note 24, at 286 (quoting 1 U.S. CONGRESS, OFFICE OF TECHNOLOGY ASSESSMENT, NEW DEVELOPMENTS IN BIOTECHNOLOGY: OWNERSHIP OF HUMAN TISSUES AND CELLS—SPECIAL REPORT 24 (1987)).

35. See Charlotte H. Harrison, *Neither Moore nor the Market: Alternative Models for Compensating Contributors of Human Tissue*, 28 AM. J.L. & MED. 77, 83 (2002); see also Laura B. Rowe, *You Don't Own Me: Recommendations to Protect Human Contributors of Biological Material After Washington University v. Catalona*, 84 CHI.-KENT L. REV. 227, 228 (2009).

36. Garner, *supra* note 18, at C6.

37. Elizabeth E. Appel Blue, *Redefining Stewardship Over Body Parts*, 21 J.L. & HEALTH 75, 97 (2008).

38. Mary Taylor Danforth, *Cells, Sales, and Royalties: The Patient's Right to a Portion of the Profits*, 6 YALE L. & POL'Y REV. 179, 190–91 (1988).

39. Andrews, *supra* note 33, at 5. The Supreme Court held that living organisms may be patented in *Diamond v. Chakrabarty*, 447 U.S. 303, 318 (1980).

40. Andrews, *supra* note 33, at 5.

41. Martin Harvey, Note, *Towards a Public Human Tissue Trust*, 59 CASE W. RES. L. REV. 1171, 1208 (2009) (quoting *Canterbury v. Spence*, 464 F.2d 772, 780 (D.C. Cir. 1972)).

42. *Schloendorff v. Soc'y of the N.Y. Hosp.*, 105 N.E. 92, 93 (N.Y. 1914), *abrogated on other grounds by* *Bing v. Thunig*, 163 N.Y.S.2d 3 (N.Y. 1957), *superseded by statute*, N.Y. PUB HEALTH LAW

was recognized and codified by the California State Legislature: “[M]edical experimentation on human subjects is vital for the benefit of mankind, however such experimentation shall be undertaken with due respect to the preciousness of human life and the right of individuals to determine what is done to their own bodies.”⁴³

To provide meaning and substance to this right, individuals need to be able to decide what happens to their cells and tissues and how they may be used. Individuals should maintain the power to control the use of their body parts because those parts originated in, and once were a part of, their own body.⁴⁴ Even after being extracted from the body, “[t]here is something very special about human organs and tissues. We . . . retain moral interests in them, so that at least they are not misused or treated in an undignified manner.”⁴⁵ The principal of individual autonomy dictates that the individual possess the power to control what becomes of that tissue.⁴⁶ As the California Court of Appeal recognized, an individual “must have the ultimate power to control what becomes of his or her tissues. To hold otherwise would open the door to a massive invasion of human privacy and dignity in the name of medical progress.”⁴⁷ Thus, in developing a framework, it is imperative to respect the autonomy, dignity, and integrity of the donor.

C. Compensation: *Who Has Rights to the Profits Derived from the Cells?*

The question of ownership raises further issues regarding compensation, the tangible problem of determining who has the rights to the profits, if any, derived from the cells. Generally, the right to receive income generated by an asset belongs to the owner. Accordingly, whoever owns the cells has a right to compensation from profits derived from the cells.

The issue of compensation is most clearly highlighted by blockbuster drugs, when research on the cells proves fruitful and results in the discovery and development of a drug yielding substantial profits. It is this subset of cases, where researchers stand to gain significant profits and donors receive nothing, that most starkly illustrates the core issue of fairness that motivate a desire to reform. This inequity is particularly egregious in cases like Lacks’s that result in development of multimillion dollar drugs and vaccinations. Some state that it is unjust to allow

§ 2805-d (McKinney 2012), as recognized in *Retkwa v. Orentreich*, 584 N.Y.S.2d 710, 711 (N.Y. Sup. Ct. 1992).

43. Protection of Human Subjects in Medical Experimentation Act, CAL. HEALTH & SAFETY CODE § 24171 (2006).

44. Javitt, *supra* note 3, at 751.

45. Danforth, *supra* note 38, at 191 (quoting Thomas H. Murray, *Who Owns the Body? On the Ethics of Using Human Tissue for Commercial Purposes*, 8 IRB: ETHICS & HUM. RES. 1, 3(1986)).

46. Gitter, *supra* note 24, at 303.

47. *Moore v. Regents of the Univ. of Cal.*, 249 Cal. Rptr. 494, 508 (Cal. Ct. App. 1988), *aff’d in part, rev’d in part*, 793 P.2d 479 (1990).

researchers and companies to profit from the cells without sharing proceeds with the donor who provided the raw materials.⁴⁸ As Lacks's daughter Deborah put it, "I always have thought it was strange, if our mother cells done so much for medicine, how come her family can't afford to see no doctors? Don't make no sense. People got rich off my mother without us even knowin [sic] about them takin [sic] her cells, now we don't get a dime."⁴⁹

Denying the donor "a fair share of these ample benefits is both unfair and morally wrong."⁵⁰ Intuitively, it makes sense that the individual donor whose cells are "being commercially exploited, should profit from that exploitation."⁵¹ Thus, to the extent that financial benefits can be derived from their cellular contributions, donors should be compensated. Although blockbuster cases are rare, it is important to have a framework in place for any time money is made from products derived from human cells.

However, determining the value attributable to the cells is nearly impossible without removal of the cells from the body and the application of the researchers' efforts. The biggest issue is how to allocate the value that is inherent to the cells compared to the value added in the course of research, discovery, and production of a marketable product. The commercial market in raw human tissue has been limited for public policy reasons, including concerns about coercion and exploitation of the poor and the vulnerable, as well as favoring individuals who are able to pay for organs rather than those who need them most.⁵² Without a well-functioning market, however, there is no way to determine price.

Any value the cells may have is latent and not apparent until after they have been removed from the body and tested for markers. At the time of removal, the researcher may have some idea of the potential value, but no way of knowing the actual value without investing significant time and money.⁵³ When collecting samples for research, researchers are taking a risk—most of the time the cells have little scientific value and it is only after considerable time and effort that the value of the cells becomes apparent.

There is an imbalance of information because researchers have the ability to evaluate the potential value of cells, whereas donors do not. Only researchers have the means to test for markers and are able to see the potential value of cells. Donors are unaware of the value of their cells unless someone informs them of the value. Because there is an informational asymmetry and no market, the donor

48. See Harrison, *supra* note 35, at 81.

49. SKLOOT, *supra* note 16, at 9.

50. Moore, 793 P.2d at 517 (Mosk, J., dissenting) (quoting Roy Hardiman, *Toward the Right of Commerciality: Recognizing Property Rights in the Commercial Value of Human Tissue*, 34 UCLA L. REV. 207, 229 (1986)).

51. Hardiman, *supra* note 50, at 229.

52. 42 U.S.C. § 274(c) (2006).

53. Javitt, *supra* note 3, at 749.

has no way to know the potential value of the cells or what to ask for in exchange for them. Unlike with an antique clock, where a potential seller can go to another pawnshop or obtain an independent appraisal of value, a cell donor cannot shop around for a better price for the cells or obtain a second opinion on their value. Instead, the donor must rely on the researcher, compromising the donor's bargaining power. As a result, the donor may be undercompensated or, as in the case of Lacks, entirely uncompensated for the value of the cells.

The use of human cells and tissues in biomedical research raises complex issues of ownership and control and the unique nature of biomaterials gives rise to challenges in determining rights to consent and compensation.

II. CURRENT LAW

The current law surrounding ownership of biomaterials has developed from the few cases where donors learned of researchers' profits and sued to assert their rights to their cells and the profits derived from them. There is no *ex ante* legislative solution governing allocation of rights to biomaterials used in research. Ultimately, the existing doctrine provides little guidance on allocating control to biomaterials, and does little to resolve issues of consent and compensation.

