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# Formalism and the Legal Status of Body Parts

*Michele Goodwin*<sup>†</sup>

Our function cannot be limited to a mere blind adherence to precedent. We must determine with the best exercise of our mental powers of which we are capable that law which in all probability will be applied ... If this means the discovering and applying of a “new doctrinal trend” ... this is our task to be performed directly and straightforwardly, rather than “artfully” dodged.<sup>1</sup>

## INTRODUCTION

This article addresses a narrow aspect of the body commodification debate, specifically the remedy for nonconsensual appropriation of human body parts, including tissues, bones, heart valves, and other substances unique in value to the human body. The answer to whether there is a remedy for the malfeasance of “stealing” a body part, however, depends upon how we legally conceptualize the body and rights associated with it. Is it property, a product, our mere possession (a borrowed vessel belonging to the state or god), or a service? Each of these terms embodies social values and legal statuses, both of which are significant to judicial interpretation.

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<sup>†</sup> Professor of Law and Director of the Health Law Institute at DePaul University College of Law. I would like to thank June Carbone, Martha Ertman, Stephen Siegel, Stephan Landsman, Dorothy Roberts and Andrew Gold for discussing these ideas with me. This article is an attempt to push the discourse on commodification beyond its immediate perimeters and to think more deeply about the legal and social status of the body and how our interpretations on this question impact biotechnology and legal claims on the micro and macro levels. This is a first attempt to stumble through the woods on particular status questions and to create a clearing where others may venture to debate. I am grateful for the dedicated research assistance provided by Erin Crow. I am also grateful to Basil Cherian, Mark Premo-Hopkins, and their colleagues at the University of Chicago Legal Forum.

<sup>1</sup> *Spector Motor Service v Walsh*, 139 F2d 809, 814 (2d Cir 1943). See also Benjamin Cardozo, *The Growth of The Law* 56-80 (1924) (charting the evolution of decisionmaking from pure adherence to precedent to a less rigid and more flexible approach commonly associated with shift from naturalism to pragmatism).

If the body were to be redefined as property, it would violate the established normative view of the body as a sacred, inalienable object.<sup>2</sup> For some the question posed might be a false one—the property interest they might suggest is not in the body itself, but in the right to the body. Yet this layer of abstraction, while certainly convenient for my perspective, is yet a matter of obfuscation from the question itself, which technology demands that we answer. Equally, without a legal status the body is also vulnerable to the unremedied exploitation of others.<sup>3</sup> Thus, as property, a legitimate claim of ownership can be made, and the ability to redress nonconsensual appropriation is better established.<sup>4</sup> If the body exists only for the purpose of carrying our souls and it is violated, it would seem that whatever cause of action that might exist is not one to be adjudicated in courts of law.

A determination of whether the body is property might influence the outcome of several cases currently in litigation, including whether heart valves and tissues used for donation are products, whether universities have a property claim or proprietary interest in research subjects' DNA and tissues, the constitutionality of body part conscription laws, and whether causes of action can be sustained for wrongful implantation, directed implantation, and likely a host of other foreseeable and also unimaginable problems. This determination will be a significant factor in future product liability claims, including *Miller v Hartford Hospital*,<sup>5</sup> a case involving the implantation of contaminated heart valve tissue, which is in the initial stages of litigation in Connecticut,<sup>6</sup> the final disposition of *Martin v Young Kim*,<sup>7</sup> now in district court litigation in Indiana, and likely many more.

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<sup>2</sup> See Margaret Jane Radin, *Market-Inalienability*, 100 Harv L Rev 1849, 1851 (1987) ("In conceiving of all rights as property rights that can (at least theoretically) be alienated in markets, economic analysis has ... invited us to view all inalienabilities as problematic.").

<sup>3</sup> See, for example, Judith D. Fischer, *Misappropriation of Human Eggs and Embryos and the Tort of Conversion: A Relational View*, 32 Loyola LA L Rev 381, 381 (1999) (noting that "[a]s technological breakthroughs change the world, old legal theories may seem inadequate to address new legal problems").

<sup>4</sup> Id at 402–03 (advocating a torts conversion remedy for patient-victims in order to make them whole again).

<sup>5</sup> 40 Conn L Rptr 508 (Superior Ct Conn 2005).

<sup>6</sup> See, for example, *Human Aorta Valve May Qualify as Product*, Ct Law Trib 33 (Jan 9, 2006) (discussing the suit against doctors and Cryolife, alleging medical malpractice, wrongful death and products liability based on the death of Leonard Klein who received a heart valve in a transplant that was allegedly infected with fungus).

<sup>7</sup> See *Martin v Young Kim*, 2005 US Dist LEXIS 20595 (N D Ind 2005) (where a young man was killed and the parents wished to have his kidney donated to his uncle, but were denied because the coroner determined an autopsy would be necessary render-

Anticommodification scholars would be right to suggest that we transgress, to some extent, established ethical norms and settled law by introducing financial considerations to the body.<sup>8</sup> A central tenet in contemporary biotechnology jurisprudence exempts the body from being tangible “property.”<sup>9</sup> Yet, such perspectives are also ahistorical—not of the brutality found in seventeenth to nineteenth century slavery in the United States—but of our immediate past and predictable future. To be sure, we may not *like* discussing the human body in market-like terms, with values and assessments. However, market realities in the body already exist<sup>10</sup> and our failure to recognize this has its own set of consequences, including a sorely lacking and undeveloped nomenclature, the exploitation of human subjects,<sup>11</sup> a loosely monitored but robust market in buying and selling purloined human tissues,<sup>12</sup> and an expanding, conflicting common law.<sup>13</sup> The rapid

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ing the kidneys unavailable, the court held the claim survived summary judgment because Indiana case law supported a property right in a deceased family member).

<sup>8</sup> Consider Radin, 100 Harv L Rev at 1851 (cited in note 2) (asserting that “the characteristic rhetoric of economic analysis is morally wrong when it is put forward as the sole discourse of human life”).

<sup>9</sup> See, for example, *Shults v United States*, 995 F Supp 1270, 1275-76 (D Kan 1998) (holding that parents of a deceased airman had no claim for conversion where portions of their son’s tissues and organs were discarded after autopsy); *Perry v St Francis Hosp and Med Ctr*, 886 F Supp 1551, 1553 (D Kan 1995) (denying recovery for breach of contract based on the defendant’s removal of more body parts than were authorized); *Bauer v North Fulton Med Ctr*, 527 SE2d 240, 244 (Ga Ct App 1999) (concluding that a widow could not maintain a claim for conversion based on the unauthorized removal of her husband’s eye tissue); *Moore v Regents of University of California*, 793 P2d 479 (Cal 1990) (denying conversion claim of patient whose tissues had been nonconsensually tested, conveyed to third parties, and patented); *Hasselbach v Mt Sinai Hosp*, 173 AD 89, 92 (1st Dept NY 1916) (opining that a widow could not maintain a conversion claim for an unauthorized autopsy performed on her husband). See also Richard Gold, *Owning Our Bodies: An Examination of Property Law and Biotechnology*, 32 San Diego L Rev 1167, 1171 (1995) (“The human body and its component parts are not, however, market goods.”)

<sup>10</sup> Medical researchers, for example, partake in the market of human tissues when they obtain authorization for medical tests and samples that later result in patenting of cell lines or other similar financially beneficial medical products. See, for example, Donna Dickenson, *Consent, Commodification and Benefit-Sharing in Genetic Research*, 4(2) Developing World Bioethics 109 (2004) (focusing on disadvantaged populations both in the developing world and First World countries). In addition, a rather robust market in human eggs exists and is well-publicized and documented. See, for example, Kenneth Baum, *Golden Eggs: Towards the Rational Regulation of Oocyte Donation*, 2001 BYU L Rev 107, 107-112 (2001) (discussing an infertile couple’s solicitation of female students attending prestigious universities for oocyte donation and a website advertising auctions for oocytes and sperm, and documenting the resulting media coverage).

<sup>11</sup> For a thorough discussion of exploitation of disadvantaged populations in medical research, consider Dickenson, 4(2) Developing World Bioethics 109 (cited in note 10).

<sup>12</sup> The most recent purloined tissue incident occurred in New York. Robert Smith, *Four Indicted in Case of Tissue Theft*, National Public Radio, (Feb 23, 2006) available at <<http://www.npr.org/templates/story/story.php?storyId=5230544>> (last visited May 4, 2006).

growth of biotechnology has produced overwhelming demand and uses for human body parts.<sup>14</sup> Body parts now captured for biotechnological purposes were once considered human waste and were thus discarded by doctors, hospitals, and clinics.<sup>15</sup> Yet, today there is a market in body parts—and physicians, hospitals, and patients have come to rely on their availability. How human substances are acquired may be more troubling than the fact that a black market exists. Acquisition occurs through such means as coercion and fraud (in other words, tissues donated for altruistic purposes, but later sold by the donees),<sup>16</sup> funeral homes and crematoriums desecrating and selling body parts,<sup>17</sup> and misappropriation from some physicians, scientists, and researchers.<sup>18</sup>

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<sup>13</sup> Even the state of the law governing the transfers of human eggs (a rather common occurrence among couples facing infertility) is conflicting. For a discussion of this conflict see Baum, 2001 BYU L Rev at 123–34 (cited in note 10).

<sup>14</sup> Office of Technology Assessment, United States Congress, *Ownership of Human Tissues and Cells: New Developments in Biotechnology* 23 (Books for Business 2001):

Over the past decade, however, technological advances have resulted in new, enhanced methods for studying and using human body parts—particularly tissues and cells . . . . Human samples are not only an integral part of the biomedical research process, but they are now also used as a component of (or in the production of) a variety of commercial products ranging from drugs and vaccines to pregnancy test kits.

Id.

<sup>15</sup> One of the seminal cases regarding pecuniary gain from material otherwise considered to be medical waste occurred in 1990. *Moore v Regents of The University of California*, 793 P2d 479 (Cal 1990). A leukemia patient underwent treatment at UCLA's Medical Center. After removing the patient's spleen as part of his treatment, one of the doctors who treated the patient used his cells to develop and patent a profitable cell line. Id at 480–82.

<sup>16</sup> See Michele Goodwin, *Commerce in Cadavers is an Open Secret*, LA Times B15 (Mar 11, 2004) (discussing litigation in state and federal courts involving the black market sale of body parts taken from cadavers donated by family members); Charles Ornstein and Monte Morin, *UC Got Body Parts Warning a Year Ago*, LA Times A1 (Mar 16, 2004) (discussing the alleged black market sales of donated cadavers by UCLA employees).

<sup>17</sup> Jeff Nesmith, *Funeral Home Thefts: Body Parts May Be Tainted—Patients Tested as 'Ripple of Fear' Reaches Atlanta*, The Atlanta Journal-Constitution A1 (April 23, 2006); Paul Harris, *They Replaced Stolen Bones With Pipes: Organs With Rags—1077 Corpses Carved Up By Illegal Body Snatchers Who Sold Their 'Harves' On The Donor Market*, The Observer (England) 20 (April 2, 2006). See also *Jackson v Biomedical Tissue Servs Ltd*, No 06-CV-1323 (D NJ complaint filed Mar 30, 2006) (plaintiff alleging that hepatitis was contracted through purloined body parts sold in the donor market).

<sup>18</sup> See *Moore*, 793 P2d at 480-81 (involving a UCLA Medical Center physician who concealed from his patient that additional cells were being removed from the patient in order to conduct profitable research); Dickenson, 4(2) Developing World Bioethics at 110 (cited in note 10) (discussing one researcher's misrepresentation to a certain population in New Guinea that she wanted blood samples to check for insects, when she actually wanted the samples to enhance research in pursuit of a patent, and another set of researcher's misrepresentations to Chinese villagers that they would receive medical care in exchange for DNA samples).

Nevertheless, some scholars conclude that to place a financial value on the body is to diminish its personhood and pollute our otherwise homogeneous understanding of its legal, social, and moral status.<sup>19</sup> To formalists, the human body is a sacred entity, and its status as such is violated by any associations with financial evaluations and market terms and conditions.<sup>20</sup> An extrapolation of this theory is that the body should remain an inalienable vessel, without regard to the uses governments and private entities find for it, lawful or not.<sup>21</sup> Legal and social commentators invoke the horrific slave experience in the United States to buttress their claim and to demonstrate in graspable, stark terms the significant consequences of placing financial value on human beings.<sup>22</sup> To suggest that their arguments are dated invites remonstrance from varied ideological corners wedded to the anticommodification, incommensurability perspective. Their reasons for avoiding what I believe are overdue dialogues about what ultimately involves the reach of biotechnology into our personal spheres are not altogether difficult to understand, even if slightly overstated.

These are the new formalists—or formalists just on the point of body parts. They reject or ignore the evolving nuances of body parts with respect to law and biotechnology.<sup>23</sup> Typically, they

<sup>19</sup> Consider Radin, 100 Harv L Rev at 1865 (cited in note 2) (arguing that economic analysis is morally wrong when applied to the human body).

<sup>20</sup> Id.

<sup>21</sup> Id.

<sup>22</sup> Ronald Arnold, et al, *Financial Incentives for Cadaver Organ Donation: An Ethical Reappraisal*, 73 *Transplantation* 1361, 1366 (2002) (“It is also important to note that our society does not permit its capitalistic system to operate in certain commodified exchanges because they are considered to be intrinsically wrong.”).

<sup>23</sup> Legal formalists typically regard legal texts, such as statutes, regulations, the Constitution, and prior precedent as the basis of, and usually the exclusive foundation for, judicial opinions. At its epicenter, formalism embraces the concept that law is created by the state and its agencies and the legal rules that result from the legislature’s deliberations are the state’s imperative. Formalists argue that the judiciary is restrained by the separation of powers to reach beyond legal texts and their plain meaning. Their role is to determine what the law is and not what the law should be. To infuse the law with their social and political sympathies would undermine the rule of law.

The new formalists are unlike traditional formalists—and in fact they may be formalists only on the subject of the body itself. Ironically, the new formalists would have very little in common with their more traditional counterparts. Indeed, they are likely to be critics of the conventional formalists.

The traditional formalists are considered rigid and constrained in their thinking; limited in their willingness to view the law as an evolving set of principles. See Guido Calabresi, *An Introduction to Legal Thought: Four Approaches to Law and to the Allocation of Body Parts*, 55 *Stan L Rev* 2113, 2115-16 (2003) (describing a range of inherent conservatism in traditional formalist thinking). Rather, the old formalists “speak of law as a science, with its own principles, processes of reasoning, and discoverable facts.” Id at 2115 n 4.

might have nothing in common with those considered to be the traditional formalists, hewn from a more conservative understanding of the law and what the rule of law should be. They are not necessarily “right wing” or neoconservatives; their values are rooted in the “cause” behind their scholarship.<sup>24</sup> No, the new formalists might consider themselves even radical within their own discourses.

For example, feminist legal theorists often critique market-based body valuation as a form of sexual exploitation and oppression of women.<sup>25</sup> To these theorists, deliberation on the body in market terms reifies the subordinate status of women in society and vertical power relationships.<sup>26</sup> Others may find the race-sensitive dialogue of slavery altogether uncomfortable and thus avoid the broader debate about body parts.<sup>27</sup> Scholars of Critical Race Theory may be loath to venture down the politically unpopular terrain of body part commodification, simply opposed as a *de facto* position, or perhaps they believe there are other, far more important legal issues with which to contend.<sup>28</sup> Those within the liberal left concerned about politically appropriate critique may wish to consider the validity of incommensurability claims, but only if other valued constituencies within the academy are not offended. Antimarket conservatives equally disapprove of valuations placed on human biological resources, but for different reasons than those speculated above. Their concerns

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<sup>24</sup> Id at 2116.

<sup>25</sup> Consider Catharine A. MacKinnon, *Toward a Feminist Theory of the State* 3-12 (Harvard 1989); Naomi Wolf, *The Beauty Myth: How Images of Beauty Are Used Against Women* (Perennial 2002) (arguing the “wealth” women possess via their beauty is illusory, and actually a form of social and political oppression). Wolf discusses what she called the “professional beauty qualification” as a “condition for women’s hiring and promotion.” Id at 27.

<sup>26</sup> Andrea Dworkin, *Pornography: Men Possessing Women* 14-18, 53-56 (E.P. Dutton 1989).

<sup>27</sup> See, for example, Alice M. Noble-Allgire, *In Pursuit of Justice Powell’s Vision: Diversity-Conscious Admissions is Just the First Step*, 14 Berkeley La Raza L J 255, 257-59 (2003) (illustrating a scenario where two law professors avoid discussing relevant racial issues, and suggesting that this country cannot be color blind as some would suggest without avoiding other necessary discourse). The thought that we can be color blind induces individuals who avoid the issue of race completely to feel as if “African Americans should ‘not belabor the question of what happened in the past.’” Id at 259.

<sup>28</sup> Not all Critical Race Theorists, however, have avoided the issue of body commodification. See, for example, Khiara M. Bridges, Note, *On the Commodification of the Black Female Body: The Critical Implications of the Alienability of Fetal Tissue*, 102 Colum L Rev 123 (2002). Bridges’ Note “explores the question ... [of what impact] a market in fetal tissue will have on Black women [from a Critical Race Theory perspective].” Id at 123. Bridges “concludes that because Black women will be disproportionately exploited, as well as disenfranchised from the benefits produced by a market in fetal tissue, fetal tissue should not be made market alienable.” Id.

are often grounded in the abortion debate,<sup>29</sup> religious terms,<sup>30</sup> and moral claims (not to suggest that these considerations are not important on some level to the others). There are some scholars in other schools of thought who may equally reject the notion of property in the body, including the doctrinalists and formalists, whose devoted following of precedent (judicial or legislative) indicates an inflexibility to the introduction of exogenous values (in other words, if the law never granted such status to the body, why do it now?).<sup>31</sup>

Ultimately, the fear to speculate and even contemplate the body in any legal terms other than our late nineteenth century understanding, based on the possibility we will cross *into* the bounds of slavery or for the love of *stare decisis*, limits the potential for robust, informed, meaningful contemporary dialogue and debate on a critical topic of our times.<sup>32</sup> Furthermore, this apprehension undermines scholars' ability to credibly engage in policy debates on the reach and normative positioning of biotechnology within the law. Biotechnology can, will, and has run amok amid this indeterminacy. Such fears might actively serve to deflect race issues, but in doing so, also lead to the avoidance of substantive investigation and analysis of markets that already exist and affect racialized bodies.

Therefore, that biotechnology outpaces legal response, including the development of regulation and meaningful social policy (that could be attentive to racial, gender, and cultural issues) should not come as a surprise. Nor is it a revelation that courts seem unprepared in their review of modern cases dealing with

<sup>29</sup> See Maxwell J. Mehlman, *The Story of Moore v Regents of the University of California*, in Gerald Korngold and Andrew P. Morriss, eds, *Property Stories* 49 (Foundation 2004) (“[C]onservatives worry that commodifying the body would weaken opposition to abortion and to fetal embryo experimentation.”).

<sup>30</sup> Stephen Wilkinson, *Bodies for Sale: Ethics and Exploitation in the Human Body Trade* 210–11 (Routledge 2003) (Members of the Southern Baptist Convention’s Christian Life Committee argue against the commodification of human DNA patents: “any gene that belongs to the human genome [is] ... sacred. Furthermore, all life, as created by God and thus a gift of God, has intrinsic value.”).

<sup>31</sup> See Calabresi, 55 *Stan L Rev* at 2114–15 (cited in note 23) (discussing the traditional formalist tendency to focus on rules as they exist in the status quo). Calabresi describes formalism (and doctrinalism) as “enjoying something of a renaissance.” *Id.* at 2114. Calabresi further describes both formalism and doctrinalism as viewing the “law as autonomous and distinct from other fields of learning.” *Id.* at 2115.

Legal analysis, under this approach, at least in its pure form, can be carried out without reference to other disciplines or other sources of values. The principal job of such analysis is to render the rules of law consistent and coherent with each other, so that like cases are treated alike. *Id.*

<sup>32</sup> See, for example, Wilkinson, *Bodies For Sale* at 136, 174, 207–09 (cited in note 30) (comparing paid surrogacy, DNA patenting and slavery).



these issues.<sup>33</sup> The judicial opinions that result from months of pondering the legitimacy of aggrieved plaintiffs' claims or pleas for injunctions often reflect that ambivalence and result in judicial formalism.<sup>34</sup> Meaningful public policy about the use and value of stem cells, organ transplantation, cloning, pre-implantation genetic diagnosis, and xenotransplantation cannot (and should not) be developed in a vacuum.

Part I of the Article considers what a deprivation in the context of the human body actually means to our nascent jurisprudence in this domain. That is to say, I address whether all deprivations are the same or should be treated as so. Perhaps some deprivations are worthy of legal scrutiny and others best left alone. This idea is simple to grasp, but as Devon Carbado asserts, "simple ideas often mask complex social realities."<sup>35</sup> Lest these decisions as to how we conceptualize the body for purposes of legal remedy be measured by diverse religious criteria or episodic moral outrage (in other words recent incidences of tissue banks misappropriating human tissue and bones from funeral homes), let us consider what the law should be.

Therefore, in Part I, I offer three simple thought experiments to study whether some deprivations amount to a legally cognizable wrong. Rather than view the harms in terms of a hierarchy of wrongs, I argue for a different approach, one that for now treats the *status* of the body equally. I necessarily concede that not all bodies are situated equally, as the status of the body follows the social, political, and economic status of the citizen or individual. That said, this Article puts aside the question as to whether a particular harm to bodies unequally situated creates an unequal harm. Part I concludes by examining the pitfalls of judicial formalism. It argues that our indifference to "naming" the body and denying it a defined legal status in this biotechno-

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<sup>33</sup> See, for example, Ryan M.T. Iwasaka, Note, *Chakrabarty to Chimeras: The Growing Need for Evolutionary Biology in Patent Law*, 109 Yale L J 1505, 1506 (2000) (discussing the "tumultuous and confusing decade-long struggle over the patentability of animals," and the need for modernization in the patent law field to keep pace with ever-expanding technological discoveries).

<sup>34</sup> See *Greenberg v Miami Children's Hosp Research Inst, Inc*, 264 F Supp 2d 1064 (S D Fla 2003) (denying relief for families whose donated cell lines and fluids were later patented by their physician); *Cryolife, Inc v Superior Court*, 110 Cal App 4th 1145 (Cal Ct App 2003) (denying strict liability recovery for plaintiff who purchased contaminated body part from Cryolife tissue bank); *Bauer v N Fulton Med Ctr*, 527 SE2d 240, 244 (Ga Ct App 1999) (concluding that a widow could not maintain a claim for conversion based on the unauthorized removal of her husband's eye tissue).

<sup>35</sup> Devon Carbado, *Race to The Bottom*, 49 UCLA L Rev 1283, 1285 (2002).

logical era renders the law weak and ineffectual. It explores specific cases and adopts a narrative framework for the Article.

In Part II, I suggest that valuing the body differently depending upon the setting and misfeasor of the harm does not provide a stable foundation on which the law can rest, nor predictability for the aggrieved, nor a deterrent to body part prospectors. Furthermore, scholars are mistaken to argue that to assign a value-based or market status to the body for which a remedy can be granted would create a disincentive for producers of human-based biologics to create medicines or retard biotechnology and scientific creativity.