In this Part, I discuss the inconsistent and incorrect results that have evolved in current law as legislatures and courts have grappled with these issues. The response has been chaotic and disordered, as courts have not applied any consistent legal construct but instead have haphazardly reached decisions on an *ad hoc* basis, resulting in a legal landscape that is messy and unpredictable. Because there is no coherent framework for dealing with allocation of control of human cells and tissues, different courts have reached different conclusions. This has resulted in inconsistent and incorrect results that often fail to provide meaning and substance to autonomy and neglect to provide for an adequate system of compensation to individual donors. Without a framework that completely addresses allocation of control in biomaterials, individual interests in autonomy and compensation are not adequately protected.

A. Regulatory/Statutory

There is no legislation explicitly regulating research using human cells and tissues.⁵⁴ Such research is generally exempt from the statutory and regulatory schemes governing research on humans and also from those regulating organ donations. The statutes and regulations that exist are generally inapplicable and provide little guidance to researchers using human cells.

54. *Id.* at 730–31.

1. *The Common Rule*

The Department of Health and Human Services has promulgated regulations, called the Federal Policy for the Protection of Human Subjects, or the “Common Rule,” for research on human subjects.⁵⁵ The Common Rule is the baseline standard for ethics in government-funded research involving human subjects in the United States. Penalties for violation of the Common Rule include withdrawal or restriction of funding or approval, or even suspension or termination of research.⁵⁶ Under the Common Rule, a researcher must provide the research participant with information about the potential risks and benefits of participating in the research and must obtain informed consent.⁵⁷ The Common Rule does not address compensation of research participants.

It is unclear to what extent these regulations apply to excised human cells and tissues because the Common Rule was developed for “research on living, breathing humans, not their disembodied tissues.”⁵⁸ When enacting current regulations, lawmakers did not imagine the widespread use of tissues in research that exists today and the regulations have not been updated to address the issues of control and ownership that arise.⁵⁹

Most research using excised biomaterials appears to be exempt from the Common Rule, which only applies to “human subjects.”⁶⁰ In order for research to fall within the scope of the Common Rule, a researcher must obtain information through direct interaction with a living individual or receive private information that can be directly traced back to the individual.⁶¹ Additionally, the Common Rule only applies to federally conducted, funded, or supported research. The Common Rule exempts research that involves “the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens, if the sources are publicly available or if the information is recorded by the investigator in such a manner that subjects cannot be identified”⁶² Thus, it does not apply if the research is not federally funded, if the subject is deceased, or if the samples are anonymous or publicly available.⁶³

If research on human cells falls within the scope of the Common Rule, researchers must obtain informed consent. However, there are no clear standards

55. 45 C.F.R. § 46 (2012); *see also* Skloot, *supra* note 1, at 45.

56. ADVISORY COMM. ON HUMAN RADIATION EXPERIMENTS, FINAL REPORT 684 (1995).

57. 45 C.F.R. § 46.116 (2012).

58. Skloot, *supra* note 1, at 45.

59. Javitt, *supra* note 3, at 730–31 (“[T]he use of tissue in research was not contemplated at the time current regulations were put in place.”); Skloot, *supra* note 1, at 45.

60. Javitt, *supra* note 3, at 732–34.

61. 45 C.F.R. § 46.102 (2012); *Frequently Asked Questions: Human Subjects Research—Human Specimens, Cell Lines or Data*, NAT’L INSTS. HEALTH OFFICIAL EXTRAMURAL RESEARCH, http://grants.nih.gov/grants/policy/hs/faqs_specimens.htm#250 (last updated Feb. 11, 2010).

62. 45 C.F.R. § 46.101(b)(4) (2012).

63. Javitt, *supra* note 3, at 732–34; *see also* Skloot, *supra* note 1, at 45.

as to what constitutes adequate informed consent.⁶⁴ As the court acknowledged in *Greenberg v. Miami Children's Hospital*, "the law regarding a duty for informed consent for research subjects is unsettled and fact-specific . . ."⁶⁵ The method for obtaining consent varies largely depending on the institution collecting the samples.⁶⁶ Most commonly, physicians collect tissue during the provision of necessary medical treatment, rather than during a research study.⁶⁷ Doctors frequently save excised samples to use for research following routine blood tests, biopsies, surgery, and other medical procedures.⁶⁸ Typically, consent forms for medical patients include a clause informing the patient that leftover samples may be used for research.⁶⁹ Some doctors ask for permission to keep the tissues, letting the donors specify what the samples may be used for; others inform the donor that the institution may use, give away, or sell the sample.⁷⁰ Some consent forms are purposely vague about compensation to the donors for their contribution to or participation in the research.⁷¹ Even if the Common Rule does apply to human tissue research, it provides little protection to individual donors; the regulations do not create a cause of action for research subjects.⁷²

2. Organ Laws

Laws restricting donation and transplantation of organs similarly fail to provide guidance in allocating rights to biomaterials in the research context. The National Organ Transplant Act regulates organ procurement, donation, and transplantation, and specifically prohibits buying or selling organs for valuable consideration.⁷³ However, the definition of "organ" does not include blood, sperm, and ova, which can all be legally sold.⁷⁴ The Uniform Anatomical Gift Act (UAGA) similarly prohibits the purchase or sale of human organs for transplant, authorizing criminal punishment for violations.⁷⁵ The UAGA permits organ

64. Skloot, *supra* note 1, at 45.

65. *Greenberg v. Miami Children's Hosp. Research Inst., Inc.*, 264 F. Supp. 2d 1064, 1070 (S.D. Fla. 2003).

66. Skloot, *supra* note 1, at 45.

67. *Id.* at 40.

68. *Id.* at 44.

69. *Id.* at 45.

70. *Id.*

71. *Id.*

72. *See, e.g., Wright v. Fred Hutchinson Cancer Research Ctr.*, 269 F. Supp. 2d 1286, 1289 (W.D. Wash. 2002) (holding that there is no private right of action under the Common Rule); Ram, *supra* note 21, at 140.

73. 42 U.S.C. § 274 (2006); *see also id.* § 274e(a) ("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.").

74. The statute defines the term "human organ" as any "human (including fetal) kidney, liver, heart, lung, pancreas, bone marrow, cornea, eye, bone, and skin or any subpart thereof and any other human organ (or any subpart thereof, including that derived from a fetus) . . ." *Id.* § 274e(c) (1).

75. *See* UNIF. ANATOMICAL GIFT ACT § 10, 8A U.L.A. 62 (1987) (explaining that selling

donations for transplant and other purposes, such as research or education, and specifically allows for directed donations. However, the UAGA is limited to donations that take effect after the donor's death.⁷⁶

B. Common Law

In the absence of legislation or regulation, it has been up to the courts to determine issues of ownership and control of cells and tissues. “Recent cases indicate a great disparity in both the methods of analysis and outcomes of decisions involving property interests in the human body or its parts.”⁷⁷ The existing doctrine has developed from the few cases where researchers were able to earn significant profits from cells and donors subsequently found out and sued to assert their rights to the profits. Because excised cells do not often prove valuable and donors rarely find out, the case law regarding allocation of rights to biomaterials is quite sparse.⁷⁸

The law that has evolved provides little guidance on allocating control of biomaterials and does little to resolve issues of consent and compensation.⁷⁹ The courts' response has been chaotic and disordered, resulting in a legal landscape that is messy and inconsistent.⁸⁰ In addressing issues of control, courts have taken varying approaches. Decisions determining property interests in biomaterials have varied wildly as “different courts have invoked different legal theories to resolve disputes between researchers, participants, and institutions.”⁸¹

Unfortunately, courts have not applied any consistent legal construct but have instead applied “various legal theories in [pursuit] of what sometimes appear to be preordained policy goals.”⁸² Courts have reached decisions on an ad hoc basis, looking to the relationship of the parties to determine the donor's rights, if any, in the cells.⁸³ Courts have alternatively found biomaterials to be property, quasi property, or sometimes not property at all.⁸⁴ In analyzing biomaterials,

human organs for transplantation or treatment purposes is a felony punishable by up to \$50,000 in fines or up to five years' imprisonment or both) (amended 2006). The Uniform Anatomical Gift Act has been adopted in some form by all fifty states. It was adopted in California in CAL. HEALTH & SAFETY CODE §§ 7150–7151.40 (2007).