In Part III, I turn to the difficulties of changing the nomenclature and status of the body. The technical aspect of such reorganization is easy enough; legislatively, judicially, or both, the introduction of legislation or adaptation in the common law will not be difficult—the foundation for this already exists as briefly discussed in Part III. What I propose, an alternative conception of the body in light of biotechnology, requires a fundamental reevaluation of the body. This invites certain perspectives and dialogues that may be deemed offensive to various classes of people. There are pitfalls to the introduction of valuations in the body; those insensitive to America's slave past could promote as the best alternative a valuation system that starkly resembles (at least in tone) an auction block where bodies are valued based on immutable factors of race, gender, or physical ability. Individuals may wish to go to the marketplace with their body parts in far greater numbers than they do now and for unforeseen purposes. We would be sensible to give considerable thought to such concerns and possible consequences. Also, it is possible that we might go too far to accommodate biotechnology rather than rethinking the society that we wish to be in light of the rapid expanse of technology. I conclude by arguing that although pitfalls to redefining the body exist, our failure to be proactive in light of privatized biotechnology and its drive for body parts will produce nefarious systems that will result (as will be demonstrated in Part IV) in unequal treatment, exploitation of the vulnerable, and lack of recourse for the aggrieved.

Part IV explores what valuations of the body truly mean in a socioeconomic context. It recommends two specific causes of action for the two spheres of biotechnology that most affect the human body—simply stated, input and output. Thus, Part IV.A recommends the application of strict liability to cases involving biotech firms distributing (selling) insalubrious human tissue for transplantation. Part IV.B proposes that when the state or its

agent, including scholars funded by federal grants or at state universities, nonconsensually assume ownership over an individual's body (or parts), a "taking" has occurred for which remedies should exist. This article concludes in Part V.

### I. PROPERTY, STATE POSSESSION, OR SERVICE?

In Part I, I illuminate three conceptions of the body and identify the flaws in each model. The first conception, the *Moore* model, based on a case ubiquitously read during law school, will be more familiar to law audiences. The other two conceptions are slightly more obscure. Most obvious in these thought experiments is that a wrong has occurred. Defining what that wrong is, in light of contemporary formalistic jurisprudence and legislative silence, is another matter.

#### A. The *Moore* Model: Body Part As Intellectual Property

##### Model A:

If G (physician) persuades M to have his spleen removed (under pretense of imminent death), and M complies, but is unaware that G has pre-established pecuniary and organizational interests (established business relationships) in exploiting the spleen and cells, and G and his associates actively exploit the cells, and G withholds this information from M, including notice of a patent derived from the use of M's spleen, sperm, and blood, has there been a violation of M's rights? If so what kind? Can a claim be made for which relief is available?

##### Model A(2):

X, clueless, kept raw diamonds in his pocket, but was convinced by Y (his lawyer) to remove the diamonds to save his life, and X complied. Y conspired to and did obtain the diamonds after X removed the diamonds from the pocket. Three years later, the newly polished, cut diamonds are ready for the market and Y successfully transfers them to new owners for millions of dollars. Has there been a violation of X's rights? If so what kind? Can a claim be made for which relief is available?

Model A, based on *Moore v Regents of the University of California*,<sup>36</sup> is perhaps the most recognized body part appropriation case. On October 8, 1976, Dr. David Golde, an employee of the University of California at Los Angeles Medical Center, informed Mr. Moore "that he had reason to fear for his life, and that the proposed splenectomy operation ... was necessary to slow down the progress of his disease."<sup>37</sup> Moore consented to the operation. Within days of the meeting with Moore, Dr. Golde and Shirley Quan, a researcher at UCLA, formed a partnership with the intent of making "arrangements to obtain portions of [Moore's] spleen following its removal and to take them to a separate research unit."<sup>38</sup> Over the next few years, Golde subjected Moore to additional tests (extracting blood, sperm, bone marrow, and other fluids), inducing him to commute to Los Angeles from Seattle under the pretense of medical necessity.<sup>39</sup> Nearly three years later, according to the court record, "Golde established a cell line from Moore's T-lymphocytes."<sup>40</sup> In 1981, the Regents applied for a patent on the cell lines and listed Quan and Golde as "inventors,"<sup>41</sup> the royalties and profits from which would be shared by the inventors and Regents. It is estimated that billions of dollars have been recouped from the exploitation of Moore's spleen and other tissues.

Without an appreciation for "what" the legal status of Moore's cells, sperm, and spleen were, the justices were ill equipped to define what the legal remedy should be. The court, finding that there was no other judicial or legislative guidance that would treat Moore's spleen and the cell line as property, dismissed his conversion claim.<sup>42</sup> To suggest, as the court did,

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<sup>36</sup> 793 P2d 479 (Cal 1990).

<sup>37</sup> Id at 481 (internal quotation marks omitted).

<sup>38</sup> Id (internal quotation marks omitted).

<sup>39</sup> Id.

<sup>40</sup> *Moore*, 793 P2d at 481. The particular lymphocyte derived from Moore's spleen is described as:

[a] type of white blood cell. T-lymphocytes produce lymphokines, or proteins that regulate the immune system. Some lymphokines have potential therapeutic value. If the genetic material responsible for producing a particular lymphokine can be identified, it can sometimes be used to manufacture large quantities of the lymphokine through the techniques of recombinant DNA.

Id at 481 n 2.

<sup>41</sup> Id at 482.

<sup>42</sup> *Moore*, 793 P2d at 488. Moore's original complaint raised thirteen causes of action. The court observed, "each defendant demurred to each purported cause of action. The lower court, however, expressly considered the validity of only the first cause of action, conversion." Id. The court reasoned that the other causes of action were defective. The

that his biological materials were *sui generis*, addresses only Moore's health condition, but provides little guidance as to the plaintiff's legal status. The court incorrectly suggests that there was no possessory interest in Moore's cell line. In fact, Dr. Golde possessed an interest protected by law. But why didn't Moore?

If "clueless" man, X, can have an interest in the diamonds in his custody, how can we deduce that one lacks an equal interest in his spleen, cells, sperm, and other biological materials? The distinction seems arbitrary; crafting a rule where skin is the barrier to ownership seems absurd. In other words, diamonds external to the skin (in one's pocket) is a possession for which there is a rule of ownership, but that which is within the skin has no ownership value? Or that which has external value, has no value if it is trapped within the body? If Moore had swallowed diamonds, would the value of the goods have been lost because they were no longer external?

Consider also that X's recovery is not limited to his awareness or ability to *guess* the value of the diamonds. Even the shamelessly ignorant plaintiff is entitled to relief. If the diamonds were worth five million dollars, but he guessed their relative value at five dollars, the law refuses to be punitive towards him or punish him for his ignorance, by limiting his recovery to five dollars.<sup>43</sup> To do so would unjustly enrich Y, his lawyer, and provide an incentive for lawyers to defraud their clients. As between the two models above, the California Supreme Court would have no difficulty divining the remedy for someone coerced out of his diamonds by his lawyer. Scholars should not be comfortable with the fact that the court would be blind to an equally hostile action, involving a doctor secretly obtaining his patient's cell line and exploiting it for his financial interests. In Model A, G, the physician and his collaborators, were likely in the best position to honestly describe the value of Moore's body parts. They were aware of the value that could be derived from isolating particular products from his cell line. They understood the

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other claims included: (1) lack of informed consent; (2) breach of fiduciary duty; (3) fraud and deceit; (4) unjust enrichment; (5) quasi-contract; (6) bad faith breach of implied covenant of good faith and fair dealing; (7) intentional infliction of emotional distress; (8) negligent misrepresentation; (9) intentional interference with prospective advantageous economic relationships; (10) slander of title; (11) accounting; and (12) declaratory relief. *Id.* at 482 n 4.

<sup>43</sup> *Childs v Haussecker*, 974 SW 2d 31, 38 (Tex 1998) ("[P]ermitting the cause of action of a 'blamelessly ignorant' plaintiff to accrue before he or she could possibly have been aware of the injury would be unjust."). See also Michael Green, *The Paradox of Statutes of Limitations in Toxic Substances Litigation*, 76 Cal L Rev 965 (1988).

nature of the market's demand for the products they could derive. G and his collaborators also understood their unique market advantage; securing a patent on Moore's cell line gave them a legal monopoly on all its derivatives. Nevertheless, the *Moore* court flatly rejected the concept of *self* ownership in one's body.<sup>44</sup>

## B. Presumed Consent: Body Part As State Good

### Model B: The Good Samaritan

B dies of sudden infant death syndrome (SIDS). D, a hospital staff member, removes B's corneas pursuant to a statute intended to increase the supply of corneas in the state. Parents later learn of the extraction and file a law suit, claiming the statute is unconstitutional because it fails to provide notice and an opportunity to object. Is the statute unconstitutional? Has a constitutionally protected right been breached?

Model B represents the presumed consent scheme, which acknowledges that the body has value as a source of transplantable goods. However, that value is gifted to the state unless notification is given to the state that the gift is revoked.<sup>45</sup> First enacted in Maryland,<sup>46</sup> presumed consent laws operate much like

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<sup>44</sup> *Moore*, 793 P2d at 488 (holding that the tort of conversion does not apply to his "biological materials"). However, the holding in *Moore* does not signify that harm has not occurred nor that an injury has not been sustained. Rather, the court does indicate that damages might be difficult to calculate.

<sup>45</sup> Uniform Anatomical Gift Act § 4 (National Conference of Commissioners on Uniform State Law 1987).

<sup>46</sup> See Md Estates and Trusts Code Ann § 4-509.1 (2005), which sets forth the following framework for determining when a corneal may be provided for transplant:

(a) *Requirements* – In any case where a patient is in need of corneal tissue for a transplant, the Chief Medical Examiner, the deputy chief medical examiner, or an assistant medical examiner may provide the cornea upon the request of the Medical Eye Bank of Maryland, Incorporated ... under the following conditions:

- (1) The medical examiner has charge of a decedent who may provide a suitable cornea for the transplant or research;
- (2) No autopsy will be required;
- (3) No objection by the next of kin is known by the medical examiner;
- (4) No religious objection made by the decedent before his death is known by the medical examiner; and
- (5) Removal of the cornea for transplant will not interfere with the subsequent course of an investigation or autopsy or alter the postmortem facial appearance. . .

substituted judgment, whereby one's choice to pursue or not to pursue a particular course of action with her body is usurped by the state.<sup>47</sup> Pursuant to statutory authority, medical examiners, coroners, and their designated personnel are authorized to extract corneas, heart valves, and other tissues from cadavers without first obtaining consent from the "donor" if the donor has not declined a donation.<sup>48</sup> The illusory opt-out provision veils the fact that such laws are more like conscription measures and less like an option or choice. Where, after all, is one to opt out? How do the dead opt out? How can the uninformed relative opt out? Indeed, studies demonstrate that most people, even local legislators such as aldermen and city council members, are relatively ignorant about presumed consent (in their own states) and possess a limited understanding of what the term signifies or what the law authorizes.<sup>49</sup>

Cornea extraction may be perceived as less invasive than spleen removal; it certainly is less disfiguring, and thus less noticeable. Cornea extraction does not leave signs easily noticeable

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(c) *Liability of Medical Examiner, Medical Eye Bank of Maryland etc.*—The Chief Medical Examiner, the deputy chief medical examiner, an assistant medical examiner, and the Medical Eye Bank of Maryland, Incorporated ... are not liable for civil action if the next of kin subsequently contends that authorization of that kin was required.

Id.

<sup>47</sup> Uniform Anatomical Gift Act § 4 (stating that "[t]he [coroner] [medical examiner] may release and permit the removal of a part from a body within that official's custody").

<sup>48</sup> Ariz Rev Stat Ann §§ 36-851, 36-852 (West 1989); Ark Code Ann. § 12-12-325 (Michie 2005); Cal Govt Code § 27491.46-.47 (West 2006); Colo Rev Stat § 30-10-621 (2005); Conn Gen Stat Ann § 19a-281 (West 2005); Del Code Ann § 29-4712 (2004); Fla Stat Ann § 765.5185 (West 2006); Ga Code Ann § 31-23-6 (Lexis 1985); Haw Rev Stat Ann § 327-4 (Michie 2004); Idaho Code § 39-3405 (2005); Ill Ann Stat § ch 110 1/2, § 351-354 (Smith-Hurd 1983); Ky Rev Stat Ann § 311.187 (Michie 2001); La Rev Stat Ann § 17:2354, 33:1565 (West 2005); Md Est and Trusts Code Ann § 4-509.1 (2005); Mass Ann Laws ch 113, § 14 (Law Co-op Supp 1989); Mich Comp Laws Ann § 333.10202 (West 2005); Miss Code Ann § 41-61-71 (1989); Mo Ann Stat § 58.770 (Vernon 2006); Mont Code Ann § 72-17-215 (2005); N C Gen Stat § 130A-391 (2003); N D Cent Code § 23-06.2-04 (Supp 1989); Ohio Rev Code Ann § 2108.60 (Baldwin 2005); Okla Stat Ann § 63-944.1 (West 2006); R I Gen Laws § 23- 18.6-4 (2001); Tenn Code Ann § 68-30-204 (1989); Tex Health and Safety Code Ann § 693.012 (Vernon 2005); Utah Code Ann § 26-4-23 (2005); Wash Rev Code Ann § 68.50.280 (2006); 2005 Wis Laws § 157.06; W Va Code § 16-19-4 (2005).

<sup>49</sup> Ralph Frammolino, *Harvest of Corneas at Morgue Questioned*, LA Times (Nov 2, 1997) (investigating over 570 cases of nonconsensual cornea harvesting during a 12 month period, and explaining that families "were shocked that they had not been asked or told"). See also, Michele Goodwin, *Organ Transplant Survey Analysis* (Feb 16, 2000) (unpublished, on file with the author). This survey was administered in Lexington, Kentucky, with the assistance of Janet Givens, special assistant to former Mayor Pam Miller. Participants consisted of administrators in the Mayor's Office and members of the City Council of Lexington, Kentucky. Only one of fifteen government officials surveyed (or 6.6 percent) in this group was aware of the term "presumed consent," although Kentucky had authorized legislative consent over ten years prior to the survey.

to lay people; there are no bruises on the face and no scratches on the eye lids.<sup>50</sup> Thus, if the deceased is prepared for burial, particularly with her eyes closed, her family would be completely unaware of the medical intrusion.<sup>51</sup> For this reason, critics of presumed consent legislation regard these laws as surreptitious and unethical, while proponents argue that statutory consent measures are creative efforts to procure corneas.<sup>52</sup> That individuals can be laid to rest with the appearance of "wholeness" is persuasive if appearances are the only impediment to broader support of presumed consent measures. Proponents also argue that compulsory donations require so little and that families hardly notice.<sup>53</sup>

Presumed consent statutes are compulsory measures that obligate individuals to donate. The legislation authorizing this type of body part conscription operates pursuant to mandatory autopsy statutes.<sup>54</sup> Thus, the only bodies to which presumed consent applies are victims of homicide or catastrophic deaths requiring a medical investigation. Disproportionately in some states, blacks and Latinos are the overwhelming majority of the presumed consent donors.<sup>55</sup> In California, according to a 1997

<sup>50</sup> See, for example, Frammolino, *Harvest of Corneas at Morgue Questioned*, LA Times A1 (cited in note 49) (noting that the lack of noticeable physical differences is how coroners have managed to remove corneas without the knowledge of relatives); S. Gregory Boyd, Comment, *Considering a Market in Human Organs*, 4 NC J L & Tech 417, 441 (2003) (discussing a Florida court's characterization of corneal removal as a small intrusion).

<sup>51</sup> See, for example, Frammolino, *Harvest of Corneas*, LA Times at A1 (cited in note 49); Boyd, 4 NC J L & Tech at 441 (cited in note 50).

<sup>52</sup> Marie-Andree Jacob, *On Silencing and Slicing: Presumed Consent to Post-Mortem Organ "Donation" in Diversified Societies*, 11 Tul J Intl & Comp L 239, 254-55 (2003) (describing the criticism that presumed consent is unethical); Maryellen Liddy, *The "New Body Snatchers": Analyzing the Effect of Presumed Consent Organ Donation Laws on Privacy, Autonomy, and Liberty*, 28 Fordham Urban L J 815, 819 (2001) (describing that many supporters believe presumed consent will increase the supply of organs available for transplant).

<sup>53</sup> Linda C. Fentiman, *Organ Donation as National Service: A Proposed Federal Organ Donation Law*, 27 Suffolk U L Rev 1593 (1993); Boyd, 4 NC J L & Tech at 441 (cited in note 50); Theodore Silver, *The Case For A Post-Mortem Organ Draft and A Proposed Model Organ Draft Act*, 68 BU L Rev 681 (1988).

<sup>54</sup> See, for example, Fred H. Cate, Symposium: *Organ Donation, Human Organ Transplantation: The Role of Law*, 20 J Corp L 69, 84 (1995) (noting that presumed consent "laws generally provide that a coroner or medical examiner may remove the corneas from a cadaver in the course of a legally-required autopsy").

<sup>55</sup> See Gabriel Escobar, *Deaths Pose Continuing D.C. Mystery; City Carries Hundreds of Undetermined Cases, Muddying Vital Statistics*, Washington Post A1 (Dec 22, 1997) (commenting on the rise in urban violence in the 1980s and remarking that many of the deaths of black urban Americans from that era remain unsolved); Glen Loury, *The Impossible Dilemma*, The New Republic 21 (Jan 1, 1996) (noting that the murder rate among black youths (under age 20), which was already three times that of white youths



study, over eighty percent of presumed consent donors were black and Latino.<sup>56</sup> In effect, the state presumes that a potential donor would in fact have wanted to donate were she still alive and able to make the choice. As indicated in prior scholarship, “legislatures are not shielding state regulations that authorize presumed consent from the public.”<sup>57</sup> On the other hand, neither tissue banks, which process and sell the tissues at considerable profit, nor state governments advertise the existence of such laws. It is not surprising, as discussed later in the Article, that tissue banks generate considerable revenue from processing, storing, and selling cadaver tissues. The tissue banking industry, which derives its “stocks” of tissues through mostly clandestine means, is estimated to be more than a billion dollar industry.

The compulsory aspect of the regulations makes these donations problematic. Forced use of nonconsenting individuals’ tissues is justifiable only if the donation is viewed as a form of civic duty, or if our bodies are property of the state. Donation as a civic duty is a laudable concept, though not supported by social custom or an American legal tradition. Our common law tradition abjures the duty to rescue doctrine, and more pointedly warns, “rescue at your own risk.” That our bodies belong in service to the state cannot be justified by the ways in which we organize labor, medicine, or our system of justice. Marx’s concept of a communitarian society, operating for the common good of man and woman, no matter how laudable, is not a philosophy that constitutional framers or the subsequent generations of electorate have adopted. This notion of compelled altruism belies the reality that only twenty percent of Americans carry donor cards—a more realistic reflection of their affirmative intent to donate.

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in 1986, doubled in the five years between 1986 and 1991, while the white rate remained unchanged). See also Darryl Fears, *Urban Spotlight: Is Atlanta the Next Detroit?*, Atlanta J & Const D1 (Dec 18, 1994) (pointing out that in the early 1980s, the homicide rate soared). Fears reports that between 1983 and 1987, more than 700 people were slain each year. On No Crime Day in Detroit—a 1986 event sponsored by basketball star Isaiah Thomas to prove his city was still safe—a police officer was shot dead. Id.

<sup>56</sup> Frammolino, *Harvest of Corneas*, LA Times at A1 (cited in note 49). See also *The Late Edition: Crime in the U.S. is Discussed* (CNN television broadcast) (Transcript # 4-2) (Oct 24, 1993); Eric Lichtblau, *Reporter’s Notebook: Going beyond Line Scores of Gang Carnage*, LA Times B3 (Nov 25, 1990) (noting that during a one month time span there were over 300 gang-related killings in Los Angeles County); *Larry King Live: Spying on Neighbors—The New Drug-War Strategy* (CNN television broadcast) (Transcript # 108-2) (Aug 15, 1990).

<sup>57</sup> Michele Goodwin, *Black Markets: The Supply and Demand of Body Parts* 17 (Cambridge University Press 2006).

Model B raises questions about duty, notice, appeal, and due process. In *Georgia Lions Eye Bank, Inc v Lavant*,<sup>58</sup> parents of an infant (dead as a result of SIDS) filed suit against the eye bank that was authorized by the state medical examiner to remove their son's corneas. The parents were not consulted and therefore had not authorized the removal. Essentially, they were denied the opportunity to object to the extraction.<sup>59</sup> The trial court held in favor of the parents, opining that the imposed consent statute violated due process in that it deprives a person of a property right in the corpse of her next of kin, and fails to provide notice and an opportunity to object.<sup>60</sup> Their complaint relied on a common law duty to properly bury and dispose of the deceased imposed by ecclesiastical courts on the next of kin of deceased persons.<sup>61</sup> Over time, this duty became interpreted and litigated as a "right" to dispose in any "appropriate" and "decent" manner afforded by the relatives.<sup>62</sup> Despite its own common law tradition upholding quasi property right interests in the dead for the next of kin, the Georgia Supreme Court reversed, ruling that parents have no interest in the body of their dead children.<sup>63</sup>

The ruling in *Georgia Lions* belied the status of dead bodies within the common law on the point of quasi property right interests. Previously, Georgia courts, as have other US courts, fashioned a "quasi property" right out of the duty to bury. Quasi property right interests in the dead were affirmed by a Georgia court in the 1937 *Pollard v Phelps*<sup>64</sup> case, which established that "the courts of civilized and Christian countries regard respect for the dead as not only a virtue but a duty, and hold that, in the absence of testamentary disposition, a quasi property right belongs to the husband or wife, and, if neither, to the next of kin."<sup>65</sup> Thus, if quasi property rights represent a substantive liberty, then it would seem that a violation of those interests occurs

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<sup>58</sup> 335 SE2d 127 (Ga 1985).

<sup>59</sup> Id at 128.

<sup>60</sup> Id.

<sup>61</sup> Id. See also *Rivers v Greenwood Cemetery*, 22 SE2d 134, 135 (Ga 1942) (holding "that a dead body is quasi property over which the relatives of the deceased have rights which the courts will protect").

<sup>62</sup> 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 Valp U L Rev 169, 186 (2005) (arguing that the "next of kin have a right to bury the body of a decedent in an appropriate manner").

<sup>63</sup> *Rivers*, 22 SE2d at 134.

<sup>64</sup> 193 SE 102 (Ga Ct App 1937).

<sup>65</sup> Id at 106.

when a state encroaches upon those spindles of “rights” without due process even in a utilitarian system designed to benefit a public purpose.

“Quasi property” rights diminish in their perceived value unless such interests can be protected from arbitrary state action. The *Georgia Lions* court’s assertion that statutory enactments naturally trump common law rules is correct only in instances when the statute itself does not violate constitutional protections.<sup>66</sup> *Brown v Board of Education*<sup>67</sup>, which provided that all provisions of state laws and regulation must yield to the principle that racial discrimination is unconstitutional, as well as *Skinner v Oklahoma*,<sup>68</sup> which overturned state mandated sterilization of persons considered “habitual criminals,”<sup>69</sup> demonstrate a well-established principle that legislation is subject to judicial scrutiny and more importantly constitutional protections. These cases persuasively remind us that regulations crafted from legislative authority are neither absolute nor immune from constitutional scrutiny.<sup>70</sup>

Thus, in the transplantation context, whether presumed consent laws can pass constitutional muster deserves serious judicial scrutiny. Because presumed consent procurement is triggered by homicide deaths in most states rather than all deaths, the line of proscription becomes arbitrary as the statute requires

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<sup>66</sup> *Newman v Sathyavaglswaran*, 287 F.3d 786,797 (9th Cir 2002) (explaining that “although the underlying substantive interest is created by ‘an independent source such as state law,’ federal constitutional law determines whether that interest rises to the level of a ‘legitimate claim or entitlement’ protected by the Due Process Clause”) (quoting *Memphis Light, Gas and Water Div v Craft*, 436 US 1, 9 (1978)).

<sup>67</sup> 347 US 483 (1954).

<sup>68</sup> 316 US 535 (1942).

<sup>69</sup> *Id* at 536. Oklahoma’s Habitual Criminal Sterilization Act, Okla Stat Ann §§ 57 171–95 (1935) defined a “habitual criminal” as:

a person who, having been convicted two or more times for crimes ‘amounting to felonies involving moral turpitude’ either in an Oklahoma court or in a court of any other State, is thereafter convicted of such a felony in Oklahoma and is sentenced to a term of imprisonment in an Oklahoma penal institution.

*Skinner*, 316 US at 537.

The statute required that all men and women who were “habitual criminals” submit to sterilization. Men were to receive vasectomies and women salpingectomies. The legislature was convinced that such operations could take place (for the health and safety of the community) without being a “detriment to his or her general health.” The legislature, however, took pains to make clear that “offenses arising out of the violation of the prohibitory laws, revenue acts, embezzlement, or political offenses, shall not come or be considered within the terms of this Act.” *Id* at 536–37.

<sup>70</sup> See *id* at 535 (overturning Oklahoma’s Habitual Criminal Sterilization Act that provided for the sexual sterilization of individuals convicted of three or more felonies of moral turpitude).

only those whose deaths resulted from murder or catastrophic injury to surrender body parts. And although limited in scope, this rule is not narrowly tailored to achieve its stated goal. Rather, a narrow tailoring here might advisedly involve mechanisms for consent and refusal to donate despite the laudability of body part donation.

Crafting a donor pool that draws primarily from homicide victims can exacerbate class and race distinctions.<sup>71</sup> But most importantly, the rule burdens only one classification of the deceased.<sup>72</sup> Effectively the law distinguishes the right to bury and even *donate* by mode of death. Yet constitutional rights are neither so arbitrarily defined nor abridged.

If legislators truly believe that Americans support presumed consent policies, why not require babies to surrender one kidney at birth? Only one kidney is needed for a full and healthy life. It is conceivable that the burdens and risks associated with this type of procurement process could be justified by the benefits inured to others. Harvests could be done at the time of vaccination. Doctors could monitor the healing process. Parents would be more informed participants. Relatives, in town for the birth, could provide support and comfort the parents and child. For the baby, the scars would heal seamlessly and more importantly, a life would be saved or extended, at least, for ten to fifteen years. Every child in the United States would be part of a plan to “gift” life to another. This would surely cure the organ shortage. But alas, Americans are not so generous; nor as a nation have we embraced this type of horrific altruism.

To be sure, there is a lesser expectation of personal privacy for public health initiatives that guard against diseases, such as compelled vaccinations,<sup>73</sup> than for policies requiring individuals to surrender their bodies so that vital parts may be plucked out to benefit the common good. The line is not fine. To the contrary,

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<sup>71</sup> Frammolino, *Harvest of Corneas*, LA Times at A1 (cited in note 49) (noting the overwhelming primary pool of presumed consent donors in Los Angeles were black and Latino homicide victims). Michele Goodwin, *Deconstructing Legislative Consent Law: Organ Taking, Racial Profiling, & Distributive Justice*, 6 Va J L & Tech 2 (2001).

<sup>72</sup> If the objective of saving lives through transplantation were a compelling enough function for the state, which justified ignoring privacy, religious freedom, due process, and eliminating a principle right to bury, why limit the compelled donor pool to homicide victims or those who die by catastrophic circumstances? Doing so places the body part supply burden on a narrow population already aggrieved by the unanticipated loss.

<sup>73</sup> *Jacobson v Massachusetts*, 197 US 11 (1905) (upholding the constitutionality of a compulsory smallpox vaccination on the ground that it had a real and substantial relation to public health and safety); *McCormick v Stalder*, 105 F3d 1059 (5th Cir 1997) (finding constitutional a policy to forcibly vaccinate prisoners against tuberculosis).

vaccinations reasonably serve an interest that most Americans are inclined to support. However, even with this lesser expectation of privacy in vaccination cases or pregnancy testing for AIDS and HIV, there is powerful and persuasive dissent in the public sphere, which indicates that Americans are deeply concerned about their personal privacy, religious freedom, quality of life, autonomy, and the desire to be “free” from government interference or intrusion on their bodies.<sup>74</sup> That the statutory provisions on which presumed consent laws are implemented rely upon surreptitious planning and clandestine operations in coroners’ offices or during autopsies with medical examiners—usually without the consent of relatives—indicates their statutory weakness.

### C. Blood Shield Law Model: Body Part As a Service

#### Model C: Buyer Beware

P, a college student, receives a knee implant (a tendon) from tissues bought from TB. The implanted tissue is later found to be contaminated with bacteria typically found in the human bowel. P becomes gravely ill and dies four days later. His estate, learning that TB was aware of the contamination prior to selling the tissues, sues under a theory of product liability. Does the estate have a claim for which relief can be granted?

Few courts have ruled on the issue as to the status of a commercialized body part or whether the purchasers of such parts have recourse when the body parts are defective or contaminated. Those that have, as in *Cryolife, Inc v Superior Court*<sup>75</sup> and *Condos v Musculoskeletal Transplant Foundation*,<sup>76</sup> ruled that bone tissues sold for transplantation were not actually products or goods (although arguably property of their sellers), but rather services.<sup>77</sup> Such rulings leave duped purchasers with-

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<sup>74</sup> See *Hill v Evans*, 1993 US Dist LEXIS 19878, \*17 (M D Ala 1993) (finding unconstitutional an Alabama law authorizing HIV testing of “high risk” patients); Dan Olmsted, *The Age of Autism: Christian’s Mom Speaks*, UPI (Apr 12, 2006) (highlighting an influential parent’s campaign to propose and implement alternatives to mandatory vaccinations); Katherine Seligman, *Vaccination Backlash; There’s A Small But Stubborn Faction Of Parents Who Don’t Vaccinate Their Children. Are There Risks?*, The San Francisco Chronicle 8, (May 25, 2003); Michael Lasalandra, *BU Expert Faults CDC for Vaccine Backlash*, The Boston Herald A4 (Feb 8, 2003); Joan Lowy, *Vaccination Backlash Worries Doctors*, Pittsburgh Post-Gazette A3, (May 9, 1999).

<sup>75</sup> *Cryolife*, 110 Cal App 4th 1145 (Cal Ct App 2003).

<sup>76</sup> 208 F Supp 2d 1226 (D Utah 2002).

<sup>77</sup> *Cryolife*, 110 Cal App 4th at 1159; *Condos*, 208 F Supp 2d at 1230.

out a cause of action and tissue banks free from liability. The rulings indicate that the status of the body can change from one handler to the next. Both cases expose a problematic public policy. Now, to be sure, the courts in these cases recognized the ownership interest or property interests in body parts. The relevant question remains: who is the possessor or owner of body parts in the stream of commerce? One way to interpret these transactions that seems fairly consistent with the holdings is that the patient owned the tendon he purchased. The tissue banks "owned" the tissues prior to selling them. However, it appears from the logic of *Cryolife* that as soon as the good leaves the warehouse of the tissue bank, the body part becomes a "service."<sup>78</sup> Thus, the cases illuminate inconsistent treatment vis-à-vis the status of body parts. For example, commercial exploiters of human tissues buy, process, and sell the biological materials to patients via doctors and hospitals. Yet, the *Condos* and *Cryolife* rulings conclude that tissue banks should not be held liable for placing contaminated tissues into the stream of commerce even if their products cause the deaths or illnesses of consumers.

The contaminated tissue cases on which Model C is based represent a third class of litigation explored in Part I that involve the difficulties of naming body parts and their legal status. The model is based on the tragedy of Brian Lykins. His life was cut short after a routine knee operation. According to one of the lawyers involved in the litigation that I interviewed for this Article, Brian needed only the equivalent of a pin to be placed into his knee. Brian was healthy and an outgoing twenty-three year old engineering student.<sup>79</sup> He was a self-taught musician and very close to his family.<sup>80</sup> The operation he required was a routine, out-patient knee surgery.<sup>81</sup> What Brian received was more than he bargained for; Cryolife, the company that sold the tendon to transplant into Brian's knee, processed it from a cadaver,

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<sup>78</sup> *Cryolife*, 110 Cal App 4th at 1145.

<sup>79</sup> See M.A.J. McKenna, *Tissue Transplant Firm Linked to 14 Infections*, Atlanta J & Const A1 (Mar 15, 2002) (discussing the death of Bryan Lykins, a student in Minnesota, who died of bacterial infection as the result of his knee surgery).

<sup>80</sup> *Cryolife Litigation*, available at <<http://www.cryolifelitigation.com/bio.asp>> (last visited Apr 13, 2006).

<sup>81</sup> See Robert Pear, *FDA Delays Regulation of Tissue Transplants*, NY Times A18 (May 14, 2003) (noting that Brian Lykins died after undergoing a "routine knee surgery"). Amanda Gardner, *U.S. Strengthens Rules Governing Tissue, Organ Transplants*, Health Day (Nov 19, 2004) available at <<http://thedoctorslounge.e-healthsource.com/index.php?p=news1&&id=522463>> (last visited May 6, 2006) (describing Brian Lykins' surgery as "routine"). See also <[http://health\\_info.nmh.org/healthnews/healthday/041119HD522463.htm](http://health_info.nmh.org/healthnews/healthday/041119HD522463.htm)> (last visited April 24, 2006).

which remained unrefrigerated for nineteen hours.<sup>82</sup> The cadaver from which the allograft was acquired had been rejected by other tissue processing companies.<sup>83</sup>

Despite Cryolife's tests on the cadaver, which revealed infection, the company sold the tendon at a tremendous mark-up to the hospital where the operation took place.<sup>84</sup> On November 7, 2001, Brian's new tendon was implanted.<sup>85</sup> Within hours, his condition rapidly deteriorated.<sup>86</sup> By the evening of the operation he was extremely ill.<sup>87</sup> In four days, he was dead.<sup>88</sup> He died November 9, 2001 as a result of an allograft which had been contaminated with bacteria from the bowel of the cadaver from which parts were processed and sold by Cryolife.<sup>89</sup>

Several problems attend human tissue transplantation and the reconstitution of body parts beyond the question of ownership. First, are warranties appropriate for reconstituted, processed, or restructured body parts? Second, should recourse be granted for purchasers who unwittingly buy insalubrious tissues? Third, how do we frame remedies for injured plaintiffs—through tort or contracts law? Some of these problems are illuminated in disturbing narratives, including those of Bonny Gonyers, Ken Alescu, Sydney Steinberg (a five year-old who died from a heart valve infection possibly linked to CryoLife, the supplier of the body part that she received), and similar cases.<sup>90</sup> In

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<sup>82</sup> Gardner, *U.S. Strengthens Rules Governing Tissue*, Health Day (Nov 19, 2004) (cited in note 81).

<sup>83</sup> See Sandra Blakeslee, *Lack of Oversight in Tissue Donation Raising Concerns*, NY Times 11 (Jan 20, 2002) (noting that "[i]n many parts of the country, tissue banks that have contracts with for-profit companies will accept donors other tissue banks have rejected as unsafe for use").

<sup>84</sup> But see *Transplant Medicine*, Immunotherapy Weekly 13 (Sept 11, 2002) (noting that Cryolife allegedly failed to test for the germ that caused the deadly infection).

<sup>85</sup> See *Tissue Banks: The Dangers of Tainted Tissue and the Need for Federal Regulation: Hearing Before the US Senate Committee on Homeland Security and Governmental Affairs*, Senate Committee on Governmental Affairs, 108th Cong, 1st session, \*7 (2003) (testimony of the parents of Bryan Lykins) available at <[http://hsgac.senate.gov/\\_files/shrg108110tissuebanksreg.pdf](http://hsgac.senate.gov/_files/shrg108110tissuebanksreg.pdf)> (last visited Feb 16, 2006) (hereinafter "Lykins Hearings").

<sup>86</sup> *Id.* at \*8.

<sup>87</sup> *Id.*

<sup>88</sup> See David McNaughton, *CryoLife Tries to Bounce Back; Tissue Recall by FDA Spawns Losses*, Atlanta J & Const D1 (Aug 28, 2003) (noting that Brian Lykins died from "[c]lostridium sordelli, a bacteria that spreads from the intestine to the rest of the body after death").

<sup>89</sup> *Id.*

<sup>90</sup> See Sandra Blakeslee, *Recall is Ordered at Large Supplier of Transplant Tissue*, NY Times A1 (Aug 15, 2002) (discussing the FDA's order for Cryolife to recall all soft tissues it had sold).

each instance, plaintiffs suffered injuries connected to the implantation of infected human tissue. Severe injuries and even deaths occurred not as a result of the surgical malfeasance, but due to diseased tissues spreading deadly bacteria within the transplant hosts' bodies. Thus, the issues in dispute with relation to the cases were less about the cause of the injuries, but rather whether remedies exist for these injuries.

The question as to remedies becomes all the more relevant given the significant demand for body parts and the growth of the tissue transplantation and genetic bioprospecting industries.<sup>91</sup> This technology is useful, but imprecision and mistakes are likely to occur at many stages. And it seems likely that these problems will only increase. According to one reporter, tissue transplants, "fueled largely by demand for tissue for spine surgery ... has become a billion-dollar industry."<sup>92</sup> In 2004, "there were about a million tissue transplants in the United States."<sup>93</sup> That figure represents nearly a three-fold increase in one decade.<sup>94</sup> To the extent that treatments are now available for worn-out knees and joints and defective or blocked heart valves, doctors will continue to recommend these types of elective treatments for their patients. Their failure to do so might be actionable itself; failure to enhance, even by chance, a patient's health outcome can result in civil liability in a growing number of jurisdictions.<sup>95</sup>

Nevertheless, problems are unresolved, even with the Center for Disease Control's ("CDC") investigations revealing the numerous problems at tissue bank laboratories, and as will be discussed, the very direct links between the deaths and illnesses of consumers and cadaver sources used by the companies that processed and sold the body parts that they purchased. Recent court decisions unwisely place the burden on patients and doctors to guard against implanting contaminated body parts.<sup>96</sup> Yet, how

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<sup>91</sup> Rebecca Skloot, *Taking the Least of You*, NY Times Mag 38 (Apr 16, 2006).

<sup>92</sup> Renie Schapiro, *Banking on the Gift of Tissue*, Milwaukee J Sentinel G1 (May 2, 2005).

<sup>93</sup> Id.

<sup>94</sup> Id.

<sup>95</sup> Margaret T. Mangan, *The Loss of Chance Doctrine: A Small Price to Pay for Human Life*, 42 SD L Rev 279, 291 (1997) ("Most courts which have had an opportunity to decide upon the loss of chance doctrine recognize a cause of action for loss of chance in medical malpractice actions."). See also *Delaney v Cade*, 26 F3d 991(10th Cir 1994) (concluding that Kansas recognizes loss of chance); *LaRose v Washington Univ*, 154 SW3d 365, 370 (Mo Ct App 2004) (awarding damages against physician whose failure to diagnose cancer in patient reduced her chance of survival).

<sup>96</sup> *Cryolife*, 110 Cal App 4th at 1145; *Condos*, 208 F Supp 2d at 1226; *Lenahan v Univ*



are patients, often the least informed, to police this process?<sup>97</sup> Patients, and even their doctors, are simply uninformed and it would seem unreasonable to expect them to know health and lifestyle information about the cadavers from whom the body parts are harvested.<sup>98</sup>

Recent controversy involving the pillaging of body parts from funeral home cadavers in New York and New Jersey further illuminates this point. In February 2006, the Brooklyn District Attorney Charles Hynes charged four grave pillagers with “medical terrorism.”<sup>99</sup> Hynes claimed the body-robbing scandal was “unique in its utter disregard for human decency.”<sup>100</sup> It was the latest horrific episode in the ongoing tissue transplant industry saga. The indictment alleges that a New Jersey dentist, Michael Mastromarino, and codefendants robbed over a thousand bodies of bones, ligaments, heart valves, organs, and other valuable tissues.<sup>101</sup> The defendants stuffed the bodies with plastic tubing to deceive relatives.<sup>102</sup> Detectives and investigators unmasked their furtive scheme, but only after thousands of body parts, some from diseased corpses, were sold for transplantation to hospitals, doctors, and patients throughout the United States<sup>103</sup> and internationally.<sup>104</sup> Tissue, similar to blood transfusions, can transmit hepatitis, HIV, mad cow disease, bacteria, and various other communicable diseases to the unsuspecting transplant recipient.

That patients and their doctors are at a practical disadvantage seems clear.<sup>105</sup> Both parties lack information about the ca-

*of Chicago*, 808 NE2d 1078, 1087 (Ill App 2004) (“Plaintiffs failed to allege facts sufficient to show that the defendants knowingly and voluntarily participated in a common scheme to commit any tortious acts in relation thereto.”); *Johnson v Superior Court*, 101 Cal App 4th 869, 886-89 (2002) (limiting the recovery of parents seeking damages because sperm bank failed to disclose that purchased sperm came from a donor with a history of kidney disease, which the daughter now has).

<sup>97</sup> *Law Firms File Suit on Behalf of Transplant Patient Who Allegedly Received Illegally Harvested Body Parts; Suit Alleges That Untested Bones in Transplant Led to Positive Hepatitis Test Results*, Bus Wire (Mar 23, 2006) available at <[http://home.businesswire.com/portal/site/google/index.jsp?ndmViewId=news\\_view&newsId=20060323005497&newsLang=en](http://home.businesswire.com/portal/site/google/index.jsp?ndmViewId=news_view&newsId=20060323005497&newsLang=en)> (last visited May 6, 2006).

<sup>98</sup> *Id.*

<sup>99</sup> Tonya Maxwell, *4 Charged With Stealing Bones Implanted Locally*, Chi Trib C3 (Feb 24, 2006).

<sup>100</sup> Anthony M. Destefano, *The Body Snatchers: Funeral Home-Based Ring Charged*, Newsday A03 (Feb 24, 2006).

<sup>101</sup> *Id.*

<sup>102</sup> *Id.*

<sup>103</sup> *Id.*

<sup>104</sup> Daryl Passmore, *The Body Business*, The Sunday Mail 57 (Australia) (July 1, 2006).

<sup>105</sup> Spring of 2006, I was interviewed along with two surgeons for a nightly news pro-

daivers' lifestyles, sexual habits, prior illnesses, and whether the "donors" smoked, were alcoholic, or used drugs. Surgeons, though skilled, are not microbiologists and lack the expertise, resources, and luxury (at the time of surgery) to perform sophisticated microbial analyses on heart valves and tendons. Equally, anesthetized patients are unprepared to test or know that they should test the products purchased from tissue banks before or during surgery and implantation. Thus, placing the onus on patients and their physicians to be the gatekeepers to these industries is simply unreasonable for purposes of public policy, particularly given that tissue banks are in the best position to test their own products before placing them into the streams of commerce. Further, that many tissue banks, including Cryolife, the source of much litigation,<sup>106</sup> are for-profit, truly distinguishes the industry from not-for-profit blood processors such as the Red Cross.<sup>107</sup>

It is here that the story of tissue giant, Cryolife, its litigation history, clients' narratives, and setbacks are instructive for public policy analysis. Despite lawsuit settlements against Cryolife, the Court of Appeals of California determined in 2003 that Cryolife and arguably other tissue banks are immune from liability for the body parts they place into the stream of commerce.<sup>108</sup> Ac-

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gram in Chicago, Illinois. The doctors had transplanted possibly insalubrious tissues in patients here in Chicago. The tissues were processed from a tissue bank now closed and under investigation by the attorney general's office in New Jersey. The discovery that the tissue bank purloined body parts from a funeral home was disclosed only after the surgeons implanted tissues from cadavers that may have carried diseases or from individuals who died from cancer. Patients across the United States are now being tested for hepatitis and other communicable diseases. Several lawsuits have been filed. See Chicago Tonight, Feb 2, 2006. See <<http://www.wttw.com/main.taf?p=1,4,4,1&Date=01%2F29%2F2006>>.

<sup>106</sup> See for example, *In re Cryolife, Inc Sec Litig*, 2003 US Dist LEXIS 26170, \*36-38 (N D Ga 2003) (finding stock purchasers sufficiently alleged securities fraud by alleging that, after a transplant recipient died from contaminated tissue provided by a corporation, the corporation misrepresented its quality standards and compliance with regulations); *Cryolife, Inc v Superior Court*, 110 Cal App 4th 1145 (Cal Ct App 2003) (holding that tissue bank provided a service and not a product by collecting, storing, and selling body parts); *Talton v Arnall Golden Gregory, LLP*, 622 SE2d 589, 592-93 (Ct App Ga 2005) (concluding that injured patient failed to show that lawyers for Cryolife ever intended for their advice regarding tissue warning labels to be disclosed to or relied on by third parties, or that, when lawyers consulted with client corporation, they were "actually aware" that patients would rely on such confidential advice).

<sup>107</sup> The Food and Drug Administration ("FDA") does not require companies to be a registered member of a certified tissue bank association, such as the Tissue Bank Association of America ("TBAA"). Rather, each company selects its own method for testing tissues, determining whether it will test and treat tissues at all, and whether it will inform patients and physicians about the results of those tests. FDA, *Keeping Human Tissue Transplants Safe*, FDA Consumer Mag Vol 39:3 (May-June 2005), available at <[http://www.fda.gov/fdac/features/2005/305\\_tissue.html](http://www.fda.gov/fdac/features/2005/305_tissue.html)> (last visited Apr 13, 2006).

<sup>108</sup> See *Cryolife*, 110 Cal App 4th at 1155 (concluding that the California Health and

According to the Court of Appeals of California, Cryolife's immunity from placing insalubrious tissues in the marketplace arises from the fact that buying, collecting, processing, storing, and selling body parts are collectively and essentially a "service" and that the parts sold are not "goods."<sup>109</sup>

The *Cryolife*<sup>110</sup> holding invites scrutiny as to how body parts should be classified and what their legal status ought to be. In facts similar to Model C, Alan Minvielle sued the tissue bank after the allograft he received was found to be contaminated by deadly bacteria.<sup>111</sup> The court's conclusion that *body parts are a service* rather than the *performance of a service* precluded his recovery and is a striking feature of the case.<sup>112</sup> It is a conclusion that is hard to support; arguably few people would consider his or her knee, heart, hip, or spine a service. Likewise, of course, tissue banks leery of litigation are equally reluctant to treat knees as goods, which will expose them to liability when contaminated cadaver tissues are placed into the stream of commerce. This tension and incoherence in the law exposes the need for a common lexicon and understanding of the legal and social status of cadaver body parts and tissues. Arguably, in the changing function and use of body parts, our common understanding of the parts' post-harvesting classification should also evolve. In other words, what Cryolife *processes* describes its service, what it *produces* through that processing is a good or product for which it receives value.