76. CAL. HEALTH & SAFETY CODE § 7150.10(a)(3) (2007).

77. Collieran, *supra* note 26, at 1204.

78. Harvey, *supra* note 41, at 1172.

79. Harrison, *supra* note 35, at 83 (“The occasional lawsuit which seeks individual relief is unlikely to produce a coherent and predictable policy for the variety of circumstances in which samples are collected, distributed and used in biomedical research and development.”).

80. Radhika Rao, *Property, Privacy, and the Human Body*, 80 B.U. L. REV. 359, 363 (2000) (“The law of the body is currently in a state of confusion and chaos.”).

81. Javitt, *supra* note 3, at 731–32.

82. Javitt, *supra* note 3, at 715; *see also* Hecht v. Superior Court (*Hecht III*), 59 Cal. Rptr. 2d 222, 227–28 (Cal. Ct. App. 1996) (depublished).

83. Rao, *supra* note 80, at 364 (“[T]he choice of legal category often appears automatic and reflexive.”).

84. *Id.* at 363.

courts have developed little analysis regarding whether biomaterials fit within the property framework or whether the distinction of classifying biomaterials as property or nonproperty even matters.⁸⁵ Rather, “courts have tiptoed around the issue, leaving an unsettled area of the law.”⁸⁶

This “piecemeal approach” has resulted in a bizarre “patchwork of doctrinal rules,” leaving no coherent framework for dealing with the allocation of control in human cells and tissue.⁸⁷ Instead, the “status of body parts is shaped by sporadic, inconsistent judicial analysis, which is woefully unmindful of the rapidly expanding, unregulated biotechnological terrain.”⁸⁸ The lack of a coherent approach has led to inconsistent and incorrect results and disparate treatment of biomaterials in similar circumstances.⁸⁹ The makeshift doctrine currently in place is insufficient to protect the autonomy of cell donors and fails to provide a system for compensation to donors.⁹⁰ This section discusses the different ways that courts have mangled issues of consent and compensation in allocating control of biomaterials.

1. Doctor-Patient Relationship

In *Moore v. Regents of the University of California*, the California Supreme Court addressed allocation of control in a dispute between a patient and his doctor over ownership of a cell line derived from the patient’s cells.⁹¹ John Moore underwent treatment for hairy-cell leukemia at the University of California, Los Angeles Medical Center.⁹² After taking multiple samples of blood and bone marrow from his patient, Moore’s physician, David Golde, realized that the cells were unique and potentially profitable.⁹³ He recommended removal of Moore’s spleen and arranged with a researcher to conduct research on the cells after the surgery.⁹⁴ Moore consented to the procedure and underwent surgery to have his spleen removed.⁹⁵ Neither doctor nor researcher informed Moore of their research plans or their potential gain, nor did they obtain Moore’s permission to use the cells for research.⁹⁶ During the seven years following the surgery, Golde repeatedly asked

85. *Id.* at 363–64.

86. Gwen Mayes, *Buying and Selling Organs for Transplantation in the United States*, MEDSCAPE, <http://www.medscape.org/viewarticle/465200> (last visited Feb. 15, 2013) (registration required) (on file with the *UC Irvine Law Review*).

87. Feldman, *supra* note 32, at 1402; Colleran, *supra* note 26, at 1228.

88. Goodwin, *supra* note 9, at 387.

89. Rao, *supra* note 80, at 364; Colleran, *supra* note 26.

90. Gitter, *supra* note 24, at 304.

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

92. *Id.* at 481.

93. *Id.*

94. *Id.*

95. *Id.*

96. *Id.*

Moore to return for follow-up visits, collecting more tissue during each one.⁹⁷ Golde did not inform Moore that he was taking the samples for his own research and commercial endeavors, rather than Moore's medical treatment.⁹⁸ Using these samples, the researchers established the "Mo-Cell Line," which the University of California Regents subsequently patented.⁹⁹ The university arranged to share the profits with the doctor and the researcher.¹⁰⁰

It was not until several years had passed and Golde had taken many samples that Moore found out about the patent. In 1983, Golde gave Moore a consent form requesting that he voluntarily grant his rights "in any cell line or any other potential product which might be developed from the blood and/or bone marrow obtained from [plaintiff]" to the university.¹⁰¹ Moore signed the form, but "circled the words 'do not,' proceeding a provision relinquishing his 'rights . . . in any cell line . . . which might be developed from'" his blood.¹⁰² Upon learning of these events, Moore filed a lawsuit against his physician, the researcher, and the university regents, alleging conversion and breach of physician's disclosure obligations, becoming the first person to assert a legal right to his own tissue and sue for profits.¹⁰³ Moore alleged that the tissues, including his spleen, blood, and the cell line derived from his cells were "his tangible personal property"¹⁰⁴ and that "defendants' unauthorized use of his cells constitutes a conversion."¹⁰⁵

The *Moore* decision is noteworthy because it is the first case to address the allocation of control in research involving human cells. The California Supreme Court held that Moore did not have a cause of action for conversion.¹⁰⁶ The court explained that Moore did not have ownership of his cells or the right to possess them at the time of the conversion because he "clearly did not expect to retain possession of his cells following their removal . . ."¹⁰⁷ Moore did have a cause of action for breach of fiduciary duty and failure to obtain informed consent, however.¹⁰⁸ The court held that "a physician who is seeking a patient's consent for a medical procedure must, in order to satisfy his fiduciary duty and to obtain the patient's informed consent, disclose personal interests unrelated to the patient's health, whether research or economic, that may affect his medical judgment."¹⁰⁹

97. *Id.*

98. *Moore v. Regents of the Univ. of Cal.*, 249 Cal. Rptr. 494, 500 (Cal. Ct. App. 1988), *aff'd in part, rev'd in part*, 793 P.2d 479 (Cal. 1990).

99. *Moore*, 249 Cal. Rptr. at 500; Danforth, *supra* note 38, at 179–80 n.4.

100. *Moore*, 793 P.2d at 482.

101. *Moore*, 249 Cal. Rptr. at 536 n.5 (George, J., dissenting).

102. *Id.*

103. SKLOOT, *supra* note 16, at 203.

104. *Moore*, 249 Cal. Rptr. at 503.

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

106. *Id.* at 497.

107. *Id.* at 488–89.

108. *Id.* at 497.

109. *Id.* at 485.

Where there is a doctor-patient relationship, the fiduciary duty gives rise to a duty of informed consent, which mandates disclosure of conflicts of interest, including economic interests. As for the researcher and the university, the court held that “none of these defendants stood in a fiduciary relationship with Moore or had the duty to obtain Moore’s informed consent to medical procedures.”¹¹⁰

The doctrine announced in *Moore* only applies if there is a doctor-patient relationship. It does not apply when the researcher is not a treating physician, or to research participants generally. The holding is constrained to the injuries that Moore suffered as a patient, and does not extend to the intangible violation of his personal autonomy, the “injuries he might have suffered as a source of human tissue used in scientific research and commercial product development.”¹¹¹ The consequences of this narrow holding became apparent in subsequent cases involving researchers and participants, where there was no doctor-patient relationship. It does little to protect the interests of tissue donors who are not patients.¹¹² *Moore* stands for the idea that once an individual consents to removal of cells or tissues, that donor no longer has any right to control the use of the biomaterials.¹¹³ The donor has no rights in them.¹¹⁴

Unlike other research participants, patients, like Moore, often need to have cells removed out of medical necessity. Cells, such as the spleen or appendix, are often removed because they are no longer useful in the body, or more critically, in the case of cancer, because they are harmful to the patient. In such situations, the donor is actually better off without the cells. Because of the medical necessity of removal in such situations, some courts, like *Moore*, are hesitant to provide compensation to the donor for something that would otherwise have been removed and discarded.

2. Researcher-Participant Relationship

In *Greenberg v. Miami Children’s Hospital Research Institute, Inc.*, a U.S. district court in Florida addressed the allocation of rights to cells in a dispute between a researcher and cell donors, rather than in a doctor-patient relationship as in *Moore*.¹¹⁵ Like the California Supreme Court in *Moore*, the Florida court in *Greenberg* declined to recognize a property interest in biomaterials used in research.¹¹⁶

Daniel Greenberg’s child was afflicted with Canavan disease, a rare genetic

110. *Id.* at 486.

111. Harrison, *supra* note 35, at 80.

112. Javitt, *supra* note 3, at 740.

113. David C. Szostak, *Something More to the Story: Moore v. Regents of the University of California Two Decades Later*, 31 J. LEGAL MED. 443, 449 (2010).

114. *Id.*

115. *Greenberg v. Miami Children’s Hosp. Research Inst., Inc.*, 264 F. Supp. 2d 1064, 1070–71 (S.D. Fla. 2003).

116. Paula C. Evans, *Patent Rights in Biological Material: Implications of Principle of Unjust Enrichment Remain Uncertain*, GENETIC ENGINEERING NEWS, Oct. 1, 2006, at 12.

disorder.¹¹⁷ Greenberg approached Reuben Matalon, a research physician, for help discovering the gene linked to Canavan disease and developing a test for prenatal screening to detect the disease.¹¹⁸ Greenberg recruited other families and nonprofit organizations to provide tissue samples and monetary support for the research and to set up a national Canavan registry.¹¹⁹ Matalon successfully isolated the gene and his research institution patented it, providing exclusive access to any activity related to the gene.¹²⁰ The families and nonprofits who provided the cells claimed that they were unaware of Matalon's intention to patent the gene, believing that any "testing developed in connection with the research . . . would be provided on an affordable and accessible basis, and that Matalon's research would remain in the public domain . . ."¹²¹ When they found out about the patent, they sued Matalon and the research institution, asserting lack of informed consent, breach of fiduciary duty, unjust enrichment, and conversion.¹²²

Although recognizing that "a duty does attach at some point in the relationship" and "in certain circumstances a medical researcher does have a duty of informed consent," the court declined "to extend the duty of informed consent to cover a researcher's economic interests . . ."¹²³ The court held that a physician is not required to obtain informed consent from donors of biomaterials. Matalon did not have a duty of informed consent with respect to the plaintiffs because, unlike the doctor in *Moore*, Matalon was not a treating physician and thus did not owe a fiduciary duty to the research participants.¹²⁴ The court further held that the plaintiffs had failed to state a claim of conversion, because, as in *Moore*, they did not retain an ownership interest in the cells after removal.¹²⁵ The court allowed the case to proceed on a theory of unjust enrichment and the parties eventually settled out of court.¹²⁶

3. Researcher-Institute Relationship

In *Washington University v. Catalona*, the court examined the relationship between a researcher and a research institution.¹²⁷ Unlike the previous cases, where the dispute involved donors asserting rights to their cells, the dispute in *Catalona* was between a researcher and the research institution where the samples were stored. William Catalona, a research physician, founded a biobank at

117. *Greenberg*, 264 F. Supp. 2d at 1066.

118. *Id.*

119. *Id.* at 1067.

120. *Id.*

121. *Id.* (citation omitted).

122. *Id.* at 1068.

123. *Id.* at 1070.

124. *Id.*

125. *Id.* at 1074.

126. *Id.* at 1072.

127. *Wash. Univ. v. Catalona*, 437 F. Supp. 2d 985 (E.D. Mo. 2006).

Washington University to collect and store biological samples for prostate cancer research.¹²⁸ Patients at the university were invited to contribute samples and were asked to sign informed consent forms, acknowledging that the collection of samples was for medical research and not for treatment.¹²⁹ More than 30,000 individuals participated, providing approximately 3500 prostate tissue samples and 100,000 serum samples that were stored in the biobank.¹³⁰ Eventually, Catalona left the university and asked the research participants to sign an authorization form releasing the samples to him. The university sought a declaratory judgment establishing that it, not Catalona nor the donors, owned the samples stored in the biobank.¹³¹ The court held that the university owned all the tissues in the repository and that Catalona and the research participants did not have any ownership interests in the samples.¹³² Unlike in *Moore*, the donors here had expressly consented to the use of their cells in research at the university and had contractually waived their rights to the cells.

4. Donor-Recipient Relationship

In *Colavito v. New York Organ Donor Network*, the Second Circuit addressed the rights belonging to the intended recipient of an organ donation.¹³³ Unlike the previous cases, *Colavito* did not arise in a research context, but from a failed organ transplant. After Peter Lucia died suddenly, his family donated his kidneys to his close friend, Robert Colavito, who was suffering from end-stage renal disease.¹³⁴ The allocation decision was made not by the donor, but by his survivors. The defendant, New York Organ Donor Network, sent one of Lucia's kidneys to the hospital where Colavito was being prepared for surgery.¹³⁵ Minutes before surgery, Colavito's surgeon discovered that the kidney was too damaged to transplant.¹³⁶ When the surgeons contacted the defendant, they were told that the other kidney had already been transplanted into another patient and cancelled Colavito's surgery.¹³⁷ Colavito sued the New York Organ Donor Network, alleging conversion of the organs.¹³⁸ The parties later discovered that the kidneys could not have been successfully transplanted into Colavatio, because they were

128. *Id.* at 988.

129. *Id.* at 990.

130. *Id.* at 988–89.

131. *Id.* at 987.

132. *Id.* at 1002–03.

133. *Colavito v. N.Y. Organ Donor Network, Inc.*, 438 F.3d 214 (2d Cir. 2006).

134. *Id.* at 217.

135. *Id.* at 218.

136. *Id.*

137. *Id.* at 218–19.

138. *Id.* at 220.

incompatible with his immune system.¹³⁹ Tragically, Colavito died during the appeal of his case, still waiting for a kidney transplant.¹⁴⁰

The court held that Colavito, although a specified donee, did not have a property interest in the donated organ. Based on the assumption that Lucia's kidneys were incompatible with Colavito's immune system, preventing successful transplantation to Colavito, the court concluded that Colavito could not have derived a medical benefit from the organ, and therefore had no cause of action for conversion.¹⁴¹ However, the court recognized that there could be a situation where an individual would have an actionable right in the body or organ of a deceased person, stating that "although the intended recipient of a donated organ might have a common law right to it under New York law, no such right exists for the 'specified donee of an *incompatible* kidney.'"¹⁴²

III. PROPOSED FRAMEWORKS

The current legal treatment does not address the issues of consent and compensation that arise in research involving human cells. In this Part, I offer solutions to these problems in allocating control over biomaterials, providing a framework that respects the autonomy of the donor and provides for fairer outcomes in blockbuster cases.

I first analyze two approaches to the problem of ownership of human cells once they have been removed from the body. One is to create a property right, giving rise to a cause of action in either conversion or unjust enrichment. The other is to enhance the framework for informed consent. Both are imperfect solutions, however, and this Part concludes with an outline of a legal regime that better protects the rights of donors. In conclusion, I recommend creating a quasi-property right that is tailored to address the issues of consent and compensation that arise in allocating control of biomaterials. This framework provides meaning and substance to autonomy in the collection of human cells for research, creating a cause of action for when disputes arise, and a remedy for compensation that is narrowly tailored to blockbuster cases.

A. Property Right

One potential solution is to grant donors an enforceable property interest in their cells after they are removed. The idea behind this approach is that donors have made a valuable contribution to the research endeavor and should be rewarded for that contribution. Donors are "a third party to the biotechnology

139. *Id.* at 219.

140. *Colavito v. N.Y. Organ Donor Network, Inc.*, 486 F.3d 78, 79 n.1 (2d Cir. 2007).

141. *Id.* at 80–81.