The relevance of this point proved significant to the court's analysis of the case and whether the plaintiff could pursue a strict liability claim for punitive damages against the tissue bank. Ultimately, the Court of Appeals of California was not persuaded by the plaintiff's charge that Cryolife did not fit within the legislative exemption provided for blood banks.<sup>113</sup> California and a majority of states enacted blood shield immunity statutes during the 1950s and throughout the subsequent two decades to

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Safety Code "provides statutory immunity from strict liability to tissue banks subject to regulation").

<sup>109</sup> Id ("By expressly deeming such activities to constitute a service, the Legislature must have intended a tissue bank to be immune from strict liability, just like a pharmacy.").

<sup>110</sup> Id.

<sup>111</sup> Id at 1148.

<sup>112</sup> *Cryolife*, 110 Cal App 4th at 1154-55.

<sup>113</sup> Id.

shield organizations that collected and processed blood from strict liability claims.<sup>114</sup>

Cryolife contended that the Health and Safety Code provisions of California, which define the status of tissue banks, barred plaintiffs from strict liability claims against tissue banks.<sup>115</sup> The statute, however, does not explicitly provide such an exemption or immunity to tissue banks. Rather, Section 1606, the codification of the blood shield law, provides in pertinent part:

[t]he procurement, processing, distribution, or use of whole blood, plasma, blood products, and blood derivatives for the purpose of injecting or transfusing the same, or any of them, into the human body shall be construed to be, and is declared to be, for all purposes whatsoever, the rendition of a service by each and every person, firm, or corporation participating therein.<sup>116</sup>

The public policy rationale for blood shield laws was to promote an adequate blood supply, particularly as most surgeries requiring blood are not elective, but rather a matter of life and death. Thus, the policy militates against liability in the absence of a negligent or intentional tort. Yet, whether the same rationale should hold true for tissue banks is a different matter.

Ultimately, the court agreed with Cryolife's nuanced definition of its business. The tissue bank claimed that its business status, although for profit, is similar to that of blood banks—which traditionally have been not-for-profit—within the definition of the blood shield immunity law.<sup>117</sup> Both sections of the law (1606 and 1635.2) describe the banks as providing services, however, only the blood shield statute provides an immunity provision—and only for blood banks.<sup>118</sup> Despite the “difference in language of section 1606 and section 1635.2,”<sup>119</sup> the court held that the legislature must have intended to shield tissue banks from strict liability claims.

The court's analysis leaves much to be pondered considering its leap is not supported by any legislative history, legislative comment, nor does the court point to comment sections from the

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<sup>114</sup> *Id.* at 1153.

<sup>115</sup> *Id.* See also Cal Health & Saf Code § 1635.2 (2006).

<sup>116</sup> Cal Health & Saf Code § 1606.

<sup>117</sup> *Cryolife*, 110 Cal App 4th at 1150.

<sup>118</sup> Cal Health & Saf Code § 1606.

<sup>119</sup> *Cryolife*, 110 Cal App 4th at 1155.

Health and Safety Code. Instead, the court offers that the legislature (in 1991) should have known or predicted that in 2003 “tissue banks are paid for their activities in connection with providing human cadaver tissue for medical use” and thus must have “intended tissue banks to be immune from strict liability.”<sup>120</sup> The court errs here as the legislature instead would have been aware of the 1984 National Organ Transplantation Act, which prohibits the buying and selling of body parts, including human tissues.

However, the court’s effort to be guided by the legislature is undermined by the very judicial activism that it seems to reject, but actually embraces.<sup>121</sup> To explicate, the court extends immunity protection to tissue banks when the statute that it relies upon fails on its face to grant that type of protection to the industry.<sup>122</sup> Without citation to studies, cases, or other data that would support such a conclusion, the court crafted a new immunity provision for tissue banks. The court gives a new and unusual application of the tissue bank statute, which does not provide any immunity language, without an effort to investigate or explain if the legislature actually intended for tissue banks to be immune from strict liability lawsuits. It is more common to look at the legislative history, or at least to examine the record of the legislative committee enacting the statute when a case is under *de novo* review. Had the court examined the legislative history of the blood bank statute and the later tissue bank regulations, it might have discovered that the public policy rationales for blood bank immunity were quite unique to that industry.

Blood banks in the 1950s were mostly not-for-profit and often connected with hospitals. Legislatures treated the collection, processing, storage, and administration of blood as a service and not as a sale subject to warranty because blood banks were organized around altruistic principles, which were consistent with their not-for-profit status. The legislative intent was to promote the procurement of blood and protect blood banks from the possibility of frivolous (and more serious) lawsuits. Blood supply was vital as a domestic and military issue given cold war aggressions and wars in Korea and later Vietnam. Blood banks were not in the position to warrant the quality of blood that donors provided despite the fact that they processed, transported, and adminis-

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<sup>120</sup> *Id.*

<sup>121</sup> *Id.* at 1153-55.

<sup>122</sup> *Id.*

tered blood; they were limited by the available science at the time. Nor was the technology available to perform sophisticated blood analyses. Thus viruses transfused through blood were often undetectable during this era.

Tissue banks, on the other hand, are a different business and social concept. While some tissue banks supply heart valves, others focus on cosmetic services, such as products to enhance lips, penis size, cheekbones, and other non-essential elective medical products. Moreover, the technology is available for highly sophisticated testing of tissues before they enter the stream of commerce. The *Cryolife* court's grand leap leads one only to guess what other industries would qualify for immunity simply because they provide a medical service. Why not grant immunity to the makers or providers of all medical devices, including pacemakers, prosthetics, wheel chairs, and heart pumps?

The court too easily dismissed the plaintiff's claim that he received a defective product and not a service. Minvielle's surgeon successfully implanted a contaminated body part. The service received was perfectly fine. The product was the problem. The court made a significant error in expanding the protection of blood shield statutes (promulgated over forty years prior)<sup>123</sup> to an industry neither so altruistic, nor anticipated by state legislatures in the 1950s and 60s. Ironically, the court concludes its dismissal of the plaintiffs strict liability claim against a tissue bank by quoting from an earlier *blood shield law case*, *Hyland Therapeutics v Superior Court*,<sup>124</sup> to support its rationale that the California legislature intended for blood banks to be free from fault.

We concur in the perception that legislatures have determined that the production and use of human blood *and its derivatives* for therapeutic purposes should be encouraged; and for this purpose those who provide these products, and who are themselves free from fault, should not be required to bear the economic loss which might otherwise be imposed under the rules of strict liability which are applicable to sellers of commercial products generally.<sup>125</sup>

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<sup>123</sup> Cal AB 2209, 1991 Regular Session (March 8, 1991) in Cal Health and Safety Code § 1635.2 (West 2006). The 1606 statute discussed in the case goes back over forty years.

<sup>124</sup> 175 Cal App 3d 509 (Cal Ct App 1985).

<sup>125</sup> *Cryolife*, 110 Cal App 4th at 1157.

#### D. Indifference

The models discussed in Part I demonstrate that entrenched formalism in a rapidly expanding biotechnological era will stymie meaningful development of common law jurisprudence on the ownership, dispensation, and remedies involving body parts. Without judicial adaptation to an evolving society in which litigation involves body parts, plaintiffs will never prevail.<sup>126</sup> A common element of the three very different scenarios presented in the above models is that absent a finding that deems the body as “property,” plaintiffs will be barred from recovery—even in the more disturbing cases that involve the most egregious breaches of medical trust and ethics. Formalistic rule making (or the lack thereof), conflicts with reasoned, evolved decisionmaking. It fails to acknowledge and respond to the shifting of culture, society, and biotechnology.<sup>127</sup> Such rule making, “to put it baldly,” according to the Honorable Mary Schroeder, is to devise “pontifical formulas which relieve [courts] of the burden of reasoned decisionmaking.”<sup>128</sup>

The law too must evolve to address the nuanced byproducts of biotechnology. Legislative and judicial indifference to the ways in which biotechnology interferes with individual liberties, however, poses several serious problems.

##### 1. Illusory negative rights.

For example, presumed consent legislation tramples individual autonomy while purportedly designed to promote health and safety. However, that worthy goal is defeated through surreptitious tissue harvesting exclusively from unsafe victims, including those whose deaths resulted from homicides, poisonings, and other catastrophic means.<sup>129</sup> Failure to collect social history

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<sup>126</sup> See, for example, *Moore*, 793 P2d 479 (a case of first impression, rejecting conversion claims for nonconsensual use of cells to develop a valuable patent). The majority pointed out that Moore failed to cite a decision supporting his argument that the excised spleen and cell line were property. *Id.* at 489 n 28 (“[N]o party has cited a decision supporting Moore’s argument that excised cells are ‘a species of tangible personal property capable of being converted.’”).

<sup>127</sup> As even *Moore* illuminates, what was previously considered medical waste and ordered to be incinerated (even by state statute) is now a patentable good. *Id.* at 491.

<sup>128</sup> Mary M. Schroeder, *Fairness or Formulas*, 1994 Wis L Rev 9, 9-10 (1994).

<sup>129</sup> Four individuals became infected with AIDS after one Virginia Beach tissue bank, LifeNet, sold tissues to 58 people in 16 states. The donor, who was shot and killed, had also previously been infected with AIDS. Bill Sizemore, *Body Parts: Big Business Medical Advances And A Growing Willingness To Donate Organs Have Bolstered The Largely Unregulated Trade Of Human Parts*, *The Virginian-Pilot* A1 (Apr 29, 2001). According to

data increases the likelihood that insalubrious tissues will enter the marketplace and harm those whom the statutes are designed to protect.<sup>130</sup> The opt-out provision, as discussed earlier, is more illusory than real.<sup>131</sup> The fact that there isn't a national or state registry, except in Iowa, where one can opt-out of tissue donation is a significant barrier.

States that enacted presumed consent laws failed to take secondary measures to give full meaning to an individual or her family's choice to decline extraction. Their failure to do so unquestionably contributes to legal and social backlash against presumed consent policies.<sup>132</sup> Thus, without a more serious effort to capture assent or dissent, the opt-out provision is meaningless. Even in some instances when families refused to donate, state actors successfully claimed immunity for the "accidental" taking of tissues used for a legitimate state purpose.<sup>133</sup> Why then, has formalism dominated judicial response to nonconsensual tissue taking and the collateral outgrowths of biotechnology (in other words, Model C)?

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the author:

Organizations such as LifeNet list prices for 300 or more products. A kidney goes for \$19,000; a heart valve, \$5,000; a 3-by-8-inch patch of skin, \$144. Routinely, doctors turn to these catalogs for tendons and ligaments to repair athletes' blown-out knees. They buy arteries to improve circulation and valves to repair hearts. Cadaver bone fragments are used in spinal fusion surgery on aging baby boomers' aching backs, or ground into powder to replenish bone eroded away by gum disease. Skin is used to treat severe burns. But plastic surgeons also use it to smooth out facial wrinkles, puff up lips and enlarge penises.

Id.

<sup>130</sup> See, for example, Michele Goodwin, *Altruism's Limits: Law, Capacity, and Organ Commodification*, 56 Rutgers L Rev 305 (2004) (discussing the inefficiencies of the "public" or legal method of obtaining body parts, and the "private" or black market method for obtaining body parts); Ronald N. Robin, *Elderly Heart Surgery Candidate with Concerns about Transfusion: What's the "Take Home"?*, *Pearls from Clinical Cases*, Consultant 1000 (July 1, 2003) (noting that "prior infections, such as ... Creutzfeldt-Jakob disease, have been transmitted by donation of contaminated tissue, such as dura or cornea").

<sup>131</sup> See, for example, Goodwin, *Black Markets* at 131-33 (cited in note 57).

<sup>132</sup> See *Newman v Sathyavaglswaran*, 287 F3d 786, 789 (9th Cir 2002) (describing removal of body parts from a decedent against the wishes of the decedent or their family as a violation of fundamental human dignity); *Brotherton v Cleveland*, 923 F2d 477, 482 (6th Cir 1991) (referring to the presumed consent law in Ohio as "an egregious abuse of government power").

<sup>133</sup> See Alexa Boer and Steve Sternberg, *Suit Filed Over Removal of Dead Girl's Organs: Mother Says She Didn't Give Consent*, Atlanta J Const B2 (June 15, 1991) (discussing a case where a mother consented to the removal of portions of the pelvic bone because she was under the impression that doctors would remove only small and indiscernible amounts, while large pieces were allegedly removed); Goodwin, 6 Va J L & Tech 2 (cited in note 71).



## 2. Episodic or collective.

Judges tend to view biotechnology cases involving body parts episodically and not collectively.<sup>134</sup> Viewed narrowly, Mr. Moore seems to be one lone individual—a single plaintiff—with an isolated case. His disease is rare and the defendants are located in Los Angeles—their reach falls short of all other Moore-like patients at California's borders. It appears the instance will not be repeated and the means justify the utilitarian ends; Moore pays the emotional costs for a private industry gaining competitive strength and furthering scientific understanding and possibly engineering treatment options for a broader class of individuals affected by leukemia. Here the California justices are responding to a nationalist principle, an American advantage. Were the company that collaborated with Dr. Golde a foreign corporation, they may well have reached a different conclusion. Thus, the case is not simply about the random expansion of biotechnology, but specifically American technology.<sup>135</sup>

## 3. Formalism entrenched.

Formalists necessarily ignore exogenous sources, instead choosing to concentrate on adhering to traditional norms,<sup>136</sup> lest they be viewed as unmindful of their role, radical or even judi-

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<sup>134</sup> *Georgia Lions Eye Bank*, 335 SE2d at 129 (opining “[c]ertainly, the General Assembly has it within its power, in the interest of the public welfare, to authorize this procedure, which yearly benefits hundreds of Georgians”). Explained by *Welch v Welch*, 505 SE2d 470 (Ga 1998). Cited by *State v Moseley*, 436 SE2d 632 (Ga 1993); *Schneider v Susquehanna Radio Corp.*, 581 SE2d 603 (Ga Ct App 2003); *Bauer v North Fulton Med Ctr, Inc.*, 527 SE2d 240 (Ga Ct App 1999); *Alternative Health Care Sys, Inc v McCown*, 514 SE2d 691 (Ga Ct App 1999); *Brotherton v Cleveland*, 1992 US App LEXIS 15947 (6th Cir June 30, 1992); *Perry v Saint Francis Hosp & Medical Ctr*, 886 F Supp 1551 (10th Cir 1995); *Moore v Regents of University of California*, 215 Cal App 3d 709 (Cal Ct App 1988); *State v Powell*, 497 So 2d 1188 (Fla 1986). Cited in dissenting opinion by *Jackson v State*, 430 SE2d 781 (Ga Ct App 1993); *Brotherton v Cleveland*, 923 F2d 477, (6th Cir Ohio 1991). Criticized by *Mansaw v Midwest Organ Bank*, 1998 US Dist LEXIS 10307 (WD Mo July 8, 1998); *Newman v Sathyavaglswaran*, 287 F3d 786 (9th Cir 2002).

<sup>135</sup> *Moore*, 51 Cal 3d at 144 (describing the efforts of US researchers as “beginning to bear fruit. Products developed through biotechnology that have already been approved for marketing in this country include treatments and tests for leukemia, cancer, diabetes, dwarfism, hepatitis-B, kidney transplant rejection, emphysema, osteoporosis, ulcers, anemia, infertility, and gynecological tumors, to name but a few.”). The court further explains, “the extension of conversion law into this area will hinder research by restricting access to the necessary raw materials. Thousands of human cell lines already exist in tissue repositories, such as the American Type Culture Collection and those operated by the National Institutes of Health and the American Cancer Society.” *Id.* See also Robert Gatter, *Walking the Talk of Trust In Human Subjects Research: The Challenge of Regulating Financial Conflicts of Interest*, 52 *Emory L J* 327 (2003).

<sup>136</sup> Calabresi, 55 *Stan L Rev* at 2115 (cited in note 23).

cially activist. In essence, judges do not believe it is their role to *change* the law to respond to biotechnology. They would argue that it is the legislature's role to introduce *new* meaning to the law; the courts simply sort out the statutory "mishmash."<sup>137</sup> Judge Guido Calabresi suggests that the formalist approach "does not contemplate the introduction of new or modified values into the scheme as part of the[ir] role."<sup>138</sup> Thus the court's function to hear the new biotechnology cases with an objective ear is usurped not by judicial indifference to plaintiffs, but rather a defense "of the values it finds embedded in the system."<sup>139</sup> In strictly adhering to formalism, judges ignore the independence of the bench and its secondary function, which is to sort out the mishmash. Obsequious loyalty to doctrine necessarily inures heightened blindness to external factors, and in the face of biotechnological harms to plaintiffs, may undermine the perception of the judiciary as an independent, fair, competent arm of the government.

Although Calabresi suggests that today's formalists "take a bow to exogenous values," Models A-C (and there are many more) do not support that conclusion. Rather, the refusal to tamper with almost biblically derived notions of the body by introducing new values, recognizing alternative paradigms and hermeneutics, suffocates the law. Thus, while the law of body parts could be a robust representation of nuanced thinking on a very complex issue, instead it appears weak, ragged, and arbitrary.

## II. PROTECTING GOLIATH: THE FEAR OF RETARDING BIOTECHNOLOGY

The ramifications of recognizing and enforcing a property interest in body tissues are not known, but are greatly feared—the effect on human dignity of a marketplace in human body parts, the impact on research and development of competitive bidding for such materials, and the

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<sup>137</sup> See, for example, *Moore*, 793 P 2d at 493 (noting that "it is inappropriate to impose liability for conversion based upon the allegations of Moore's complaint [because] problems in this area are better suited to legislative resolution").

<sup>138</sup> See Calabresi, 55 *Stan L Rev* at 2115–16 (cited in note 23) (explaining four dominant legal schools of thought: doctrinalism or autonomism, 'law and ...', legal process school, and law and status).

<sup>139</sup> *Id.*

exposure of researchers to potentially limitless and uncharted tort liability.<sup>140</sup>

One pattern that seems clear among Models A-C in Part I is judicial deference to the furtherance of biotechnology, or a fear of retarding the industry's growth by reaching outcomes that deserve biotech interests.<sup>141</sup> Likewise, some commentators caution against the commodification of body parts specifically because it might threaten the growth of biotechnology in the United States.<sup>142</sup> Their opposition has little to do with respect for personhood or ideals about sacredness of the body.<sup>143</sup> Rather, commentators interested in the advancement of biotechnology are concerned about the impact of litigation undermining the permanence, reputation, and financial stability of the biotech industry—and so are the courts.<sup>144</sup> Justice Arabian's concurrence in *Moore v Regents* speaks directly to the "impact on research and development" and the desire to avoid the potentially "limitless" litigation against biotech firms.<sup>145</sup> Justice Arabian and the majority's approach was one of deflection, finding that with avoidance

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<sup>140</sup> *Moore*, 793 P 2d at 498 (Arabian concurring). Justice Arabian's passionate concurrence shares the outrage of the dissenting justices, but stops short of offering a substantive remedy for Moore. Arabian's concurring opinion is very concerned with the sacredness of the body. He distinguishes *Moore* from prior holdings requiring courts to grapple with indelicate subject matter, by suggesting that "the difference here, however, lies in the nature of the conflicting moral, philosophical and even religious values at stake, and in the profound implications of the position urged." *Id.*

<sup>141</sup> *Id.*

<sup>142</sup> Kevin Oberdorfer, *The Lessons of Greenberg: Informed Consent and the Protection of Tissue Sources' Research Interests*, 93 *Geo L J* 365, 366 (2004) ("[C]ase law does not support a common-law duty to disclose a researcher's commercial interests in tissue-based research. Because no such duty exists, claims for failure to obtain informed consent cannot be used by tissue sources and disease advocacy organizations to exert control over intellectual property rights to tissue-based research.").

<sup>143</sup> *Id.*

<sup>144</sup> See Natasha N. Aljalilian, *The Role Of Patent Scope In Biopharmaceutical Patents*, 11 *BU J Sci & Tech L* 1 (2005) (arguing that biopharmaceutical patents should be limited in scope so as to encourage research and investment); Brandon White, *Protecting Patent Owners From Infringement By The States: Will The Intellectual Property Rights Restoration Act Of 1999 Finally Satisfy The Court?*, 35 *Akron L Rev* 531 (2002) (arguing that sovereign immunity mitigates the effectiveness of the patent system); Lisa J. Raines, *The Mouse That Roared: Patent Protection for Genetically Engineered Animals Makes Legal, Moral, and Economic Sense*, *Issues Sci & Tech* 64 (1988); Reid G. Adler, *Controlling the Applications of Biotechnology: A Critical Analysis of the Proposed Moratorium on Animal Patenting*, 1 *Harv J L & Tech* 1 (1988) (arguing that technology will help to engineer safer and better foods, and that a moratorium on the patentability of living things will have serious negative consequences without much gain). But see Gloria Banks, *Legal & Ethical Safeguards: Protection Of Society's Most Vulnerable Participants In A Commercialized Organ Transplantation System*, 21 *Am J L & Med* 45 (1995) (discussing the ethical implications of a commercial organ transplant system).

<sup>145</sup> *Moore*, 793 P 2d at 498.

of the conversion claim at issue an aspect of Moore's case could survive based on breach of fiduciary duty.<sup>146</sup> Arabian regarded the court's deflection of the conversion claim as "a mark of wisdom."<sup>147</sup> After all, he conjectured, "courts cannot and should not seek to fashion a remedy for every 'heartache and the thousand natural shocks that flesh is heir to.'"<sup>148</sup> Such risk averse decisionmaking by courts with regard to biotechnological claims involving body parts may ultimately undermine plaintiffs' confidence in the neutrality of the judiciary.<sup>149</sup> The *Moore* case also illuminates the underlying conflicts of interests that shadow biotechnology cases in general.<sup>150</sup>

#### A. Conflicting Interests Not Resolved By *Moore*

In each Model, there is an inherent conflict of economic interest. Conflicts of interest appear to be the outgrowth and collateral burdens of privatized biotechnology, particularly in the sphere of body part procurement and distribution.<sup>151</sup> Consider

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<sup>146</sup> Id.

<sup>147</sup> Id.

<sup>148</sup> Id at 498 ("Sometimes, the discretion of forbearance is the better part of responsive valor. This is such an occasion.").

<sup>149</sup> See Danielle Wagner, *Property Rights in the Human Body: The Commercialization of Organ Transplantation and Biotechnology*, 33 Duquesne L Rev 931, 942 (1995) (agreeing with the dissent in *Moore* that there is a legally cognizable property interest in the body, and that a researcher's ability to profit by defrauding a medical patient violates the principal of unjust enrichment).