142. *Id.* at 79 (quoting *Colavito v. N.Y. Organ Donor Network, Inc.*, 860 N.E.2d 713, 719 (N.Y. 2006)).

enterprise,” as Justice Mosk wrote in his dissent in *Moore*, and “[w]hile he may be a silent partner, his contribution to the venture is absolutely crucial”¹⁴³

Granting donors a property right in their cells would promote donor autonomy, preserving a donor’s ability to decide what is done with his or her body.¹⁴⁴ Donors would be “able to exercise self-ownership in the form of property rights, with a capacity to exercise rights of inclusion and exclusion”¹⁴⁵ A property right would also include a right to compensation, ensuring that donors are entitled to a share of the profits, giving effect to notions of equity and fairness.¹⁴⁶ With a property interest, “a legitimate claim of ownership can be made, and the ability to redress nonconsensual appropriation is better established.”¹⁴⁷

However, there are several public policy arguments against recognizing a donor’s property right in biomaterials. Opponents of such a move argue that extending property rights could “impair scientific advancement”¹⁴⁸ and “hamper vital biomedical progress.”¹⁴⁹ Because cells are a fundamental part of biomedical research, the *Moore* court declined to grant donors a property right in cells out of fear that it would “hinder research by restricting access to the necessary raw materials.”¹⁵⁰ Opponents also express alarm that a property right would “create massive liability for scientists, chilling important medical research across the country.”¹⁵¹

Arguably, cells only have value in the hands of researchers who are able to coax valuable medications or vaccinations from them. Only researchers, experts in the field, know how to turn biomaterials into something of value and much of the

143. *Moore v. Regents of the Univ. of Cal.*, 793 P.2d 479, 516 (Cal. 1990) (Mosk, J., dissenting).

144. Hardiman, *supra* note 50, at 235–36; see also Aaron F. Carbone, *What Do I Own, if Not Myself?*, 18 ALB. L.J. SCI. & TECH. 569, 591 (2008) (concluding that amending New York state law to give people a property interest in donated tissue expands freedom of contract); Harrison, *supra* note 35, at 82 (citing injustice between researchers and contributors as a reason for providing a property right in donated tissue); Rowe, *supra* note 35, at 256 (arguing that giving donors the right to control research conducted on their biological material is the most effective means of preventing nonphysical harm).

145. Peter Halewood, *On Commodification and Self-Ownership*, 20 YALE J.L. & HUMAN. 131, 156 (2008).

146. Hardiman, *supra* note 50, at 229–30.

147. Goodwin, *supra* note 9, at 318 (citing Judith D. Fischer, *Misappropriation of Human Eggs and Embryos and the Tort of Conversion: A Relational View*, 32 LOY. L.A. L. REV. 381, 402–03 (1999)).

148. Hardiman, *supra* note 50, at 240–41; see also Goodwin, *supra* note 9, at 362 (discussing the *Moore* court’s attempts to balance the rights of individual patients and medical researchers); Szostak, *supra* note 113, at 451 (quoting *Greenberg v. Miami Children’s Hosp. Research Inst., Inc.*, 264 F. Supp. 2d 1064, 1076 (S.D. Fla. 2003) (“[T]he expansive theory championed by 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.”)).

149. LoBiondo, *supra* note 1, at 305.

150. *Moore v. Regents of the Univ. of Cal.*, 793 P.2d 479, 494 (Cal. 1990).

151. Szostak, *supra* note 113, at 453.

value of blockbuster drugs is the result of efforts of the researchers and drug companies. Opponents of a property interest argue that researchers and medical professionals must have control over biomaterials because “people in the scientific community know how best to use these resources”¹⁵²

1. Current Law

Although not widely accepted, property rights in human cells and tissues are not unprecedented. The California Court of Appeal recognized a property right in sperm cells in *Hecht v. Superior Court*.¹⁵³ Deborah Hecht inherited sperm that her boyfriend, William Kane, had deposited in a sperm bank before taking his own life, bequeathing the sperm to her for her use “should she so desire.”¹⁵⁴ Kane’s college-age children contested Hecht’s ownership of the sperm, arguing that it was part of the estate.¹⁵⁵ Focusing on the donor’s intent, the appellate court concluded that Kane had an ownership interest in the sperm at the time of his death “to the extent that he had decision making authority as to the use of his sperm for reproduction.”¹⁵⁶ Recognizing “the right of the *donor* to control the disposition of his own body,”¹⁵⁷ the court held that “[s]uch interest is sufficient to constitute ‘property’”¹⁵⁸

In a subsequent, unpublished decision, the court recognized that Hecht had a limited property interest in the sperm, based on the donor’s testamentary wishes.¹⁵⁹ Thus, Hecht had a right to possess and use the sperm as bequeathed to her in the will, although she “lack[ed] the legal entitlement to give, sell, or otherwise dispose of [the] sperm.”¹⁶⁰ Her interest in the sperm derived exclusively from the donor’s intent. The court stated,

If we are to honor decedent’s intent as expressed in several written documents, his sperm can only be used by and thus only has value to one person, the petitioner in this case. . . .

From decedent’s clear expressions of intent, it is apparent he created these vials of sperm for one purpose, to produce a child with this woman.¹⁶¹

The *Hecht* decision “establishes the principle [that] the intent of the sperm donor—and no one else’s—controls the disposition and use of the sperm. . . .

152. *Id.*

153. *Hecht v. Superior Court (Hecht I)*, 20 Cal. Rptr. 2d 275 (Cal. Ct. App. 1993).

154. *Id.* at 276.

155. *Id.* at 278–79.

156. *Id.* at 283.

157. Colleran, *supra* note 26, at 1227.

158. *Hecht I*, 20 Cal. Rptr. 2d at 283.

159. *Hecht v. Superior Court (Hecht III)*, 59 Cal. Rptr. 2d 222 (Cal. Ct. App. 1996) (depublished).

160. *Id.* at 226.

161. *Id.*

‘[T]he fate of the sperm must be decided by the *person from whom it is drawn*.’¹⁶² Ultimately, “*no other person or entity* has an interest sufficient to permit interference with [his] decision”¹⁶³

In *Venner v. State*, the Maryland Court of Appeals acknowledged that an individual may have a property right in his body parts. The court noted in dicta that “[i]t could not be said that a person has no property right in wastes or other materials which were once a part of or contained within his body, but which normally are discarded after their separation from the body.”¹⁶⁴ *Venner* involved a determination of whether police searching for narcotics had illegally seized a criminal defendant’s feces from a bedpan. Although the court ultimately held that the defendant had abandoned his excrement for purposes of the Fourth Amendment, the court recognized that

[i]t is not unknown for a person to assert a continuing right of ownership, dominion, or control, for good reason or for no reason, over such things as excrement, . . . blood, and organs or other parts of the body, whether their separation from the body is intentional, accidental, or merely the result of normal body functions.¹⁶⁵

2. Causes of Action

A property right would provide for donors in blockbuster cases to receive compensation, while also respecting the autonomy of donors. Because a property right would give donors a legally cognizable right in their cells, it would enable donors to be in a better bargaining position and empower individuals to protect themselves from affronts to personal dignity as well as unjust enrichment. A property right would also provide for a substantive cause of action—allowing donors to sue, alleging conversion or unjust enrichment.

a. Conversion

A donor with a property right can sue for conversion of the cells. Conversion is a strict-liability tort for wrongful possession or exercise of dominion of property, depriving the rightful owner of use and possession, without the owner’s consent.¹⁶⁶ To establish conversion, a plaintiff must show that (1) he had “ownership or right to possession of the property” at the time the defendant took

162. *Id.* (quoting *Hecht I*, 20 Cal. Rptr. 2d at 857 (quoting E. Donald Shapiro & Benedec Sonnenblick, *The Widow and the Sperm: The Law of Post-Mortem Insemination*, 1 J.L. & HEALTH 229, 232 (1983))).

163. *Hecht I*, 20 Cal. Rptr. 2d at 289 (emphasis added) (quoting *Davis v. Davis*, 842 S.W.2d 588, 602 (Tenn. 1992)).

164. *Venner v. State*, 354 A.2d 483, 498 (Md. Ct. Spec. App. 1976).

165. *Id.*

166. *De Vries v. Brumback*, 349 P.2d 532, 535 (Cal. 1960); *Hernandez v. Lopez*, 103 Cal. Rptr. 3d 376, 381 (Cal. Ct. App. 2009); *Mendoza v. Rast Produce Co., Inc.*, 45 Cal. Rptr. 3d 525, 533 (Cal. Ct. App. 2006); BLACK’S LAW DICTIONARY 356 (8th ed. 2004).

possession by a wrongful act and (2) he suffered damages (3) as a result of the defendant's wrongful taking.¹⁶⁷ The *Moore* court held that Moore did not have a cause of action for conversion because he did not have ownership or possession of the cells at the time of the conversion.¹⁶⁸

b. Unjust Enrichment

Alternatively, armed with a property right, donor plaintiffs can seek restitution for unjust enrichment. Restitution provides plaintiffs an award based on defendants' gains rather than plaintiffs' losses. The theory is that researchers, by taking cells without providing compensation, have been unjustly enriched. As the *Moore* court explained, "Failing to compensate the patient unjustly enriches the researcher because only the researcher's contribution is recognized."¹⁶⁹ Under a theory of unjust enrichment, the donor is entitled to disgorgement of all of the researcher's profits that were gained from the researcher's wrongful use of the donor's cells. The *Greenberg* court allowed the plaintiffs to proceed on a cause of action for unjust enrichment.

Unjust enrichment is particularly useful in blockbuster cases because it is a cause of action when the cells are profitable. But if the cells lack scientific value, there is no case to litigate. Additionally, this avoids the problem of valuation of cells because donors would be entitled to all of the profits. However, if all of the profits go to the donor, it would also be unfair because the donor's contribution was not the result of personal effort, but rather the result of the individual's status as a donor.

3. Conclusion

Creating a property right will not work as a solution. Granting individuals a property right in their cells is potentially both overinclusive and overcompensatory, providing too much to donors at the expense of furthering research. Conversion is a strict-liability tort; it runs the risk of being overinclusive, because any doctor or researcher involved in research with the cells would potentially be liable, no matter how minor a role he played. Unjust enrichment, on the other hand, may be underinclusive because the donor would have to prove that the researcher's conduct was wrongful. Unjust enrichment also runs the risk of overcompensating donors because it disgorges all profits. It does not take into account value added by the researcher. It "provides an economic windfall to a patient who, by chance, has rare tissues."¹⁷⁰

167. *Hernandez*, 103 Cal. Rptr. 3d at 381; *Baldwin v. Marina City Props., Inc.*, 145 Cal. Rptr. 406, 416 (Cal. Ct. App. 1978).

168. *Moore v. Regents of the Univ. of Cal.*, 793 P.2d 479, 488-89 (Cal. 1990).

169. *Id.* at 517 (Mosk, J., dissenting) (citation omitted).

170. *LoBiondo*, *supra* note 1, at 304.

B. Informed Consent

An alternate approach is enhancing the framework for informed consent by expanding upon the already existing informed consent doctrine or creating an additional duty of continuing information, requiring researchers to keep donors informed throughout the research process.

1. "Turbo" Consent

"Turbo" consent calls for expanding upon the already existing informed consent doctrine to give more content and strength to informed consent and disclosure requirements and also to clarify to donors whether they are giving up any rights they may have in their cells.

"It is axiomatic that patients must consent to their own medical treatment. Here, however, the question is not whether one must consent to undergo certain treatment, but whether one must consent to the particular use of one's cells, i.e., incorporation of them into a valuable product."¹⁷¹

The decision to participate in research cannot be truly autonomous unless the participant is sufficiently informed. Because there is often a great informational disparity between the researcher and the donor, a duty must be imposed on the former to obtain the informed consent of the latter.¹⁷² "Respect for these interests requires that would-be contributors be asked if they are willing to have their tissue used for research, and a meaningful opportunity to decline to have it used."¹⁷³

In a report on *Case Studies of Existing Human Tissue Repositories*, the RAND Corporation determined that best practices for research using biomaterials include obtaining fully informed consent from research participants in a tiered-consent process.¹⁷⁴ Ideally, researchers should obtain two-part consent from participants.¹⁷⁵ First, researchers should obtain consent to the collection of the biomaterials, allowing the participant to decide the type of biomaterials (e.g., tissue, blood, or urine) to be donated.¹⁷⁶ Second, researchers should obtain consent to the use of the biomaterials for research purposes, allowing the participant to decide the type of research the biomaterials can be used for (e.g., a specific research project, general research, or genetic research).¹⁷⁷

Ownership must be clarified during the informed-consent process to ensure

171. Danforth, *supra* note 38, at 182 (footnote omitted).

172. Russell Korobkin, *Autonomy and Informed Consent in Nontherapeutic Biomedical Research*, 54 UCLA L. REV. 605, 616 (2007).

173. Javitt, *supra* note 3, at 752.

174. EISEMAN ET AL., *supra* note 5, at 135–37.

175. *Id.* at 135–36.

176. *Id.* at 137.

177. *Id.*; see also Javitt, *supra* note 3, at 752.

that donors are clear about the terms of the legal transaction.¹⁷⁸ Donors need to know whether they retain ownership or control over donated tissue. Ideally, consent to donation should occur separately from consent to the surgical procedure, or at least in a separate section of the consent form requiring a separate signature.¹⁷⁹

Currently, the Common Rule provides for informed consent, but as explained in Part II.A.1, above, it is unclear the extent to which the regulations apply to cells once they are removed from the body. Under the current consent regime, researchers may fulfill their obligations by presenting donors with a boilerplate form. Standard consent forms disclose nothing about research on the biomaterials and give the donors no rights. Generally, so long as the donors give informed consent to the removal procedure, no further consent is required for research on excised cells.

One solution is to reform the Common Rule to better protect contributors by expanding the requirements for informed consent. Proposals for modifying the doctrine of informed consent include clarifying that the Common Rule applies to research using human biological material, granting contributors the right to determine the type of research that is conducted on their biomaterials, requiring disclosure as part of the informed-consent process, prohibiting blanket consent, and specifying that researchers may not continue to use a sample if the donor has objected to its use.¹⁸⁰ This solution will permit the collective advancement of biomedical research, without sacrificing the individual rights and interests of donors.¹⁸¹ No matter how urgent the need to advance biomedical science, that urgency cannot surpass the need to respect the dignity of the individual.¹⁸² “It is better for the integrity of the overall scientific research establishment to lose subjects by providing full information than it is to lose subjects because they lack trust in that research establishment.”¹⁸³

However, informed consent alone does not work as a solution because it does not give donors sufficient control over their cells. It is likely that researchers would respond to such a duty by adding boilerplate language to consent forms requiring donors to waive any interests in the cells and rights to future profits.¹⁸⁴ The potential for coercion is great, especially if the cells are being removed in a medical context. As in *Moore*, the distinction between when cells are removed for research purposes, as opposed to medical purposes, may be blurred. Patients may

178. EISEMAN ET AL., *supra* note 5, at 143.

179. *Id.* at 135–36.

180. Rowe, *supra* note 35, at 255–56, 258, 262, 266.

181. *Id.* at 269.

182. *Id.*

183. *Id.* at 261 (quoting Sheri Alpert, *Privacy and the Analysis of Stored Tissues*, in 2 NAT'L BIOETHICS ADVISORY COMM'N, RESEARCH INVOLVING HUMAN BIOLOGICAL MATERIALS: ETHICAL ISSUES AND POLICY GUIDANCE A-1, A-14 (2000) (internal quotation marks omitted)).