<sup>150</sup> See, for example, Jose Cardo, *Former Lifequest (FL) Organ Recovery Director Arrested On Charges Of Selling Organs To His Own Company*, 13 Transplant News (Apr 14, 2003) (noting that most body parts are donated for "noble," altruistic reasons, while those who accept donations can be motivated by profits); Gatter, 52 Emory L J at 331 (cited in note 135) (noting that "as with abuses of trust among accountants, corporate executives, and priests, there has been a call for new rules to prevent the erosion of trust in the human research enterprise"); Lars Noah, *Medicine's Epistemology: Mapping the Haphazard Diffusion of Knowledge in the Biomedical Community*, 44 Ariz L Rev 373, 395 (2002) (noting that conflicts of interest now "permeate medical literature"); Cynthia Ho, *Who Deserves The Patent Pot Of Gold?: An Inquiry Into The Proper Inventorship Of Patient-Based Discoveries*, 7 DePaul J Health Care L 185, 197-202 (2004) (discussing medical researchers commercial interests and patients typical unawareness of that interest); Emily J. Schaffer, *Is the Fox Guarding the Henhouse? Who Makes the Rules in American Nutrition Policy?*, 57 Food Drug L J 371 (2002) (asserting that the government often faces conflicts of interests between individual interests and public interests, specifically regarding nutrition policy).

<sup>151</sup> See Jim Warren, *Stolen Body Parts Scandal Generating Gruesome Headlines, Fears of Infection; NY Grand Jury Meeting*, Transplant News (Jan 13, 2006) (describing the recent scandal in New York and New Jersey involving funeral homes selling bones and other body parts to brokers who then resell the body parts for thousands of dollars); *In Wake Of National Body Part Transplant Scandal, Schumer To Unveil Critical Legislation To Regulate Tissue Transplants*, States News Service (Jan 23, 2006) available at <[http://www.senate.gov/~schumer/SchumerWebsite/pressroom/press\\_releases/2006/PR18\\_Transplant.012306.html](http://www.senate.gov/~schumer/SchumerWebsite/pressroom/press_releases/2006/PR18_Transplant.012306.html)> (discussing a New York Senator's call for increased regulation

the recent flux of proposed legislation and investigation into body part selling from funeral homes in New York and New Jersey. One commentator reports:

A grand jury in Brooklyn was hearing evidence against the suspected source of the tissue, Biomedical Tissue Services Ltd. of Fort Lee, N.J., the Associated Press reported last month. Operating in New York City, company representatives may have procured bone, skin and tendons from the bodies of people who were not signed up to be tissue donors .... There is suspicion that records were forged to make the procured parts more profitable through such moves as changing the cause of death from cancer, a disqualifying condition, to heart attack. It's illegal to procure body parts without consent and to sell them for a profit.<sup>152</sup>

That Dr. Golde, in the *Moore* case, and his research team had conflicted loyalties is indicated in the court's holding.<sup>153</sup> The court limits Moore's remedy to breach of fiduciary duty because Golde failed to inform him about the pecuniary projects associated with the exploitation of the excised spleen and cells.<sup>154</sup> In support of this limited remedy, Justice Panelli concludes that Moore should have been able to go elsewhere—namely, to a doctor who would not defraud him. This is true enough but less realistic given the scope of the doctrine elucidated by the majority. Does Moore *really* have the “option” to seek unbiased medical assistance elsewhere? Given the model left by the court, it is

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of the tissue transplant industry); Jeff Sturgeon, *Possibly Stolen Body Parts Find Way to Carilion*, Roanoke Times A1 (Jan 7, 2006) (investigating the possible link between stolen tissues and bones in New York and those purchased by Carilion). The author noted that there were safety concerns as well: “Carilion buys from one affected company, LifeCell Corp., a manufacturer of reconstructive, urogynecologic and orthopedic surgical products, and had received merchandise from a lot of goods deemed suspect because the lot was manufactured or might have been manufactured using raw material from Biomedical Tissue Services.” Sturgeon, *Possibly Stolen Body Parts Find Way to Carilion*, Roanoke Times at A1 (cited in note 151).

<sup>152</sup> Sturgeon, *Possibly Stolen Body Parts Find Way to Carilion*, Roanoke Times at A1 (cited in note 151).

<sup>153</sup> See, for example, *Moore*, 793 P2d at 481 (noting that Moore “can make an informed decision to consent to treatment, or to withhold consent and look elsewhere for medical assistance”). However, it is absurd to think that other researchers would not also seek to exploit Moore's body in general and cell line in particular given the very unique opportunity presented by his case. If Moore is told that death is imminent without an operation, but physicians insist upon keeping and profiting from Moore's body parts, (which raises an issue about the veracity of medical statements that suggest medical intervention is necessary) or refuse to perform the operation, Moore is left to deal with a quid pro quo. The majority fails to acknowledge this.

<sup>154</sup> *Id.* at 485.

more illusory than real to suggest that Moore can go anywhere he wants for the operation—or a surgical procedure free from financial conflicts between the physician and patient. Rather than crafting a rule that discourages or strongly disfavors the underlying coercion, deception and fraud, the court has simply placed an economic burden on that activity. Deception is “incentivised” in the formalist approach to adjudication of biotechnology disputes.

If manipulating Moore and his cell line are worth over \$3 billion dollars,<sup>155</sup> and the risk of litigation and possible loss will cost only \$250,000,<sup>156</sup> then it seems economically prudent to lie to and deceive patients and research subjects like Moore. When viewed in economic terms, the cost of litigation inures significant benefit to defendant biotechnologists; the biotech industry has been spared the potential loss of billions of dollars as a result of formalist decisionmaking. Further, the *Moore* court’s strict adherence to doctrinalism or prior law creates a prophylactic veil of protection for the biotech industry, particularly in California.<sup>157</sup> One can regard the limited remedy for Moore as providing a financial windfall and protection for the defendants. The court’s ruling that plaintiffs are not entitled to economic relief when their body parts are fraudulently obtained was worth the payout to Mr. Moore as it protects an entire research industry.<sup>158</sup>

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<sup>155</sup> The complaint in *Moore* alleged that “the true clinical potential of each of the lymphokines ... [is] difficult to predict, [but] ... competing commercial firms in these relevant fields have published reports in biotechnology industry periodicals predicting a potential market of approximately \$3.01 Billion Dollars by the year 1990.” *Id.* at 482.

<sup>156</sup> See Mehlman, *The Story of Moore v. Regents of the University of California* at 53 (cited in note 29) (discussing California’s limitations on medical malpractice recovery). Moore’s claim would be limited according to California’s medical malpractice reform, which “limits damages to actual losses plus a maximum of \$250,000 for pain and suffering.” *Id.*

<sup>157</sup> *Moore* is regarded as the seminal case of the biotechnology era. Some scholars consider the case to be a “classic” in the field of property. For example, Gerald Korngold and Andrew P. Morriss refer to the case as the “brave new frontier of property—given that human tissues and other by-products now have commercial value.” Gerald Korngold and Andrew P. Morriss, eds, *Property Stories* 4 (Foundation 2004). In their book, *Property Stories*, *Moore* is one of the most substantive property cases to be discussed. *Id.*

<sup>158</sup> Numerous cases now cite *Moore* for the proposition that plaintiffs have no property interests in their body parts nonconsensually removed, removed under duress or fraud, or body parts purchased for implantation. See, for example, *Ananda Church of Self-Realization v Mass Bay Ins Co*, 95 Cal App 4th 1273, 1282 (Cal App 2002); *Miles, Inc v Scripps Clinic and Research Foundation*, 810 F Supp 1091, 1095 (S D Cal 1993); *Kremen v Cohen*, 325 F3d 1035, 1040 (9th Cir 2003). The reach of *Moore* and its progeny of cases is quite extensive. One of its legacy cases, *Cryolife v Superior Court*, although a relatively recent adjudication, has already been cited thirteen times in treatises for the proposition that tissue banks sell services and not products, extending the misguided notion that the tangible items bought and sold by tissue banks are simply services. See, for example, 1

The court's ambitious claim that similarly situated university researchers, physicians, or tissue banks will find the *Moore* holding to be a deterrent demonstrates the majority's naiveté with regard to the power of unregulated biotechnology.<sup>159</sup> Evidence that the case has had little impact on enhancing informed consent or heightening attention to fiduciary duties is easily gleaned from recent controversies<sup>160</sup> involving universities selling cadavers and body parts to tissue banks,<sup>161</sup> coroner offices working intimately with tissue banks,<sup>162</sup> funeral homes and cremato-

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California Courtroom Evidence 452; 15-177 California Forms of Pleading and Practice—Annotated 177.51; 40-460 California Forms of Pleading and Practice—Annotated 460.11; 40-460 California Forms of Pleading and Practice—Annotated 460.104; 17-175 California Points & Authorities Form 43; 19-190 California Points & Authorities Form 11.1; 1-2 California Products Liability Actions 2.14; 3-31 California Torts 31.02; 1-8 Products Liability Practice Guide 8.01; 2-10 Drug Product Liability 10.05; 2-14 Drug Product Liability 14.06; 1-1 Products Liability 1.07; 2-20 Punitive Damages 20.1 (Cont).

There is a diverse line of cases that all cite *Moore* and limit plaintiff's relief against tissue banks, coroners, physicians like Dr. Golde, and others involved in contemporary biotechnology. See, for example, *Greenberg v Miami Children's Hosp Research Inst, Inc*, 264 F Supp 2d 1064, 1074 (2003) (citing *Moore* for the proposition that plaintiffs had no property interests in the genetic material they supplied to doctor for specific purpose of finding cure to disease affecting their children when physician failed to inform them of his research developments and patent based on their genetic material); *Condos*, 208 F Supp 2d at 1226 (reasoning transplant of bone tissue held not to be a sale of product for purposes of strict liability, holding in part that the contaminated body part is not property nor a product when bought by a patient); *Cryolife*, 110 Cal App 4th at 1145 (opining that for-profit tissue bank provides a service when it sells body parts, not a product because the body is not property); *Perry v Saint Francis Hosp & Medical Ctr*, 886 F Supp 1551, 1563 (D Kan 1995) (concluding that plaintiffs lacked property right in the body of relative whose organs were harvested pursuant after misinformation provided by nurse); *Miles, Inc v Scripps Clinic & Research Found*, 810 F Supp 1091, 1095-96 (S D Cal 1993) (holding there was an intangible property interest in the commercialization of a cell line, but declining to extend California law to recognize a cause of action for conversion of that interest).

<sup>159</sup> The majority clarifies that *Moore* does have a right associated with his cell line. According to the court, "a fully informed patient may always withhold consent to treatment by a physician whose research plans the patient does not approve." *Moore*, 793 P 2d at 492.

<sup>160</sup> See Goodwin, *Commerce in Cadavers is an Open Secret*, LA Times at B15 (cited in note 16); Skloot, *Taking the Least of You*, NY Times Mag at 38 (cited in note 91) (discussing pending lawsuits involving questions of ownership and proprietary interests); Ron Nissimov and Kevin Moran, *The Body Business: Demand High for Tissues, Organs*, Houston Chron A1 (July 7, 2002) (discussing recent misappropriations of donated body parts to various institutions); Michael Fisher and Sandy Stokes, *Body Parts a Brisk Market*, The Press Enterprise A01 (Mar 3, 2002) (discussing the lack of regulation of "[c]ompanies trading in human parts" and the resulting in the removal of parts from decedents without permission of the families).

<sup>161</sup> Tom Henderson, *Company Taps Research Boom*, Detroit News 4B (Apr 17, 2005); James T. Mulder, *Body Parts, Tissue Collection Big Business in CNY*, Post-Standard A1 (Feb 27, 2005); Anne Belli, *Families of Donors Rarely Get Full Story*, Houston Chron A01 (Feb 13, 2005).

<sup>162</sup> See, for example, Ron Seely, *Tissue Bank Criticized for Offer of Trip to Coroners*, Wisc St J (Aug 27, 2005) (discussing a free three-day trip to Las Vegas that was offered by tissue bank to coroners and medical examiners); Frammolino, *Harvest of Corneas*, LA

riums selling body parts to brokers,<sup>163</sup> and organ procurement organizations channeling donated body parts to for-profit tissue banks.<sup>164</sup> Much can be gleaned from recent headlines across the United States: “A Dispute Over Brain Donations; Families Allege Improper Consent in Lawsuits Against Bethesda Institute”<sup>165</sup>; “Former Lifequest (FL) Organ Recovery Director Arrested On Charges Of Selling Organs To His Own Company”<sup>166</sup>; “UW Organ Audit Cites Coziness, Bad Records”<sup>167</sup>; “Little Shop of Horror”<sup>168</sup>; “Massachusetts: ‘Secret’ Tissue Bank Contract Questioned”<sup>169</sup>; “Med Examiner’s Office Has Secret Body-Parts Deal: Conflict Eyed In M.E., Tissue Bank Pact”<sup>170</sup>; “Grief Counselors At Morgue Funded By Transplant Group Some Have Qualms About Part-

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Times at A1 (cited in note 49) (exposing the harvesting and selling of cadaver tissues at coroner’s office to tissue banks at tremendous profits).

<sup>163</sup> See Michael Brick, *At a Brooklyn Funeral Home, an Investigation Considers the Macabre*, NY Times B3 (Oct 31, 2005) (discussing a criminal inquiry into whether an embalmer was removing body parts and selling them); Ellis Henican, *Bone-Rattling Scandal*, Newsday A8 (Jan 6, 2006) (discussing one allegation of a funeral home removing bones and selling them on the black market); Samuel Bruchey, *Her Fearful Discovery; North Shore LIJ Patient, Among 42 Notified Of Possible Faulty Transplants, Says She Has Syphilis*, Newsday A8 (Jan 5, 2006) (discussing Patricia Battisti’s contraction of syphilis from tissue used in her bone graft that might not have been screened for diseases).

<sup>164</sup> See Jose Cardo, *Former Lifequest (FL) Organ Recovery Director Arrested On Charges Of Selling Organs To His Own Company*, 13 Transplant News (cited in note 150) (exposing the conflicts of interests inherent in modern biotechnology where director of tissue recovery for an organ procurement organization began siphoning the body parts to the tissue bank that he owned); *St. Jude Medical to Focus on Future of Cardiac Surgery and Surgical Ablation at Annual Meeting of the Society of Thoracic Surgeons*, Bus Wire (Jan 26, 2006) (pointing out that biotechnology companies are “moving to the future,” reporting “[a]lready the exclusive distributor of LifeNet’s cardiac allograft products, St. Jude Medical has recently extended its agreement with LifeNet—the nation’s largest full service organ procurement organization and tissue-banking system—to include exclusive distribution of vascular allografts for use in cardiac applications”); *In Wake Of National Body Part Transplant Scandal, Schumer To Unveil Critical Legislation To Regulate Tissue Transplants*, States News Service (Jan 23, 2006); Patricia Simms, *Organ Program Not Monitored*, Wisc St J 1A (Aug 19, 2000).

<sup>165</sup> David Snyder, *A Dispute Over Brain Donations; Families Allege Improper Consent in Lawsuits Against Bethesda Institute*, Wash Post B1 (June 30, 2005).

<sup>166</sup> Jose Cardo, *Former Lifequest (FL) Organ Recovery Director Arrested On Charges Of Selling Organs To His Own Company*, 13 Transplant News (cited in note 150).

<sup>167</sup> Aaron Nathans, *UW Organ Audit Cites Coziness, Bad Records*, Capital Times 2A (Aug 19, 2000).

<sup>168</sup> Katy Vine, *Little Shop of Horrors*, Texas Monthly 90 (Aug 2003) (reporting on the macabre enterprise of body procurement specialist employed by a Texas university who began funneling the body parts to his private company, which he opened after realizing how lucrative selling human tissue and body parts can be).

<sup>169</sup> *Massachusetts: ‘Secret’ Tissue Bank Contract Questioned*, American Health Line (May 21, 2002).

<sup>170</sup> Tom Mashberg, *Med Examiner’s Office Has Secret Body-Parts Deal*, The Boston Herald 001 (May 20, 2002).



nership<sup>171</sup>; “Organ Procurement Chief Resigns; He Took Pay From Tissue Banks He Did Business With, Investigation Shows”<sup>172</sup>; and “FDA Cracks Down on Seattle Tissue Bank: Agency Targeting Use of Suspected Contaminated Body Parts.”<sup>173</sup>

In *Moore*, if the defendants had no overriding moral objections to deceiving a patient, surreptitiously harvesting and patenting the derivatives from human life, then what moral objections would they have to nondisclosure of financial interests? The penalty for exploiting Moore is infinitesimal compared to the lucrative incentives to deceive him.<sup>174</sup> Justice Panelli’s majority ruling in *Moore* essentially established a tax; John Moore’s payoff for Dr. Golde’s breach of informed consent was the fee for doing business. In the larger scheme it was a small price to pay. The incentive crafted by the court is to exploit human research, even if it means harming vulnerable subjects. The court presents no clear disincentives to curtail physicians’ and researchers’ breaches of duty here. The notion that Moore can shop for other physicians who will be less interested in the recognition, reward, tenure, publications, and research opportunities derived from Moore’s unique case is fundamentally out of touch with academic research and university promotion and reward policies in general.<sup>175</sup>

Yet, we need not focus exclusively on the conflicts of interest that arise out of the *Moore* case; its progeny also create an inter-

<sup>171</sup> Sally Farhat, *Grief Counselors At Morgue Funded By Transplant Group Some Have Qualms About Partnership*, Detroit Free Press B6 (Apr 12, 2001).

<sup>172</sup> Patricia Hoftiezer Simms and Andy Hall, *Organ Procurement Chief Resigns; He Took Pay From Tissue Banks He Did Business With, Investigation Shows*, Wisc St J A1 (May 13, 2000).

<sup>173</sup> Tom Paulson, *FDA Cracks Down on Seattle Tissue Bank: Agency Targeting Use of Suspected Contaminated Body Parts*, Seattle Post-Intelligencer A1 (Apr 12, 1995).

<sup>174</sup> It is estimated that the cell line derived from John Moore is worth billions of dollars. *Moore*, 793 P2d at 482. Beyond the future value derived from Moore’s cell line, the defendants recouped immediate benefits:

With the Regents’ assistance, Golde negotiated agreements for commercial development of the cell line and products to be derived from it. Under an agreement with Genetics Institute, Golde “became a paid consultant” and “acquired the rights to 75,000 shares of common stock.” Genetics Institute also agreed to pay Golde and the Regents “at least \$330,000 over three years, including a pro-rata share of [Golde’s] salary and fringe benefits, in exchange for . . . exclusive access to the materials and research performed” on the cell line and products derived from it. [Later] Sandoz “was added to the agreement” and compensation payable to Golde and the Regents was increased by \$110,000.

Id.

<sup>175</sup> See Gatter, 52 Emory L Journal at 331, 344 (cited in note 135) (discussing influence commercial interests in health research, and the pervasiveness of such influence).

esting body of case law. Consider for example the conflicting interests of Georgia Lion's Eye Bank<sup>176</sup> and its thorny relationships with entities that buy tissues it harvests at huge mark-ups. Or consider attempts by Cryolife,<sup>177</sup> a financially successful, aggressive, corporation,<sup>178</sup> to reject industry health and safety standards, despite a spate of illnesses resulting from the implantation its contaminated products.<sup>179</sup> According to the Georgia district court, although Cryolife's processing protocols are detailed and specific, "they are not as rigorous as other tissue banks."<sup>180</sup> Cryolife procures cadavers that are rejected by other tissue banks, including unrefrigerated corpses and dead bodies of suicide victims usually rejected because the time of death is difficult to establish.<sup>181</sup> Cryolife accepts cadavers of persons with meningitis, cancer, and other diseases and reprocesses and sells them to unwitting patients at a significant mark-up and profit margin.<sup>182</sup> Thus, the notion that the biotech industry is an effective self-regulator of patients and plaintiffs' interests stretches reality and belies the truth. Moreover, placing such a burden on the nascent industry to police itself and establish equitable norms seems untenable given the mixed social motivation to encourage industry and yet protect research subjects.

Accordingly, financial conflicts of interests in the biotechnology industry must be placed in context.<sup>183</sup> According to Robert

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<sup>176</sup> See Boer and Sternberg, *Suit Filed Over Removal of Dead Girl's Organs: Mother Says She Didn't Give Consent*, Atlanta J and Const B2 (cited in note 133) (discussing the allegations against the Georgia Lions Eye Bank, that they mutilated a woman killed in a car accident and removed her body parts without proper consent).

<sup>177</sup> *Cryolife Heart Valve Patients Cry Foul*, CBS News (Aug 27, 2002) available at <<http://www.cbsnews.com/stories/2002/08/27/eveningnews/main519937.shtm>> (last visited Oct 22, 2005).

<sup>178</sup> See *In re Cryolife, Inc Securities Litigation*, 2003 US Dist LEXIS 26170 (N D Ga). James Paton, *Cryolife Defendants Settle Claims*, Rocky Mountain News B12 (Sept 16, 2005) (discussing a settlement by Cryolife managers for engaging in illegal trading); *Cryolife Inc. Agrees To \$23 Million Settlement To End Shareholder Suit*, Securities Class Action Reporter 8 (Aug 15, 2005).

<sup>179</sup> Cryolife is quick to defend its company by suggesting that the spate of illnesses and deaths resulting from its processed tissues are unique and rare cases. See, for example, Peralte C. Paul, *Cryolife Stock Falls After Another Tissue Problem; Not Alarmed: Analyst Says Case Unfortunate, But Doesn't Expect A Serious Problem For The Company*, Atlanta J and Const 3F (Dec 6, 2003) (providing Cryolife's response to a teenage boy developing an infection originating from tissue sold by Cryolife).

<sup>180</sup> See *In re Cryolife, Inc Securities Litigation*, 2003 US Dist LEXIS 26170 (N D Ga).

<sup>181</sup> *Id.*

<sup>182</sup> *Id.*

<sup>183</sup> Charlotte H. Harrison, *Neither Moore nor the Market: Alternative Models for Compensating Contributors of Human Tissue*, 28 Am J L and Med 77 (2002); Consider Sonia M. Suter, *Disentangling Privacy from Property: Toward a Deeper Understanding of Genetic Privacy*, 72 Geo Wash L Rev 737 (2004) (noting the "rush to commercialize tissue

Gatter, "financial conflicts of interest are an outgrowth of federal technology transfer policy, which has successfully employed market incentives to make researchers and their institutions more responsive to the needs of corporations creating medical products."<sup>184</sup>

## B. Knocking Down Goliath: Fear of Endangering Biotech Giants

That the social goals of most legislative enactments may also burden individuals while benefiting the general welfare, is hardly an untested concept.<sup>185</sup> Thus, to some extent legislators may have anticipated the thorny landscape created by a near deregulation of biotechnology, including the need to clarify protocols involving research subjects, emerging conflicts of interests between researchers and their universities, and managing financial conflicting interests.<sup>186</sup> Yet, it also seemed likely that Congress purposefully left these hefty issues to the courts for resolution.

The Bayh-Dole Act<sup>187</sup> and the Stevenson-Wydler Technology Innovation Act<sup>188</sup> were specifically enacted to promote the development of science and biotechnology by purposefully permitting the fruit of publicly funded research to become the private intellectual property of researchers, universities, and their affili-

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banks"); Donna M. Gitter, *Ownership of Human Tissue: A Proposal for Federal Recognition of Human Research Participants' Property Rights in Their Biological Material*, 61 Wash and Lee L Rev 257 (2004).

<sup>184</sup> See Gatter, 52 Emory L J at 334 (cited in note 135) (arguing that one must understand the political and economic context of human research subjects in order to fully understand financial conflicts of interest therein).

<sup>185</sup> The Bayh-Dole Act of 1980 was enacted to "encourage greater production of commercially valuable research." See *id.* at 335; Bayh-Dole Act, Pub L No 96-517 § 6(a), 94 Stat 3015, 3019-28 (1980), 35 USC §§ 200-212 (2000) (the Act attempts to provide incentives for collaboration among private and public researchers).

<sup>186</sup> The Office of Technology Assessment warned Congress, emphasizing "uncertainty about how courts will resolve disputes between specimen sources and specimen users could be detrimental to both academic researchers and the infant biotechnology industry, particularly when the rights are asserted long after the specimen was obtained. The assertion of rights by sources would affect not only the researcher who obtained the original specimen, but perhaps other researchers as well." Moore, 793 P 2d at 493 (citing U.S. Congress, Office of Technology Assessment, *New Developments in Biotechnology: Ownership of Human Tissues and Cells* 31-46 (1987)).

<sup>187</sup> See Bayh-Dole Act, 35 USC §§ 200-212.

<sup>188</sup> See Stevenson-Wydler Technology Innovation Act of 1980, Pub L No 96-480, 94 Stat 2311 (1980) (the Act attempts to promote technology by establishing organizations in the executive branch to stimulate technology, establish centers for industrial technology, and recognize individuals who have made outstanding contributions to technology).

ates.<sup>189</sup> To legislators, perhaps, the ends would justify the means. In other words, global market advantage in biotechnology was expected to benefit our society, perhaps through the development of effective drugs to treat illnesses, increased scientific knowledge, and improved the status of the United States among nations engaged in biotechnology. Members of Congress likely predicted that a successful biotech industry would stimulate economic growth, development, and investment in the United States.<sup>190</sup>

Their predictions were correct; “all indications are that by privatizing the ownership of scientific research results, Congress effectively created the ‘technology transfer’ market, designed to speed the transformation of science to commercial products.”<sup>191</sup> Biotechnology is arguably the most rapidly expanding sphere of the U.S. economy<sup>192</sup>; biotech companies, for better or worse, are well integrated into the university structure, and products ranging from the therapeutic (for example, regenerative skin for burn victims) to cosmetic sex therapies and lip enhancements result from this technology transfer. I would hardly argue that these are negatives, but rather that these advancements must be understood for what they are and in context with the changing social and cultural landscape. In effect, courts must examine the power dynamics between biotechnology and the individuals—the society—it is to serve. Arguably, that relationship is now out of balance (if it were ever congruent).

Biotechnology, in free reign, is perhaps different than rigorously monitored technology with checks and balances. The differences between the two may have less to do with curbing innovation than protecting the public from harm. That Congress

<sup>189</sup> See Jerry Shottenkirk, *Biomedical Research Has Become Big Business*, Kan City Daily Record (Jan 1, 2006) (discussing the purposes and effects of the Bayh-Dole Act); Goldie Blumenstyk, *Turning Research—Slowly—Into Riches*, Chronicle of Higher Ed 44 (Oct 7, 2005) (comparing American and European approaches to allowing universities to patent inventions developed by their professors).

<sup>190</sup> Technology Commercialization Improvements Act of 1993, Hearing Before the Subcommittee on Technology, Environment and Aviation of the House Committee on Science, Space and Technology, 104th Cong, 2nd session (Sept 20, 1994) (prepared testimony of Mary Lowe Good, Under Secretary of Commerce for Technology).

<sup>191</sup> Gatter, 52 Emory L J at 336 (cited in note 135).

<sup>192</sup> Karin Price Mueller, *A Fund, an ETF and a Stock: 3 Investments to Consider Now*, The Star Ledger 7 (Feb 19, 2006) (predicting that “biotechnology should remain one of the fastest growing areas of the economy”); Patricia Fischer, *Richter Opens New Biotech Lab*, Budapest Business Journal (Nov 21, 2005) (noting that “[b]iotechnology is the fastest growing industry in the world”); *Carving a Slice of Lucrative Pie*, New Straits Times (Apr 28, 2005) (declaring that biotechnology is “one of the fastest growing markets in the world”).

wanted biotechnology to thrive cannot in contemporary terms be interpreted as granting the biotech industry immunity from judicial scrutiny. Lori Andrews reminds us, “science is not the highest value in society.”<sup>193</sup>

The rationales for unrestrained biotechnology are no longer as persuasive today, nor do they correspond to the ways in which individuals engage with biotechnology. In essence, there were/are three very different goals that must be segregated. The first goal is to promote biotechnology—lift it from its nascent position—to an independently thriving and robust industry. Beyond any doubts, this objective has been achieved. The second goal, however, must be to protect individual/community liberty, to promote safety from the harms and unintended consequences of biotechnology. Finally, and likely most controversially, we must rigorously monitor and when necessary harness unethical pursuits in biotechnology. In this, of course, are lessons to be learned from the excesses of prior biotechnological regimes, including the perfidious exploitation of human subjects during the holocaust and slavery in the United States.<sup>194</sup> For some, the notion of controlling biotechnology is to limit scientific creativity, to stymie its development, and to unduly subject the industry to meaningless bureaucracy. Those perceptions, while compelling and sympathetic to the industry and those of us who find value in markets, lose their appeal when tested over time, particularly as it appears that biotechnology transfer overwhelms judicial decisionmaking and there is, at best, limited legislative guidance. Thus, I am increasingly convinced that to abjure *all* regulation, judicially, professionally, or legislatively imposed on biotechnology transfer, ultimately disserves the industry, impairs the fluid development of jurisprudence, and undermines public trust.

According to Professor Robert Gatter, there are two clear results of the technology transfer age. First, “universities and researchers are filing patent applications in unprecedented numbers that appear to grow each year,” and second, “private ownership of research has spawned a new kind of corporation—the faculty start up—through which researchers and research insti-

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<sup>193</sup> Skloot, *Taking the Least of You*, *The New York Times Mag* 43 (April 16, 2006) (cited in note 91) (quoting Lori Andrews).

<sup>194</sup> See Patricia Heberer, *Lessons from the Holocaust: Law, Medicine and the Future of Biotechnology*, Lecture at the University Club of Chicago (Jan 25, 2006) (examining how unregulated biotechnology and medical experimentation in Germany led to the abuse of vulnerable populations) (on file with author).

tutions exploit the commercial value of their research results.<sup>195</sup> Yet, on the other hand, given the spate of recent criticisms levied at the tissue banking industry and affiliated markets, legislators may not have given full consideration to the extent to which the human body would be exploited and commercialized through biotechnology. This oversight creates its own gap in the law and as a result courts are wisely bound to weigh the purpose and burdens of legislation and not the current misgivings of individual senators.<sup>196</sup>

Courts back away from curing the allegations that biotechnology has gone too far. Rather, given their investment in a formalist approach to rule interpretation and reliance on judicial precedent and legislative enactments, they often defer to biotechnology. In *Moore*, after reaching the conclusion that the subject matter of the Regents' patent could not be Moore's property, the court suggests that it would be unfair to encumber the biotech industry with plaintiffs' claims.<sup>197</sup> The majority declared, "the extension of conversion law into this area will hinder research by restricting access to the necessary raw materials."<sup>198</sup> Thus the court implies a biotech industry entitlement to human materials. After all, if we are to rely on the majority's holding, human materials would only be restricted from researchers' access because doctors had failed to obtain consent or a patient simply refused to surrender her body parts. It is here that the court reveals its own misgivings that physicians, researchers, and others in the biotechnology industry will act justly by revealing their research interests in their patients and informing the same of their financial interests, which undergirds its holding.

Justice Panelli reaches a befuddling conclusion (in light of recognizing Golde's breach of fiduciary duty), writing that an "important policy consideration is that we not threaten with disabling civil liability innocent parties who are engaged in socially useful activities, such as researchers who have no reason to believe that their use of a particular cell sample is, or may be, against a donor's wishes."<sup>199</sup> Pinelli's majority fashioned an untenable remedy by recognizing a limited autonomy right (for

<sup>195</sup> Gatter, 52 Emory L J at 336 (cited in note 135).

<sup>196</sup> See Ridgely Ochs, *Sen. Pushes Tissue Regulation*, Newsday A15 (New York, NY) (Jan 24, 2006) (discussing one senator's displeasure "to his call for more oversight of tissue transplants").

<sup>197</sup> *Moore*, 793 P2d at 493.

<sup>198</sup> *Id* at 494.

<sup>199</sup> *Id* at 493.

Moore) “without unnecessarily hindering research.”<sup>200</sup> The court explains that recognizing a legal status in the body might provide a remedy for plaintiffs, but would equally have broad and likely negative impacts on biotechnology.<sup>201</sup>

The *Moore* court attempts to balance competing, but not irreconcilable interests. The case is far more complex than tort and property scholars have allowed; the fact that UCLA is a state agent adds further nuance to the holding as well as its omissions. First, the *Moore* court is concerned with promoting and protecting incentives in conducting medical research. Second, the court is apprehensive about crafting a rule that recognizes traditional constitutional law claims in the context of body part theft, including due process, breach of privacy, unwarranted searches and seizures, and possibly First Amendment claims given possible violations of particular religious groups. Third, and perhaps most obviously, the court is conflicted about whether random research subjects such as Moore could destabilize biotech innovation by introducing civil litigation as the mechanism for resolving disputes with researchers and biotech companies as opposed to seeking redress through other institutional processes.<sup>202</sup> The court concludes:

As in *Brown*, the theory of liability that Moore urges us to endorse threatens to destroy the economic incentive to conduct important medical research. If the use of cells in research is a conversion, then with every cell sample a researcher purchases a ticket in a litigation lottery. Because liability for conversion is predicated on a continuing ownership interest, “companies are unlikely to invest heavily in developing, manufacturing, or marketing a product when uncertainty about clear title exists.” In our view, borrowing again from *Brown*, “it is not unreasonable to conclude in these circumstances that the imposition of a harsher test for liability would not further the public interest in the development and availability of these important products.”<sup>203</sup>

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<sup>200</sup> *Id.* at 494.

<sup>201</sup> *Moore*, 793 P2d at 495.

<sup>202</sup> *Id.* Compare Calabresi, 55 *Stan L Rev* at 2133-34 (cited in note 23) (listing the rights that follow in a doctrinalist view that we do own our bodies as property).

<sup>203</sup> *Moore*, 793 P 2d at 495-96 (citing *Brown v Superior Court*, 44 *Cal 3d* 1049, 1065 (1988)).

Similarly, in another seminal case, *Cryolife v Superior Court*, the court seems paralyzed by its ability to craft jurisprudence that responds to biotech malfeasance. The court does not disturb Cryolife's enviable market position, nor impose accountability measures.<sup>204</sup> Rather, the California Appeals Court acknowledges that the tissue bank sells its goods, but refuses to hold the company responsible for negligence and poor processing standards, which violate industry norms.<sup>205</sup> A sister court, hearing a securities fraud case against Cryolife noted that, "[i]n addition to [Cryolife's] procurement of cadavers and tissue with a risk of contamination, Cryolife, unlike other tissue processors, does not test its tissues for contamination prior to processing. Before 1997, Cryolife pre-tested its tissues; however, Cryolife discontinued this process in an effort to save money."<sup>206</sup> From a plaintiff's perspective, where will checks and balances come from if the legislature defers to the judiciary and the courts decline to develop jurisprudence that could erect guideposts?

Let us consider the *Cryolife v Superior Court* ruling and its important application in to biotechnology disputes. First, the court grants relief to a for-profit tissue company based on blood shield law immunity, which traditionally protected not-for-profit blood banks.<sup>207</sup> The majority misreads the blood shield statute and extends its application to a tissue bank. The court then makes an incongruous comparison between hospitals and tissue banks. It correctly asserts, "[t]he rationale for the blood shield law is that the supplying of blood by a hospital to a patient is 'merely incidental' to the services rendered by the hospital."<sup>208</sup> Yet how the court reaches the conclusion that a for-profit tissue bank fits into that analysis is a mind leap. To be clear, while supplying blood may be an incidental function of a hospital, supplying human tissue is the fundamental and principal function of a tissue bank. Procuring, processing, storing, and selling human tissues are not incidental to the practice of tissue banking. The court speaks to the fact that enterprises like tissue banking should be encouraged, and that tissue banks "should not be required to bear the economic loss which might otherwise be im-

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<sup>204</sup> *Cryolife, Inc v Superior Court*, 110 Cal App 4th 1145 (Cal Ct App 2003).

<sup>205</sup> *Id* at 1158.

<sup>206</sup> *In re Cryolife, Inc Securities Litigation*, 2003 US Dist LEXIS 26170 (N D Ga 2003).

<sup>207</sup> *Cryolife*, 110 Cal App 4th at 1157. It would seem that the purpose of the blood shield law does not fit squarely with the legislature's intent regarding tissue banks.

<sup>208</sup> *Id* at 1153.



posed under the rules of strict liability which are applicable to sellers of commercial products generally.<sup>209</sup>

Second, the California Appellate Court misinterprets the function and role of tissue banks. The court declared tissue banks to be health dispensaries in the very way that hospitals and clinics serve that role. The ruling suggests that tissue banks are not commercial entities and that the items the companies place in commerce are not commercial products.<sup>210</sup> In this, however, the court possibly exaggerates the role and functions of tissue banks (and ignores the privatization of hospitals too).<sup>211</sup>

Indeed, tissue banks are sophisticated entities, which function just as other corporations<sup>212</sup>; they employ business strategies to attract investors,<sup>213</sup> they attract the attention of financial analysts,<sup>214</sup> and they have been investigated by the SEC.<sup>215</sup> Unlike hospitals, which serve patients, injured individuals do not call the tissue banks for assistance or show up at their doors. Rather, tissue banks do not work directly with consumers to serve their immediate health needs. Instead, tissue banks are contacted for what they sell, just as a maker of chairlifts, wheelchairs, and walkers. Contrary to the Court of Appeals of California, the Oxford Dictionary defines commercial as "making or intended to make a profit; having profit rather than artistic or other value, as a primary aim."<sup>216</sup> Commercial tissue banks are for-profit corporations that offer stock traded on international stock exchanges, including our own in the United States. Tissue banks certainly are not artistic organizations, even though increasingly their commercial products are used for cosmetic purposes and elective surgeries. Company business plans, sometimes posted on

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<sup>209</sup> *Id.* at 1156 (quoting *Hyland Therapeutics v Superior Court*, 175 Cal App 3d 509, 516 (1985)).

<sup>210</sup> *Cryolife*, 110 Cal App 4th at 1156.

<sup>211</sup> See, for example, *In re Cryolife*, 2003 US Dist LEXIS 26170 (N D Ga 2003).

<sup>212</sup> Consider *id.* (plaintiff class of purchasers of Cryolife stock sued defendants, the corporation and its principal officers, alleging that the corporation issued false and misleading press releases and statements to artificially inflate the price of their stock).

<sup>213</sup> *Id.* See also the Cryolife corporate website, available at <<http://www.cryolife.com/>> (last visited Jan 29, 2006) (describing Cryolife's corporate philosophy, services and quality assurance measures).

<sup>214</sup> See, for example, Aaron Smith, *Tissue From Corpses In Strong Demand*, CNN Money (Oct 5, 2005) available at <<http://money.cnn.com/2005/10/4/news/midcaps/allograft>> (last visited Feb 16, 2006) (discussing how companies in the allograft industry, including Cryolife, obtain their materials and the volatility of their stock prices).

<sup>215</sup> Paton, *Cryolife Defendants Settle Claims*, Rocky Mountain News B12 (Sept 16, 2005) (cited in note 177); *Cryolife Inc. Agrees To \$23 Million Settlement To End Shareholder Suit*, Securities Class Action Reporter at 8 (cited in note 178).

<sup>216</sup> See *The New Oxford American Dictionary* 344 (Oxford University Press 2001).

tissue bank websites, outline profit initiatives, investment strategies, and describe key ways that investors can reap profits from cadavers and body parts. Within the business sphere, tissue banks compete unabashedly and project business-centered image and such efforts have been quite successful.<sup>217</sup>

These factors, probably considered exogenous to the courts, and therefore less relevant, actually help to illuminate the true status and functions of tissue banks. Consider for example that tissue banks reserve the right to contract with other businesses about the body parts they acquire. Tissue banks can and do exclude others from interfering with the tissues and body parts they trade. If a company or individual attempted to interfere with their collection of body parts, an enforceable remedy would exist. By ignoring the role and function of tissue banks, courts not only abrogate their responsibility to respond to the social, legal, and cultural complications of contemporary biotechnology, but also deny remedies to aggrieved patients.

On examination of the legal landscape, one realizes that in this complicated, nuanced terrain the varied interests of biotech companies too often outweigh the liberty interests of individuals, including strongly held values of autonomy, the right to be free from bodily intrusion, and the right to freely decide how one's body will be used. In essence, courts ultimately favor the protection of the biotech research enterprise over the liberty interests and even safety of the individual. In the battle between David and Goliath, in the biotech context, Goliath almost always wins.

### III. A NEW GENERATION OF LABELS

In Part III, I briefly explore the nuances of giving a particular legal status to the body; the pitfalls, challenges, and problems of doing so. Courts have elucidated four possible conceptions of the body and/or body parts and our relationship to it: property, inalienable, possession, and service. This section addresses only the potential status of the body as either a possession or property.

Some commentators question the utility of "naming" the body or conferring rights to individuals responsible for disposal of remains. To them, the body and body parts represent a sacred vessel that if re-characterized could lead to market concepts associated with human flesh and an eventual commodification of it.

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<sup>217</sup> Skloot, *Taking the Least of You*, *The New York Times Mag* 38 (April 16, 2006) (cited in note 91).

Accordingly, to these scholars, all market concepts in the body are understood as bad.<sup>218</sup> In a market paradigm, commentators fear that individuals will desire to alienate their bodies or those of their deceased relatives. The risk that some of these bodies if commodified, according to Richard Titmuss, might place insalubrious tissues into the marketplace is quite high.<sup>219</sup>

Scholars warn that the poor and destitute will be drawn to markets and when they are, sellers will engage in socially undesirable behaviors, including stealing body parts. Commodification of the body, according to anti-market bioethicists such as Arthur Caplan, is akin to slavery—a paradigm to be avoided. Beyond the unfounded fears of body part markets, ultimately the necessity to ascribe legal status to the body remains. The legal status we ascribe to the body will have great impact on tort, property, and contract claims and potential plaintiffs' access to the courts.

#### A. Body As Possession

Judges on the Ninth Circuit Court of Appeals recently tested the thorny divide between theories of property versus possessory interests in the body. In *Newman v Sathyavaglswaran*,<sup>220</sup> parents of deceased children whose corneas were removed by the Los Angeles County Coroner's office without notice or consent, brought a Section 1983 action alleging a taking of their property without due process of law. The complaint was dismissed by the district court for a failure to state a claim upon which relief could be granted. On review, the Ninth Circuit concluded that the longstanding recognition in the law of California, paralleled by national common law, that next of kin have the exclusive right to possess the bodies of their deceased family members created a property interest, the dispossession of which must be accorded due process of law under the U.S. Constitution Fourteenth Amendment.

*Newman* articulates a new conception of rights in the body in the majority and dissent. In this way it represents a departure from traditional formalism in body part jurisprudence. *Newman's* majority recognizes a property interest in the right to decide the disposition of a body. In contrast the dissent is far less

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<sup>218</sup> See Radin, 100 Harv L Rev at 1849 (cited in note 2).

<sup>219</sup> See, for example, Richard M. Titmuss, *The Gift Relationship: From Human Body to Social Policy* (New Press 1971).

<sup>220</sup> 287 F3d 786 (9th Cir 2002).

generous, declaring that individuals only have the authority to possess the body and that this interest is aesthetic at best. Indeed, possessions of negligible magnitude confer upon the owners or possessors the right to defend their interests in that thing. That right to defend such an interest through civil remedy is far from insignificant.

Judge Ferdinand Fernandez, in a passionate dissent, articulated an alternative, new conception of the body as a possession rather than property. In doing so, he rejected the majority's analysis in *Newman*,<sup>221</sup> which ascribed new value to the body by interpreting a property right of parents to have been violated when children's corneas were moved without consent and notice.

Fernandez attempted to move slightly beyond the stricter formalism of the Eighth Circuit and various state courts in Washington, Florida, and Georgia.<sup>222</sup> Fernandez ultimately reaches the same conclusion as his peers in other jurisdictions; the body has no property status and therefore a conversion is not an appropriate cause of action in relation to the body.<sup>223</sup> However, the nuanced approach outlined by Fernandez is worthy of note as a possible new judicial framework.

Like traditional formalists, judges adopting the possessory interest framework will first look to the legislature for guidance.<sup>224</sup> Absent legislative enactments or agency regulations, formalists will not seek to give new meaning to traditional frameworks and perhaps for this reason, Fernandez's dissent *cannot* clearly be situated within the conventional formalist paradigm despite the fact that he rejects acknowledging property interests or status in the body. Rather in the case of *Newman*, Fernandez offers an alternative modern application of quasi property theory, which is a slight, but important nuance in body part jurisprudence. By doing so, he mildly betrays the formalist convention that "the rule of law is about form."<sup>225</sup> According to the nascent theory of the body as "possession," duties are associated with individuals' relationship to the body, particularly dead

<sup>221</sup> 287 F3d 786, 800 (9th Cir 2002) (Fernandez dissenting).

<sup>222</sup> See *id* (Judge Fernandez does not address whether a body merely is or is not property with its associated rights, but rather what rights correspond with the state-imposed duty to dispose of the body).

<sup>223</sup> See *id* (declaring that states can, when conferring a duty to dispose of decedent's body, limit property rights to mere possessory interests).

<sup>224</sup> *Id*.

<sup>225</sup> Antonin Scalia, *Common-Law Courts in a Civil-Law System: The Role of United States Federal Courts in Interpreting the Constitution and Laws*, in *A Matter of Interpretation: Federal Courts and the Law* 3, 23-25 (Amy Guttmann ed, Princeton 1997).

bodies. Thus, if a right exists, it is a right only to possess the body for purposes of burial and to destroy it.<sup>226</sup>

Judge Fernandez rationalizes that “this so-called right is actually in the nature of a duty and expense designed to assure that the remains will not simply be left about, but will be quickly interred.”<sup>227</sup> He refers to this special set of responsibilities as “something like a table of intestate succession for the purpose of assuring that the right and duty land firmly on a defined group.”<sup>228</sup> Fernandez describes this right as being grounded in pragmatism, although he offers no further explanation.<sup>229</sup> Nevertheless, there are several common elements that follow this theory, which was originally conceptualized as based on a “quasi property interest.”<sup>230</sup> The core principles of quasi property interests include a concern for decency, consideration for others, pragmatism, due haste, and entitlement to burial.