184. Danforth, *supra* note 38, at 198.

feel obliged to consent to the use of their cells in research as a condition of treatment. Doctors could appear to “be linking the provision of treatment to the patient’s willingness to give up future rights to profits.”¹⁸⁵

2. Continuing Information

Currently, few biobanks maintain contact with donors.¹⁸⁶ After the initial contribution, donors have little, if any, interaction with the researchers. However, as studies with focus groups have shown, donors would like to be kept informed.¹⁸⁷ As one focus-group participant stated, “You have an obligation to tell these people. They expect something back from you. I’m volunteering some of my flesh for you to evaluate me. Tell me what’s wrong with it. Not that you could do something about it necessarily, but at least let me know”¹⁸⁸

One solution to the flaws of the consent regime is to create a duty of continuing information, requiring researchers to keep donors informed and apprised of ongoing research throughout the process. It would also encompass a duty of ongoing advice and consent—at pivotal points in the research, the participants would have the option to renew consent, withdraw consent, or to renegotiate. Research has shown that participants would like to “be given choices at the beginning of the study about what research results they would receive and the frequency and mode of communication in which they received them.”¹⁸⁹ As a best practice, the RAND Corporation recommends that researchers provide information about findings from research to donors and physicians via “the Internet, newsletters, and sessions at scientific meetings, or through other outreach venues.”¹⁹⁰

A duty of continuing information will respect personal autonomy and dignity of the donor. This solution allows for full disclosure and the free flow of information to enable people to make fully informed decisions about their bodies and to be active participants in the research. People are genuinely interested and want to know what is going on.

Ultimately, a duty of continuing information has the problem of being both overinclusive and undercompensating. Creating a duty of continuing information puts an added burden on the researchers because they must take extra steps to ensure that individual donors are kept in the loop. Even when the samples are duds, the researchers must still keep track of the participants and keep in touch

185. *Id.*

186. EISEMAN ET AL., *supra* note 5, at 147.

187. See Juli Murphy et al., *Public Expectations for Return of Results from Large-Cohort Genetic Research*, 8 AM. J. BIOETHICS 36, 41 (2008) (noting that focus group participants demonstrated a strong desire for access to individual research results).

188. *Id.* at 40.

189. Javitt, *supra* note 3, at 728.

190. EISEMAN ET AL., *supra* note 5, at 148.

with them. Researchers may find that administering such a program takes time and resources away from conducting research. Furthermore, a duty to provide continuing information creates no enforceable remedy. As Justice Mosk explained in his dissent in *Moore*,

[T]he nondisclosure cause of action (1) is unlikely to be successful in most cases, (2) fails to protect patients' rights to share in the proceeds of the commercial exploitation of their tissue, and (3) may allow the true exploiters to escape liability. It is thus not an adequate substitute, in my view, for the conversion cause of action.¹⁹¹

C. *Quasi-Property Right*

These aforementioned approaches range from imperfect to deeply flawed. Creating a property right grants too much to the donor, giving rise to overcompensation and disincentivization of research. On the other hand, informed consent provides too little, undercompensating the donor and allowing researchers unfettered access to biomaterials. Conversion is a strict-liability tort and unjust enrichment allows for disgorgement of *all* of a defendant's profits. On the other hand, informed consent does not provide adequate compensation to donors in blockbuster cases. Researchers can fulfill their obligations and avoid potential litigation by adding an extra clause to satisfy the informed-consent requirement. Ultimately, neither framework provides satisfactory results. The solution is to find an allocation structure in the middle, respecting autonomy and integrity and providing adequate compensation to donors in blockbuster cases.

The solution is to create a quasi-property right, which would allow donors to have a limited interest in their cells after removal. "A quasi-property right is a limited property right—the owner of the property has some but not all of the sticks in the bundle of property rights."¹⁹² This limited right would allow donors to maintain some control over the cells after their removal, recognizing the donor's right to consent to research (respecting the donor's autonomy interest) and also the donor's right to receive compensation (respecting the donor's interest in sharing in profits received from the cells).

Courts have recognized a quasi-property right in relatives of the deceased, allowing them a limited property interest in the decedent's body.¹⁹³ In this context,

191. *Moore v. Regents of the Univ. of Cal.*, 793 P.2d 479, 521 (Cal. 1990) (Mosk, J., dissenting).

192. Michelle Bourianoff Bray, *Personalizing Personality: Toward a Property Right in Human Bodies*, 69 TEX. L. REV. 209, 220 n.77 (1990).

193. *See* *Pierce v. Proprietors of Swan Point Cemetery*, 10 R.I. 227, 242 (1872) (holding that although it is not property, a dead body may be considered quasi-property); 5 B.E. WITKIN, SUMMARY OF CALIFORNIA LAW, TORTS § 460 (10th ed. 2005); *see also* *Newman v. Sathyavaglswaran*, 287 F.3d 786, 793 (9th Cir. 2002) (quoting *O'Donnell v. Slack*, 55 P. 906, 907 (Cal. 1899) ("[T]he next of kin, while not, in the full proprietary sense, 'owning' the body of the deceased, have property rights in the body which will be protected . . .")); *Enos v. Snyder*, 63 P. 170, 171 (Cal. 1900) (holding

the quasi-property right provides that the decedent's next of kin have a limited right to possess the body, in the absence of testamentary disposition.¹⁹⁴ This includes the right to possess a corpse for purposes of burial and internment, to prevent its mutilation, and to direct organ donation and research.¹⁹⁵ Courts have recognized that next of kin are entitled to indemnification for violation of this right, providing a cause of action against individuals who wrongfully interfere with this right.¹⁹⁶

1. Cornea Cases

The most common cases recognizing quasi-property rights of the next of kin involve due process claims by family members of decedents whose corneas were removed under presumed consent statutes. In each of the cases, the coroner removed the corneas of the deceased without giving notice to or obtaining consent from the decedent's next of kin. Recognizing a quasi-property right, the courts in the cornea line of cases held that the next of kin's quasi-property right constitutes an adequate property interest entitled to due process protection.

The quasi-property right of the next of kin has been recognized by both the Sixth and Ninth Circuits. In *Brotherton v. Cleveland*, the Sixth Circuit held that Deborah Brotherton had a quasi-property right in her husband's body, granting her the right to possess his body for burial, consent to organ donation, and control the disposal of his body.¹⁹⁷ The court explained that although the collection of rights regarding dead bodies is limited and is not a full property right, Brotherton had a sufficient "aggregate of rights" to rise to the level of a "legitimate claim of entitlement."¹⁹⁸ This quasi-property right provided her the "right which resides at the very core of a property interest: the right to possess."¹⁹⁹ The State's interest in promoting organ donation was not sufficient for it to "consciously disregard those property rights which it has granted" without any process.²⁰⁰

The Sixth Circuit reaffirmed the *Brotherton* decision in *Whaley v. County of Tuscola*, holding that "the next of kin [have] a legitimate claim of entitlement and

that next of kin have the right to possession of a body for purposes of burial); *Spates v. Dameron Hosp. Ass'n*, 7 Cal. Rptr. 3d 597, 608–09 (Cal. Ct. App. 2003) (recognizing the right of next of kin to bury or preserve a corpse before deciding the issue on other grounds).

194. See *Painter v. United States Fid. & Guar. Co.*, 91 A. 158, 160 (Md. 1914); 5 B.E. WITKIN, *supra* note 193, at 682.

195. See *Whaley v. Cnty. of Tuscola*, 58 F.3d 1111, 1115–16 (6th Cir. 1995); *Cohen v. Groman Mortuary, Inc.*, 41 Cal. Rptr. 481, 483–84 (Cal. Ct. App. 1964); *Jordan & Price*, *supra* note 13, at 172.

196. See *O'Donnell*, 55 P. at 907; 5 B.E. WITKIN, *supra* note 193, at 682.

197. *Brotherton v. Cleveland*, 923 F.2d 477, 480–82 (6th Cir. 1991).

198. *Id.* at 482.

199. *Id.* at 481.

200. *Id.* at 482.

thus a property interest in a dead relative's body, including the eyes."²⁰¹ The *Whaley* court recognized that next of kin have the choice of making a gift of all or part of the decedent's body as well as the "right to dispose of the body in limited circumstances, possess the body for burial, and prevent its mutilation."²⁰²

In *Newman v. Sathyavaglswaran*, the Ninth Circuit followed the *Brotherton* court's reasoning and recognized a quasi-property right belonging to the next of kin, stating that the "next of kin have the exclusive right to possess the bodies of their deceased family members . . ."²⁰³ The court emphasized that the quasi-property right protects "the premium value our society has historically placed on protecting the dignity of the human body in its final disposition."²⁰⁴ Although the next of kin may not have every "twig" in the bundle of property rights, they have enough "twigs" to maintain a "legitimate claim of entitlement" to the decedent's body.²⁰⁵

Extending and adapting the quasi-property doctrine to biomaterials would protect donor autonomy and create a right to compensation in blockbuster cases. Although this is not (yet) what courts generally are doing—the quasi-property right in the context of human bodies has been limited to the next of kin context—the doctrine can easily be extended to biomaterials. If courts are willing to find that next of kin have a quasi-property right in the body of the deceased, it is not a stretch to recognize a quasi-property right in a donor's own body parts while she is still alive. Courts often recognize quasi-property interests when there is no existing legal theory to compensate the relatives for the intangible emotional harm they have suffered.²⁰⁶

2. Application: The Case of Ted Slavin

In this section, I present Ted Slavin as an example to illustrate the application of the quasi-property right. Ted Slavin had hemophilia and required multiple blood transfusions as treatment.²⁰⁷ As a result of repeated exposure to hepatitis B through contaminated blood transfusions, Slavin's body developed antibodies to hepatitis B. His doctor realized the value of the antibodies for scientific research and, unlike doctors in other cases discussed previously,

201. *Whaley v. Cnty. of Tuscola*, 58 F.3d 1111, 1117 (6th Cir. 1995).

202. *Id.* at 1116.

203. *Newman v. Sathyavaglswaran*, 287 F.3d 786, 788 (9th Cir. 2002).

204. *Id.* at 798.

205. Kathryn E. Peterson, Note, *My Father's Eyes and My Mother's Heart: The Due Process Rights of the Next of Kin in Organ Donation*, 40 VAL. U. L. REV. 169, 209 (2005).

206. *Id.* at 186–87 (citing *Carney v. Knollwood Cemetery Ass'n*, 514 N.E.2d 430, 434 (Ohio Ct. App. 1986)); see Colleran, *supra* note 26, at 1207 (“[The] primary concern in seeking redress for harm done to dead bodies is not the injury to the body itself but the emotional harm suffered by surviving family.”).

207. See Baruch S. Blumberg et al., Letter to the Editor, *Ted Slavin's Blood and the Development of HBV Vaccine*, 312 NEW ENG. J. MED. 189, 189 (1985).

informed the patient of the potential value of his cells. Slavin was able to control the use of his cells, becoming “one of the first people in history to decide that contrary to the way things usually work in science, he would maintain complete control over any blood and tissues removed from his body.”²⁰⁸ Slavin sold vials of his blood serum to researchers for as much as ten dollars per milliliter and provided unlimited free samples to researchers looking for a cure to hepatitis B.²⁰⁹ Using his serum, researchers discovered the link between hepatitis B and liver cancer and created the first hepatitis B vaccine.²¹⁰ Because Slavin was able to take control of his cells from the beginning, he did not need to sue to assert his rights to them.²¹¹

The difference between Ted Slavin and the donors discussed previously—John Moore, Henrietta Lacks, and the Greenberg family—was information. Slavin’s doctor informed him that his cells were unique and potentially scientifically useful.²¹² As a result, Slavin was able to maintain control over his tissues on his own terms, deciding who used his cells, how the cells were used, and who profited from them.²¹³ In this scenario, Slavin had complete control over his cells. He consented to the removal of the cells from his body *and* to the research on the cells. Not only was he aware of the plans to conduct research and the potential to profit from them, he was actively involved in the process. Each time his cells were used in research, it was with his consent and he received compensation (or elected to waive compensation). Ultimately, “the question isn’t whether people have the ability to control their tissues; it is how much science should be obligated (ethically and legally) to put them in the position to do so.”²¹⁴

In an alternate scenario, if the doctor had not informed Slavin that she was using these samples for research and commercial endeavors, with a quasi-property right, Slavin would have a cause of action upon discovering that his cells had been used without his knowledge and consent. Because the cause of action is based on a quasi-property right, rather than a breach of fiduciary duty, it is not dependent on the relationship of the parties. The cause of action would extend to cases where there is no therapeutic relationship, such as *Greenberg*. And a cause of action would exist against other defendants, such as researchers who do not stand in a fiduciary relationship with the donor or have a duty to obtain informed consent to medical procedures, as well as to institutions and companies that profit from the cells.

The quasi-property right creates a duty of notice and consent and provides a

208. Skloot, *supra* note 1, at 40.

209. SKLOOT, *supra* note 16, at 202.

210. *Id.* at 203.

211. *See id.* at 202–03.

212. Skloot, *supra* note 1, at 44.

213. *Id.*

214. *Id.* at 45.

cause of action in tort in the event that the duty is breached. With a quasi-property right, potential tissue donors, like Slavin, would be empowered to decide what happens to their cells and whether and how they may be used in research, and be entitled to share in the profits. Although the entire bundle of rights is not fully recognized, the “quasi-property approach allows an individual to maintain a limited right to control the disposition” of his cells.²¹⁵

3. Public-Policy Limitations

Because it is not a full property right, the donor’s quasi-property right would be subject to limitations in accordance with public-policy concerns. The next of kin quasi-property right is limited in both time and scope—relatives have a right to possession for a short amount of time for the limited purpose of disposing of the body in a dignified manner. The quasi-property right in biomaterials may similarly be limited in time and in scope to accommodate public-policy concerns.²¹⁶ The legislature may define the boundaries of the right, setting limits on how the tissue may be used and who may financially benefit from its use. In defining the quasi-property right, courts may also limit the restrictions that donors may put on the use of their cells. Ultimately, although donors’ rights “may be subject to important limitations because of public health concerns, the absence of unlimited or unrestricted dominion and control does not negate the existence of a property right”²¹⁷

CONCLUSION

The collection and use of human tissues for research raise concerns regarding ownership of the cells once they are removed from the body. There is no clear framework for determining who owns cells when they are removed from the body, who decides what happens to the cells once they are removed, or who has the right to the profits derived from the cells. There is no relevant legislation regarding ownership of excised cells. The existing doctrine provides little guidance on allocating control of biomaterials, and does little to resolve issues of consent and compensation. Courts have haphazardly reached decisions on an ad hoc basis, leading to a legal landscape that is messy and inconsistent and provides little guidance for cell donors and researchers. Without a framework that completely addresses allocation of control of biomaterials, individual interests in autonomy and compensation are not adequately protected. Therefore, it is necessary to develop a framework that comprehensively addresses issues of control of and compensation for human cells once they have been removed.

215. Jordan & Price, *supra* note 13, at 155 (citing *Hecht v. Superior Court (Hecht I)*, 20 Cal. Rptr. 2d 275 (Cal. Ct. App. 1993)).

216. Ram, *supra* note 21, at 169–70.

217. Moore v. Regents of the Univ. of Cal., 249 Cal. Rptr. 494, 506–07 (Cal. Ct. App. 1988), *aff’d in part, rev’d in part*, 793 P.2d 479 (Cal. 1990).

One approach to the problem of ownership of human cells is to create a property right, giving rise to a cause of action in either conversion or unjust enrichment. Another approach is to enhance the already existing framework for informed consent. Both are imperfect solutions, however. Creating a property right in excised cells grants too much control to the donor, potentially impeding valuable research, while the doctrine of informed consent grants too much control to the researchers, impinging on donors' rights of autonomy. Ultimately, neither framework provides satisfactory results.

In conclusion, I recommend creating a quasi-property right that is tailored to address the issues of consent and compensation that arise in allocating control of biomaterials. A quasi-property right would allow a donor to have a limited interest in her cells after their removal. Extending and adapting the quasi-property doctrine to biomaterials would protect donor autonomy and create a right to compensation in blockbuster cases. This framework provides meaning and substance to autonomy in the collection of human cells for research, creating a cause of action for when things fall through, and a solution to the compensation issue that is narrowly tailored to blockbuster cases.