Specifically, this theory of body as possession is concerned with decency for the dead and society. In sum, according to Fernandez, our concerns should be focused simply on respect—or the negative right to be free from the disrespectful treatment of others.<sup>231</sup> Yet, Fernandez clearly articulates a division between the law’s concern for decent treatment of the dead and constitutional protection. In other words, the duty to bury is not a constitutionally protected right of property. Because possession treats the association with the body as a duty and burden on relatives, it is less concerned about relatives and their desires except for how they wish to bury or inter their deceased relatives. Thus, the theory is not concerned with any value relatives or spouses may extract from the body. It is an anticommodification position that rejects the notion that the body should have any property-like or commensurable status.

Fernandez’s theory is not completely worked out, just as there are limits in the traditional quasi property rights framework. For example, the possession theory is also concerned with timing, but its outcomes are somewhat arbitrary. Specifically, possession theory confines one’s possessory interests to the timing of death and burial. This narrow time stamping ignores contemporary medical, biotechnological, and social treatment of the

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<sup>226</sup> *Newman*, 287 F3d at 800 (Fernandez dissenting).

<sup>227</sup> *Id.*

<sup>228</sup> *Id.*

<sup>229</sup> *Id.*

<sup>230</sup> *Pollard v Phelps*, 193 SE 102, 106 (Ga Ct App 1937).

<sup>231</sup> *Newman*, 287 F3d at 801 (Fernandez dissenting).

body and its indeterminate state in cryopreservation, loans to museums, medical schools and other institutions, and when it is brain dead. In effect, the timing prong suggests that possessory interests attach only for a short period at the immediate time of death and not during life. Thus, an individual such as Moore would not pursue a conversion claim under possession theory. Moore's cells were extracted and exploited during life, not at death.

Possessory rights are empty vessels. Proponents of this theory might argue that there are no causes of action for which courts may grant a remedy even in instances where the right to possess is interfered with at death. In other words, interfering with one's right to bury is a bad thing, but courts do not possess the authority to grant a remedy. Also, the right to possess, according to Fernandez, is not confined to the individual, but by statute can also be bestowed upon the state.

In the *Newman* dissent, Fernandez declares that the state's authority to extract tissues at death is not challengeable.<sup>232</sup> Thus, an additional element to be worked out in this theory is how to decide whether the state has the controlling interest at death or the individual—irrespective of statute. As it stands, the outcome of possessory rights according to this theory will differ from state to state, offering no clear guidance for plaintiffs—even within the same federal circuits. Fernandez might also conclude that aggrieved plaintiffs do not have any remedies that a court can provide except in distinguishing who can bury or donate organs.

## B. Property

The Supreme Court has yet to address whether the rights of control, possession, and privacy in one's body are property interests and thus "protected" by the Due Process Clause. Nor has it addressed what Due Process protections are applicable to the rights of next of kin to possess and control the bodies of their deceased relatives.<sup>233</sup> However, constitutionally protected property rights extend "beyond actual ownership of real estate, chattels, or money."<sup>234</sup> Accordingly, these rights "are not created by the Constitution ... they are created and their dimensions are defined by existing rules or understandings."<sup>235</sup> Like proponents of

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<sup>232</sup> *Id.*

<sup>233</sup> *Id.* at 789–90.

<sup>234</sup> *Id.* at 790 (quoting *Board of Regents v Roth*, 408 US 564, 571–72 (1972)).

<sup>235</sup> *Newman*, 287 F3d at 790 (quoting *Board of Regents*, 408 US at 577).

possession theory, property proponents find support for giving the body legal status as property from the common law rules that affirmed a quasi property right interest in the body.

Writing for the majority in *Newman*, Judge Raymond Fisher cites an 1872 case to draw the parallel:

By the civil law of ancient Rome, the charge of burial was first upon the person to whom it was delegated by the deceased; second, upon the scripti haeredes (to whom the property was given), and if none, then upon the haeredes legitimi or cognate in order . . . . Their heirs might be compelled to comply with the provisions of the will in regard to burial. And the Pontifical College had the power of providing for the burial of those who had no place of burial in their own right.<sup>236</sup>

Unlike Fernandez, Fisher and the majority in *Newman* describe rights and duties as being jural correlatives.<sup>237</sup> At issue in this examination is whether possession and control rise to the level of a constitutionally protected interest. Property, for the majority in *Newman*, is a “group of rights inhering in the citizen’s relation to the physical thing, as the right to possess, use and dispose of it.”<sup>238</sup> The court makes clear that to have a property right or interest, one must have more than an abstract notion of a thing, but rather, a “legitimate claim of entitlement to it.”<sup>239</sup> Concomitant with this idea is the protection found in laws to shield one from interference with the thing said to be property.

The landscape however, is not clean here. Only the Ninth and Sixth circuits have affirmatively offered that the body remains property after choosing its burial.<sup>240</sup> Professor Lori Andrews cautions against being too swift in naming the body as

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<sup>236</sup> *Pierce v Proprietors of Swan Point Cemetery*, 10 RI 227, 235–36 (1872) (quoted in *Newman*, 287 F 3d at 790).

<sup>237</sup> *Newman*, 287 F3d at 790 n 5 (adopting Wesley Hohfeld’s description of rights and duties as “jural correlatives,” which are described as “different aspects of the same legal relation”).

<sup>238</sup> *Id* at 795 (quoting *United States v General Motors Corp*, 323 US 373, 378 (1945)).

<sup>239</sup> *Newman*, 287 F3d at 795.

<sup>240</sup> In defense of property, the courts articulate a distinction between property interests and an absolute right to commodify. Nor is the court convinced that simply because a thing lacks economic value or is prohibited from sale, that it is not property. *Newman*, 287 F3d at 795; *Brotherton*, 923 F2d 477 (6th Cir 1991). *Moore*, 793 P2d at 501 (noting that although Moore himself had no property interest in his cells, had “another medical center or drug company . . . stolen all of the cells . . . from the UCLA Medical Center laboratory and had used them for its own benefit, there would be no question but that a cause of action for conversion would properly lie against the thief”).

property, lest we fully comprehend the socioeconomic, cultural, and political ramifications of such judicial or legislative intervention.<sup>241</sup> She wisely challenges us to think about the praxis and pitfalls of granting property status to cells, organs, and conceivably all other parts that have recently been subject to market forces, including brains, bones, and limbs. To the extent that property rights are recognized in body parts, plaintiffs may have greater access to courts because they will actually have justiciable claims. On the other hand, it is true that alternative forms of negotiation and possible payment might arise, including joint ventures between patients and their physicians. It is also conceivable that individuals might desire to invest in the products derived from their bodies.

Property proponents, such as the majorities in *Newman*, *Brotherton*, and *Martin*, argue that “the right of every individual to the possession and control of his own person, free from all restraint or interference of others” is a well established principle, recognized by the US Supreme Court.<sup>242</sup> This right, according to the majority, is deeply rooted in the conscience, traditions, and culture of Americans.<sup>243</sup> It is “to be ranked as one of the fundamental liberties protected by the ‘substantive’ component of the Due Process Clause.”<sup>244</sup> Quoting *Schmerber v California*<sup>245</sup>, the *Newman* court asserted that “the integrity of an individual’s person is a cherished value of our society.”<sup>246</sup>

Accordingly, property proponents, just as the “body as possession” scholars, are concerned with human dignity. Property proponents argue that the physical invasion of the body is offensive to human dignity. They extend the notion of property interest to the decisions that affect end-of-life decisionmaking. They evoke the right to die cases, starting with *Cruzan v Missouri*<sup>247</sup>, to draw parallels with the contemporary biotech cases, and particularly the compelled donation/presumed consent laws. For ex-

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<sup>241</sup> See Lori Andrews and Dorothy Nelkin, *Body Bazaar: The Market for Human Tissue In The Biotechnology Age* (Crown 2001) (warning of an inevitable devaluation of human life resulting from business interests in harvesting human tissues).

<sup>242</sup> *Newman*, 287 F3d at 789; see also *Brotherton*, 923 F2d at 481 (extending rights in oneself to “quasi-property” rights in decedent’s next of kin); *Martin v Young Kim*, 2005 US Dist LEXIS 20595 (ND Ind 2005) (applying *Brotherton* reasoning to a refusal to allow a kidney transplant from decedent to decedent’s cousin due to a mandatory autopsy law for homicide victims).

<sup>243</sup> *Newman*, 287 F3d at 789.

<sup>244</sup> *Id.*

<sup>245</sup> 384 US 757 (1966).

<sup>246</sup> *Newman*, 287 F3d at 789 (quoting *Schmerber v California*, 384 US at 772).

<sup>247</sup> *Cruzan v Missouri Dept of Health*, 497 US 261 (1990).



ample, in *Cruzan*, the court expressed the view that a right to die with dignity emanates from “the right to determine what shall be done with one’s own body [which] is deeply rooted in this Nation’s traditions ... and is securely grounded in the earliest common law.”<sup>248</sup>

Finally, property rights are not absolute and it would be problematic to interpret them as so. For any number of public policy reasons, “the law limits or even forbids the exercise of certain rights over certain forms of property.”<sup>249</sup> For example, owners of property can be restricted from using their land in any manner they desire. Moreover, foods, cosmetics, drugs, alcoholic beverages, firearms, explosive materials, and other property are subject to the public health and safety laws of any given community.<sup>250</sup> Even with such limitations however, we learn that property rights can coexist with regulatory norms that limit their reach.

#### IV. LIBERTY INTERESTS AND REMEDIES

Part IV of this Article studies the applicability of traditional tort remedies for biotechnology breaches involving the body. Part IV.A examines the application of strict liability to claims against human tissue manufacturers for breach of duty. Part IV.B analyzes whether takings theory applies to cases of presumed consent and nonconsensual takings by government agents.

Tort law is a creature of the common law. The inherent ability of the common law to grow, change, and adapt to the social demands of the communities it serves is its “most significant feature.”<sup>251</sup> Thus, whatever remedies are found for plaintiffs in body-tort disputes are predicated on courts moving away from a formalist approach to body part adjudication to one that is more consistent with the contemporary ways in which the body is used in technology. As society advances, so must the law adapt and change to respond to inventions, trade, commerce, and biotechnology.

Adopting either of the approaches offered here will require an expansion in the common law and the application of tort theories in ways not envisioned centuries or even decades prior. But

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<sup>248</sup> 497 US at 305 (Brennan dissenting).

<sup>249</sup> *Moore*, 793 P2d at 509 (Mosk dissenting).

<sup>250</sup> *Id.* at 509-10.

<sup>251</sup> See *id.* at 507 (Mosk dissenting) (arguing that the Supreme Court does not need to look to the legislature to establish a claim for conversion in *Moore*'s case).

there are sound social policy reasons for expanding the law to address citizen complaints. As Justice Mosk iterates in his dissent in *Moore*, “[i]n our contemporary complex industrialized society, advances in science and technology create fungible goods which may harm consumers . . . . The response of the courts can be either to adhere rigidly to prior doctrine, denying recovery to those injured by such products, or to fashion remedies to meet these changing needs.”<sup>252</sup>

#### A. Product Liability

Most surgeries involving the use of cadaver tissues are elective; the surgeries enhance the quality of life after strain or tensions in the knees or other body parts.<sup>253</sup> Soft tissues used for heart valves, on the other hand, are life-saving products, transplanted into patients with life-threatening conditions.<sup>254</sup> Most patients who elect to use life-enhancing or life-saving therapies may be unaware of the “brands” or manufacturers of the tissues used in these routine operations. More people successfully survive implantation surgeries than die or become paralyzed. On the other hand, some illnesses will not be detected as quickly as in the stories described in Part I.

Section A visits the stories of several individuals who suffered from fatal or near fatal diseases after implantation of infected human tissue. As a market share, they are a very small group. Weeks, sometimes months later, the bacteria may be discovered and its link to the implantation may be overlooked. In addition, patients and their physicians may not attribute the postoperative diseases to the cadaveric implanted parts; most might assume that only tested tissues would end up in the stream of commerce and they would be wrong.

The first question to consider is if allegations such as those put forth in Model C (*Cryolife v Superior Court*) can be established as true, whether product liability can attach for misleading the public and placing faulty products in the marketplace. Three main theories provide plaintiff relief for product-related

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<sup>252</sup> Id (Mosk dissenting) (citing *Sindell v Abbott Laboratories*, 26 Cal 3d 588 (1980)).

<sup>253</sup> Blakeslee, *Recall is Ordered at Large Supplier of Transplant Tissue*, NY Times A1 (Aug 15, 2002) (cited in note 90); Jill Burcum and Josephine Marcotty, *'01 Death Leads to a Recall of Tissue*, Minneapolis Star Tribune 1A (Aug 15, 2002) (noting that “[s]urgery that relies on the cadaver tissue is mostly elective, meaning people can postpone or cancel it”).

<sup>254</sup> See Ginny Merriam, *Despite Recalls, Doctors Still Use Heart Technique*, The Mis-soulian B1 (Sept 11, 2002).

injuries: negligence, breach of warranty, and strict liability. Strict liability provides a more substantive remedy for plaintiffs than traditional negligence law because damages are not limited to pure economic loss. For this reason, corporations are more inclined to view product liability as a purely punitive remedy for injured plaintiffs. In most states, to prove a strict liability claim the plaintiff must demonstrate proof of an injury, but she is not required to show a lack of due care by the defendant.

*Greenman v Yuba Power Products*,<sup>255</sup> another California case, is the landmark decision for modern product liability claims. In *Greenman*, the Supreme Court of California considered whether the retailer and the manufacturer of a Shopsmith, a power tool “that could be used as a saw, drill, and wood lathe,” could be held liable for head injuries sustained by the plaintiff when an attachment advertised and sold for the tool unexpectedly flew out of the machine and struck Mr. Greenman on the forehead.

According to Justice Traynor in the *Greenman* decision, a manufacturer is strictly liable in tort “when an article he places on the market, knowing that it is to be used without inspection for defects, proves” to be defective and causes an injury to “a human being.”<sup>256</sup> The purpose of strict liability is to insure that the costs of injuries resulting from defective products are borne on manufacturers that place goods in the marketplace rather than the powerless individuals who purchase the products and are otherwise unable to protect themselves. Traynor suggested that implicit in products being on the market is the representation by its manufacturer that “it would safely do the jobs for which it was built.”<sup>257</sup>

The Restatement (Second) of Torts provides the general framework adopted by most states. Section 402 A of the Restatement establishes the test for strict liability for the manufacture or distribution of defective products. It provides:

- (1) One who sells any product in a defective condition unreasonably dangerous to the user or consumer or to his property is subject to liability for physical harm thereby caused to the ultimate user or consumer, or to his property, if

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<sup>255</sup> *Greenman v Yuba Power Products, Inc.*, 377 P2d 897 (Cal 1963).

<sup>256</sup> *Id.* at 898.

<sup>257</sup> *Id.* at 901.

- (a) the seller is engaged in the business of selling such a product, and
  - (b) it is expected to and does reach the user or consumer without substantial change in the condition in which it is sold.
- (2) The rule stated in Subsection (1) applies although
- (a) the seller has exercised all possible care in the preparation and sale of his product, and
  - (b) the user or consumer has not bought the product from or entered into any contractual relation with the seller.<sup>258</sup>

Thus, product liability claims require only that the plaintiff, the injured party, demonstrate that the product is defective. The plaintiff is not required to show privity between the plaintiff and manufacturer. Neither is the plaintiff required to demonstrate that the manufacturer acted “unreasonably.” Strict liability has been interpreted to be a “pro-plaintiff” theory of law because of its less rigid requirements to establish manufacturer liability.<sup>259</sup> Part of the rationale for this is that manufacturers are in the better position to prevent the accidents that result from their defective products.<sup>260</sup>

Plaintiffs assume that advertisements about the safety and utility of the manufacturer’s products are true and that the purchased products are free from defects. The defects covered under strict liability law can be (a) manufacturing defects (products that fail to meet the manufacturers’ specifications); (b) design defects (products with unsafe designs); and (c) defects in warnings or instructions or products that lack information to make

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<sup>258</sup> *Restatement (Second) of Torts*, § 402(a) (American Law Institute Publishers 1965).

<sup>259</sup> See David G. Owen, *The Puzzle of Comment J*, 55 *Hastings LJ* 1377, 1377 (2004) (noting that “section 402A ... generated the expansive, plaintiff-friendly doctrine of strict liability in tort for the sale of products that are defective in any of three fundamentally different ways—in manufacturing, warnings, or design”).

<sup>260</sup> Product manufacturers are almost always in a better position to prevent harm caused by defective products. See Suzanne Ernst Drummond, *Des and Market Share Liability in Ohio—A Lesson in How What You Don’t Know Can Hurt*, 67 *U Cin L Rev* 1331, 1344 n 112 (1999) (“(1) [T]he manufacturer should bear the cost of injury as between it and an innocent plaintiff, (2) manufacturers are better able to bear the cost of injury resulting from defective products, and (3) because manufacturers are in a better position to discover and prevent product defects and to warn consumers of harmful effects, imposing liability would further ensure product safety.”) (quoting *Sindell v Abbott Laboratories*, 607 P2d 924, 936 (Cal 1980)).

their use less dangerous.<sup>261</sup> That such defects are covered under the scope of strict liability law can be explained by the need to protect an otherwise vulnerable public from injurious conditions caused by manufacturers.

The public policy rationale for product liability was established by Traynor's concurring opinion in the infamous *Escola v Coca-Cola Bottling Co of Fresno*<sup>262</sup> case where he suggested that fairness in a modern, industrialized society requires making manufacturers responsible for the injuries caused by their products.<sup>263</sup> In that case, a waitress was injured by an exploding Coca-Cola bottle.<sup>264</sup> Although the court affirmed the judgment against the manufacturer based on another tort doctrine, Traynor's concurring opinion opened the door for strict liability consideration.<sup>265</sup>

To determine whether strict liability should apply to tissue manufacturers, we must consider whether their activities fall within the general framework established through the Restatement and prior case law, which involves non-tissue manufacturers. The primary prong for successfully establishing a product liability claim against a manufacturer is to demonstrate that the product was defective.<sup>266</sup> However, the defendant class is not limited to the manufacturer of products. Rather any entity that plays a role in the manufacture, distribution, or sale of a product is a potential defendant and therefore subject to liability.<sup>267</sup>

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<sup>261</sup> See Owen, 55 Hastings LJ at 1377 (cited in note 259).

<sup>262</sup> *Escola v Coca-Cola Bottling Co of Fresno*, 150 P2d 436 (Cal 1944).

<sup>263</sup> Id at 440-41 (Traynor concurring).

<sup>264</sup> Id at 437.

<sup>265</sup> *Jimenez v Superior Court*, 58 P3d 450, 452 (Cal 2002); *Murphy v E R Squibb and Sons, Inc*, 710 P2d 247, 258 (Cal 1985); *Trust v Arden Farms Co*, 324 P2d 583, 584 (Cal 1958); *Zentz v Coca Cola Bottling Co of Fresno*, 247 P2d 344, 347 (Cal 1952); *Gordon v Aztec Brewing Co*, 203 P2d 522, 524 (Cal 1949).

<sup>266</sup> Brady L. Montalbano, Comment, *It's Not Easy Being Green*, 14 Penn St Envir L Rev 111, 121-22 (2005) ("[T]he second element necessary to sustain a strict products liability cause of action is that the product must contain a defect. Under the Restatement (Second) of Torts § 402A, there are currently three types of recognized product defects: manufacturing defect, failure to warn (inadequate warning of defect), and design defect.").

<sup>267</sup> Richard C. Ausness, *Tell Me What You Eat, And I Will Tell You Whom to Sue*, 39 Ga L Rev 839, 876-77 (2005)

[T]hose who place finished products into the stream of commerce may be held liable for any defects in their products and may also have a duty to warn users or consumers about any inherent risks associated with their products. The new Restatement of Torts, however, acknowledges that suppliers of raw materials and component parts should not be held liable for injuries caused by defective finished products when the materials they supply are not themselves defective.

Id.

Within this framework, when a product does not function in a way in which its manufacturers intend, and the defect contributes to an injury suffered by the plaintiff, the product is characterized as having a manufacturing defect.<sup>268</sup> Moreover, if a product has a manufacturing or design defect, plaintiff can recover under strict liability for injuries related to those defects regardless of manufacturer warning labels being present.<sup>269</sup>

Liability in the tissue industry for the distribution, processing, handling, and selling of products is largely premised on whether we consider those processes to be the manufacturing and processing of a “product” or providing a “service.” Such issues in the nomenclature may best be resolved by turning to the dictionary for a better grasp of our social understanding of a product versus a service. According to the *American Heritage Dictionary*, a product is “something produced by human or mechanical effort or by a natural process.”<sup>270</sup> A service, on the other hand, is defined as “employment in duties or work for another.”<sup>271</sup> The dictionary compares a service with providing consultation or doing a favor for an individual.

Thus, when compared to a “service” or “product,” human tissues much more closely resemble a product. Human tissue is in fact something produced biologically, and arguably by human effort, which is a natural process. Often, the tissue is further processed by tissue banks and sometimes entirely reconstituted. Human tissues are tangible, biological materials that exist not in an ethereal state, but in real life. Medicines and other technologies derived and produced from human tissues are considered products. Yet, we must consider the question of defect and whether the manufacturer’s having control over the tissues meets the requirements established by the Restatement and prior case law. To help us determine whether Cryolife’s human tissue product was actually defective, we should turn to the prior health status of the patient and his postoperative condition. While it is true that patients could acquire diseases in hospitals,

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<sup>268</sup> See Owen, 55 Hastings LJ at 1378–79 (cited in note 259) (describing the three forms of product defects: “(1) manufacturing flaws—unintended physical irregularities that occur during the production process; (2) design inadequacies—hazards lurking in a product’s engineering or scientific conception that may reasonably be avoided by a different design or formula; and (3) insufficient warnings of danger and instructions on safe use—the absence of information needed by users to avoid product hazards”).

<sup>269</sup> See *id.*

<sup>270</sup> *American Heritage Dictionary* at 1399 (American Heritage 4th ed 2000).

<sup>271</sup> *Id.* at 1591.

it is far more direct and proximate that contaminated implants will result in life-threatening illnesses.

Consider the case of Brian Lykins; the deadly bacterium found in his implanted knee tendon, *Clostridium sordelli*, was not pre-operatively present in his body.<sup>272</sup> Yet, following Lykin's death and illnesses in several other patients that resulted from similar implants in Minnesota from Cryolife products, the FDA visited the manufacturer.<sup>273</sup> In a subsequent report, the FDA emphasized the unusual length of time the cadaver, which would become the tendon "supplier," remained unrefrigerated prior to processing.<sup>274</sup> It was clear that nineteen hours without refrigeration was well outside the tissue industry norm.<sup>275</sup> Cryolife's claims that its products were safe and that the rare bacterium could have been picked up anywhere were less persuasive when CDC investigators found "tissue from the donor's other knee, which had not been implanted in anyone, tested positive for *Clostridium sordelli*."<sup>276</sup> Moreover, of the nearly twenty tissue samples that were not implanted, at least two contained the exact bacteria that killed Lykins.<sup>277</sup> Scientists from the CDC linked all *Clostridium* infected tissues to the bacteria in the cadaver's gastrointestinal tract.<sup>278</sup>

If human tissues are more likely products than services, then their contamination would presumptively make them "unsafe" products. Moreover, an unsafe product used for medical

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<sup>272</sup> See Sandra Blakeslee, *Lack of Oversight in Tissue Donation Raising Concerns*, NY Times 11 (Jan 20, 2002) (cited in note 83) (indicating that tissue from the donor tested positive for the deadly bacteria).

<sup>273</sup> Burcum and Marcotty, *'01 Death Leads to a Recall of Tissue*, Minneapolis Star Tribune 1A (Aug 15, 2002) (cited in note 253) (describing a two-week inspection of Cryolife headquarters by FDA inspectors: the "testing methods ... to detect bacterial and other types of contamination were deficient and not reliable").

<sup>274</sup> Centers for Disease Control, *Update, Allograft-Associated Bacterial Infections—United States, 2002*, Morbidity and Mortality Weekly Report Vol 51(10) 207-210 (Mar 15, 2002), available at <<http://www.cdc.gov/mmwr/PDF/wk/mm5110.pdf>> (last visited Apr 14, 2006) (indicating that the delay in refrigeration of the donor contributed to the bacterial contamination).

<sup>275</sup> See, for example, *In re Cryolife Securities Litigation*, 2003 US Dist LEXIS 26170, \*8 (2003) ("Cryolife procures cadavers that do not meet the standards of other tissue processors. Notably, other processors do not accept cadavers that have not been refrigerated within twelve hours of death, because the decomposition of a non-refrigerated cadaver releases microorganisms that contaminate the cadaver.").

<sup>276</sup> See Blakeslee, *Recall is Ordered at Large Supplier of Transplant Tissue*, NY Times A1 (Aug 15, 2002) (cited in note 90).

<sup>277</sup> *Id.* See also Centers for Disease Control, Morbidity and Mortality Weekly Report Vol 51(10) 207-210 (Mar 15, 2002) (cited in note 274) (noting that of the "19 nonimplanted tissues" from the donor, the bacteria was identified in two samples").

<sup>278</sup> Centers for Disease Control, Morbidity and Mortality Weekly Report Vol 51(10) 207-210 (Mar 15, 2002) (cited in note 274).

processes would seem to be inconsistent with manufacturer intent, and certainly inconsistent with patient, physician, and hospital expectation. Unsafe products by their very definition are defective. Likewise, infection of deadly viruses in transplantable tissue must render the tissues defective products. According to the common law and Restatement of Torts, a manufacturer need not know nor intend to distribute a defective product in order for strict liability to attach.<sup>279</sup> Rather, it is sufficient that the item appear in the stream of commerce and a human being is injured by the product.<sup>280</sup> Recovery in strict liability is allowed if those elements are met—and they are in these cases.<sup>281</sup>

Finally, although it would seem unwise to view organs as services, doing so invites an alternative analysis far different from the Appellate Court in *Cryolife v Superior Court*. Cryolife's argument that a body part is a service might be more persuasive were the company selling kidneys rather than cadaver tissues exactly because kidneys are life-saving treatments, not elective or cosmetic surgeries. Thus, unlike with tissues, we might view the kidney as a product, and yet provide immunity from liability for entities that assist in providing them (much as we do now). As much as a kidney is tangible, are hospitals selling "products" or providing "services" when transplants are made available to patients like Brian Lykins? Hospitals provide a service in transplanting organs within a thin time frame and narrow chain of command to do so. Hospitals and surgeons (even if they might desire to do so) cannot legally purchase, nor stockpile, organs for transplantation; the supply is far too limited and organs intended for transplantation expire far more quickly than human tissue. Thus, the technology is unavailable should there even be interest in such an industry. The storage life of a kidney is hours, but for tissues it can be years after processing.

Analogies drawn between organs and tissues and the industries that "handle" them are overstated. The two are vastly different and the "controllers" far differently motivated. Surgeons and hospitals lack the ownership interests in the organs they transplant as it also seems with regard to the prospective recipient. Yet, tissue banks have a proprietary and legally recognized interest in their tissue products. The companies' rights to litigate

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<sup>279</sup> James A. Henderson, Jr. and Aaron D. Twerski, *Intent and Recklessness in Tort: The Practical Craft of Restating Law*, 54 Vand L Rev 1133, 1137 (2001) (explaining that intent, which implicates moral culpability, is not present in strict liability).

<sup>280</sup> See *id.*

<sup>281</sup> See *id.*



for the misuse, misappropriation, mischaracterization, and theft of the tissue are all legally protected. Even with an understanding that hospitals provide a service and not a product, consider that the common law has evolved to allow tort claims to proceed against hospitals for negligent actions involving organ transplantation.

Lastly, any tissue-related services that existed in 1968, the year of the Uniform Anatomical Gift Act's ("UAGA") enactment, were on the whole far less pecuniary, and focused on research.<sup>282</sup> The nature of the industry that seeks protective status through the UAGA, and immunity through blood shield regulations does not appear to be the "model" intended for protection from public accountability and scrutiny.

Strict liability is an appropriate remedy for patients injured by tissue banks placing contaminated products in the stream of commerce. Application of strict liability to tissue bank manufacturers based on their strictly pecuniary interests comports with a traditional doctrinal approach in this area. Consider the public's inability to test tissue banks' products prior to purchase and implantation. Strict liability as a legal remedy in cases where such egregious breaches in companies' duties seems consistent with contemporary social notions of fairness and justice.

Ultimately, tissue banks operate in a risk-intense industry and are in the best position to avoid accidents. Thinking otherwise exempts tissue banks from the type of liability to which sister industries are exposed, such as intra uterine device manufacturers, makers and sellers of tools, and car manufacturers. It is well established through the *Beshada v Johns-Manville Products Corp*<sup>283</sup> line of cases that courts will impose responsibility on a defendant for its failure to warn about risks that were scientifically unknowable at the time the defendant marketed its product.<sup>284</sup> Torts are about social policy—social insurance to be exact—and this being so, public policy rightfully fixes the burden of placing healthy, non-diseased human tissues on the tissue banks that collect, process, and sell these products. To place the burden of policing the industry on the consumer, without providing a

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<sup>282</sup> Alicia M. Markmann, Comment, *Organ Donation: Increasing Donations while Honoring Our Longstanding Values*, 24 Temple J Sci Tech and Envir L 499, 504–05 (2005) (explaining the altruistic roots of the UAGA).

<sup>283</sup> 447 A2d 539 (1982).

<sup>284</sup> See, for example, *In re Asbestos Litigation Venued in Middlesex County*, 491 A2d 700 (NJ 1984); *Michalko v Cooke Color and Chemical Corp*, 451 A2d 179 (NJ 1982); *Leonen v Johns-Manville Corp*, 717 FSupp 272 (D NJ 1989); *Campolongo v Celotex Corp.*, 681 FSupp 261 (D NJ 1988).

remedy for the injured consumer, ignores the purposeful civil check on markets.

### B. Takings Claims

Engaging takings law in the sphere of body parts negotiations when A is deprived by B (as well as the collective) is a natural evolution in the law itself. Inherently, there is something troubling and plain wrong when B takes from A without providing compensation—whether B is a private individual or the state. The problem beyond the obvious invasion and the emotions that attend such an action, include A bearing the transaction costs of the deprivation, exposure to E,F, and G to do the same (if there are no disincentives or penalties), and the loss of the thing itself. In the medical and biotech contexts, B might argue that A is in a pareto superior position if what was taken happened to be abnormal or even diseased. Because people tend to attach values to those dichotomous positions; A with an abnormal tumor is in a bad condition, if B takes the tumor and keeps it, A is better off—particularly if she happens to be poor and cannot afford surgery. But such logic although seductive, is deceptive, incomplete, and wrong. If A's capacity to contract and ability negotiate with C or D to develop the unique cell line found in her tumor is denied, a taking far more valuable than tissue and flesh has occurred. Rights to contract have been undermined, rights in the thing itself and its future potential, and the most basic right of autonomy—to be free from the interference of others are implicated by B's actions. Future cases will bear this out, and they will oblige us to rethink *Moore*.

The *Newman* and *Brotherton* cases will likely be instructive on whether future courts are willing to conceptualize tissues or the rights to them as property and thus provide a remedy under takings theory. Both cases involved the nonconsensual removal of corneas from cadavers and were initiated by relatives whose exclusive rights to burial had been interrupted by the state. Plaintiffs might be more inclined to pursue a takings remedy as they are not limited to one legal theory when bringing suit for such an action. In *Dico, Inc v United States*,<sup>285</sup> for example, the plaintiff claimed relief under both due process and takings theory. The court noted that the fact that the legal theories pre-

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<sup>285</sup> 48 F3d 1199 (Fed Cir 1995).

sented by the plaintiff are different does not require that the relief be different.<sup>286</sup>

In *Newman*, a presumed consent case, the Ninth Circuit recognized a property interest in a dead body. In articulating an analysis for the majority, Judge Fisher invoked the Fourteenth Amendment, noting that it prohibits states from “depriving any person of life, liberty, or property without due process of law.”<sup>287</sup> The threshold for a case alleging a state deprivation is that a plaintiff must show: 1) a deprivation; 2) of property; 3) under color of state law. If plaintiffs are able to prove those three elements, as indicated in a 48 USC section 1983 claim, the court must consider “whether the state afforded constitutionally adequate process for the deprivation.”<sup>288</sup>

How might takings theory actually apply? A property owner cannot bring a claim for just compensation until she has “sought and been denied compensation through procedures provided for this purpose.”<sup>289</sup> If the plaintiff presents a facial challenge to the regulation, no exhaustion of remedies is required. Typically, however, if the plaintiff is challenging the regulation as it applies to a particular property, the plaintiff must exhaust all remedies provided by the government. Herein lies a problem for unwitting presumed consent participants. Actual opportunities to object and be heard are more illusory than real. States have not established “opt-out” agencies or government entities where individuals can refuse to participate in a presumed consent scheme. Notice prior to harvesting is not required, but advised. Nor is there a hearing or adjudication mechanism prior to the tissue extraction.

We can also consider takings in the context of *Moore*. In recent years, scholars and commentators have pondered whether Moore’s cells became valuable only after they were no longer a part of his body. Such questions are sensitive to the investment of time, resources, and research invested by Dr. Golde in developing the cell line; yet these questions tend to overlook that it was a cell line developed from a spleen and fluids that were not his or the Regents of the University of California to “take.” It is worth scrutinizing this model detached from the more arcane (and false) notion of the body as having no intrinsic value. What if, as

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<sup>286</sup> Id at 1203.

<sup>287</sup> *Newman*, 287 F3d at 788.

<sup>288</sup> Id at 789.

<sup>289</sup> 27 Am Jur 2d Eminent Domain § 416 (2005).

in Model A(2), the goods coerced from Moore were unrefined diamonds, rather than the more valuable spleen and cell line? Would the only calculable injury have been Y's (the lawyer's) breach of fiduciary duty—the failure to disclose that he had a financial interest in the diamonds?

As discussed earlier, property rights are not absolute, meaning that they are not absolutely free from governmental interference. However, the governmental unit initiating the taking must abide by constitutional principles, and thus cannot interfere with property without providing notice and an opportunity for owners or possessors of property to contest the action.<sup>290</sup> Nor is the government's authority to take what it pleases, even for a noble public use, uncontested or absolute. Takings may also be effectuated differently depending on which arm of the government seeks use of the thing. For example, state and local government accession for public use can be effectuated by public referendum, the vote of an administrative board, and arguably a local administrative body with health and welfare oversight. At the federal level, the State can impose on a property right through legislation and by establishing a special procedure for ascertaining compensation.<sup>291</sup>

Deprivations that warrant just compensation because a government actor is involved implicate the Fourteenth Amendment. The Fourteenth Amendment prohibits states from depriving any person of life, liberty or property without due process of law. The property interests protected by procedural due process extend well beyond actual ownership of real estate, chattels, or money. The procedural protections of property under the Fourteenth Amendment are a safeguard of the security interests that each citizen has acquired.

Recent case law demonstrates the complex and sometimes inconsistent application of takings protections,<sup>292</sup> but nevertheless, the rationale for the takings clause is to prevent an unjust deprivation or imposition of costs on a few that “should be borne by the public as a whole.”<sup>293</sup> It would logically follow, then, that a government appropriation of private property (human tissue) for

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<sup>290</sup> Note however, these constitutional guarantees are also not absolute. For example, the state must not always provide a property owner a right to a hearing to determine the necessity of a particular taking if the taking is for a public use. *Id.*

<sup>291</sup> *Id.*

<sup>292</sup> See, for example, *Kelo v City of New London*, 545 US 965 (2005) (holding that the city's taking of private property to sell for private development qualified as “public use” within the meaning of the takings clause).

<sup>293</sup> *Armstrong v United States*, 364 US 40, 49 (1960).

a public good (transplantation) must be conditioned on just compensation. Presumed consent laws, passed in more than twenty-five states, and actively used in nine, raise the relevance of whether takings theory is applicable to government interference with the human body for purposes of furthering biotechnology and the public good. To be sure, the takings clause does not prohibit the state from interfering with one's body, but it requires that the government "assert its interest and subject them to scrutiny when it invades the rights of its subjects."<sup>294</sup>

*Pennsylvania Coal Company v Mahor*<sup>295</sup> established that a regulation can constitute a taking under the Fifth Amendment.<sup>296</sup> According to the court, "while property may be regulated to a certain extent, if a regulation goes too far it will be recognized as a taking."<sup>297</sup> The issue whether a taking has occurred will turn on whether the regulation or statute has penetrated the sacred boundaries of space, be it land, air, or in this case the body, and thus require just compensation. The *Pennsylvania Coal* court identified at least one important factor in determining when the provision has gone too far and must be considered a taking—the degree of diminution in value of the thing itself.<sup>298</sup> Other courts have further extended this line of reasoning to establish additional factors in determining whether a taking requiring just compensation has occurred. Some of the factors considered include: the economic effect on the individual deprived, the degree of interference with reasonable investment backed expectations, and the nature of the government action.<sup>299</sup>

Takings are not determined by the volume or amount of a "thing" which has been appropriated. Even if the property is a minuscule representation of the entirety, a successful takings action may be sustained.<sup>300</sup> In a surgical context, an appropriation of a cornea is as substantial as the severing of an arm or leg. When a medical examiner or coroner harvests corneal tissue from a cadaver's eyes and implants the material into another, it

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<sup>294</sup> *Newman*, 287 F3d at 799.

<sup>295</sup> 260 US 393 (1922).

<sup>296</sup> *Id.* at 415.

<sup>297</sup> *Id.*

<sup>298</sup> *Id.*

<sup>299</sup> *Pennsylvania Coal Company*, 260 US at 415 (discussing the diminution in value of the property); *Agins v City of Tiburon*, 447 US 255 (1980) (discussing the complete loss of economic value of the property).

<sup>300</sup> *Loretto v Teleprompter Manhattan CATV Corp*, 458 US 419 (1982) (defining the installation of a small cable box on landlord's residential apartment building as a taking, regardless of the fact that the physical invasion of the landlord's property was not large).

is apparent that an invasion has occurred. An analogous illustration is the government appropriating a narrow strip of land in the middle of an owner's property for purposes of building a road. The size of the road is not the determinate factor; one must consider only the fact that land has been excised for public benefit. Assuming that property rights have vested in the next-of-kin, that individual may successfully argue that nonconsensual cornea or heart valve removal from a cadaver is an invasion.

The public use prong of the takings clause requires that the state have a clear public interest in improving the health and well being of its citizens. One could quite easily reach the conclusion then, despite the fact that we as a society abjure the rescue doctrine, that providing sight for the blind and hearing for the deaf would be a legitimate government objective, resulting in a benefit for members of the public. However, tissue extractions without notice and an opportunity to appeal violate constitutional norms, particularly for such an intimate deprivation.<sup>301</sup> Thus, appropriating human biological materials from cadavers to benefit members of the public can be construed as a public use of private property.

Perhaps most challenging in parsing out whether takings theory has any application to the human body involves application of the just compensation element. The final prong of the takings analysis requires establishing just compensation. Just compensation for a government taking of human biological tissue is difficult. Unlike skin, ova, blood, and sperm, which are controlled to some extent by market and social forces, corneas, heart valves, and organs are banned from commercialization. Thus, determining the best way to assess compensation poses a challenge, but should not defeat a justiciable claim. Of the methods available to gauge just compensation, at least three seem viable. First, one can directly ascertain the market value applied by tissue banks and such companies to purchasers. In other words, we might look to prices established by the industry itself. Such data should not be difficult to obtain. Unlike at the time of *Moore*, such costs are now well established. Second, conversion usually applies to situations where the fair market may not be able to establish a standard value. Establishing just compensation through this method is more speculative than using market value, but might

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<sup>301</sup> Prior work discusses the racial and class implications of such policies, including issues addressing distributive justice and thus these issues will not be discussed here. See Goodwin, *Black Markets: The Supply and Demand of Body Parts* at 17 (cited in note 57).

be seen as an option by courts. Third, compensation might be based at the same level recoverable in a suit for wrongful interference with a corpse.<sup>302</sup>

Indisputably, states have an interest in aiding its citizens. Sometimes that interest might involve calling upon and burdening the collective to enhance the medical benefits of the individual or whole. Yet the nuances that shape those obligations are difficult to unpackage and are increasingly challenging as biotechnology provides a means to solve so many of our health problems. Nevertheless, the US Constitution "requires the government to assert its interests and subject them to scrutiny when it invades the rights of its subjects."<sup>303</sup> In this new world of biotechnology, citizens deprived of rights to their relatives' bodies, or defrauded by government actors in extraction of body parts, must be allowed the opportunity to fully pursue such claims. Their interests must be protected against the tyranny of biotechnology and blindness of the legislature.

#### CONCLUSION

Why does the legal status of body parts really matter? We could simply adopt a system whereby the burden of risk is placed upon patients, relatives, and buyers. Yet placing the onus on citizens to combat the excesses of biotechnology would be unfair and contrary to the best ideals of justice and sound public policy. Neither does such a proposition seem realistic. The challenge then, it seems, has much to do with how judges will judge.

Annually, over one million Americans undergo surgeries involving soft-tissues, skin, bones, and tendons acquired from cadavers.<sup>304</sup> Human tissue and organs suitable for burial at death or disposed of after medical procedures are given new life and

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<sup>302</sup> See Erik S. Jaffe, Note, *Nonconsensual Organ Removal*, 90 Colum L. Rev 528, 572 n 214 (1990) (noting that items with no market value are often converted based on subjective value rather than awarding a nominal amount).

<sup>303</sup> *Newman*, 287 F3d at 799.

<sup>304</sup> In the past few years the number of Americans utilizing human allografts has nearly doubled. Andrew Bridges, *Feds Close Body Parts Harvesting Company*, Associated Press (August 19, 2006) ("More than 1.3 million Americans each year have operations or procedures that use bone, skin, corneas or other types of tissue from donated cadavers. These range from dental implants using ground bone to knee ligament and spine repairs."). Schapiro, *Banking on the Gift of Tissue*, Milwaukee Journal Sentinel G1, (May 2, 2005) (cited in note 92). See also, Department of Health and Human Services, Office of Inspector General, *Oversight of Tissue Banking* (Jan 2001), available at <<http://www.fda.gov/cber/tissue/ovrst0101.pdf>> (last visited Feb 17, 2006) ("It is estimated that tissue banks distributed more than 750,000 [cadaveric] allografts for transplantation in 1999.").

value in research laboratories, commercial biotechnology supply companies, and human beings.<sup>305</sup> The expanded exploitation of human tissues and organs necessitates our study of their legal and social status.<sup>306</sup> Absent clear legal definition, the status of body parts is shaped by sporadic, inconsistent judicial analysis, which is woefully unmindful of the rapidly expanding, unregulated biotechnological terrain.

In *Moore*, Justice Arabian's concurrence reveals that the court's trepidation about granting the body a legal status was less grounded in the task of setting a value on the cell line or establishing its legal status. Rather, the potential denigration of personhood was his chief concern. Arguably the California Supreme Court took the path of least resistance by adopting a holding that recognized only a breach of fiduciary duty, but nothing more. By doing so, the court abrogated its responsibility to respond to factors exogenous to *stare decisis*. The difficulty for aggrieved plaintiffs is that in the absence of legislative guidance or any clear precedent on body part theft or fraud, they are left to rely on a constrained judiciary. The court's formalism is demonstrated by the majority's exclusive reliance on legislative enactments and the common law.<sup>307</sup> Absent guidance, the majority was unwilling to think as creatively as Dr. Golde and the other defendants about Moore's cell line.

Sadly, a poor example is made of the law when courts fail to engage in the dirty but necessary business of tussling, explaining, and deeply engaging with the law, with the ultimate objective being to do what is right and fair. Arbitrarily distinguishing entitlement to body parts based on the status of the possessor is but one example of the departure from the robust, thoughtful, and engaged approach of "judging" done by Traynor, Hand, and Cardozo. The Honorable Mary M. Schroeder laments the loss of that type of judicial rule-making.<sup>308</sup> She describes how Cardozo not only canvassed prior decisions of his court, but also discussed reasons why the providers of products are held to have a "duty of

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<sup>305</sup> See Goodwin, *Commerce in Cadavers*, LA Times B15 (cited in note 16).

<sup>306</sup> See, for example, Gwen Mayes, *A Rose by Any other Name: Finding a Suitable Definition of Body Parts for Legal Purposes—A Legal Commentary*, *Transplant News* (Dec 9, 2002) (explaining that biotechnological advances has changed the way individuals view themselves: we are more protective of our bodies and our right of privacy).

<sup>307</sup> See *Moore*, 793 P2d at 489 ("[F]irst, no reported judicial decision supports Moore's claim, either directly or by close analogy. Second, California statutory law drastically limits any continuing interest of a patient in excised cells.").

<sup>308</sup> See Schroeder, 1994 Wis L Rev at 14 (cited in note 128).



care toward people other than the primary purchaser."<sup>309</sup> In a case involving the manufacture of an automobile with a defective wheel, she notes, "Cardozo ... determined that the same principles of liability that applied to the producers of dangerous products should apply to a manufacturer of a defective car, even though the car itself may not have been inherently dangerous."<sup>310</sup> In effect, she notes, "Cardozo took the law out of the horse and buggy age."<sup>311</sup>

By contrast, contemporary rule-making encumbers the very pitfalls Schroeder warns against. She scolds the bench, "we defer ... we are preoccupied with applying the proper 'standard of review,' ... we avoid deciding whether there was a legal violation by discarding the question."<sup>312</sup> This type of rule-making disserves all litigants, particularly patients and research subjects, by leaving them vulnerable to the thirsty grasps of researchers, physicians, universities, and tissue banks.

When courts fail to engage with those who seek the halls of justice for a fair and informed deliberation and redress, the law is perverted. Here too, in the expansive biotech age, judges must take the law out of the horse and buggy age. Thus a discourse about *naming* the body's legal status is hardly a frivolous pursuit. Its legitimacy is derived from the fact that we lack a nomenclature to fully assess, refer to, and describe the status of the body, leaving a robust industry with a spider-like reach to perform that legislative or judicial task.

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<sup>309</sup> *Id.*

<sup>310</sup> *Id.* at 14-15.

<sup>311</sup> *Id.* at 15.

<sup>312</sup> Schroeder, 1994 *Wis L Rev* at 10 (cited in note 128).