

## Comments

# Toward a Just Model of Alienability of Human Tissue

By BRIAN BUDDS, R.N., M.S.\*

"Will you buy my hair?" asked Della.

"I buy hair," said Madame. "Take yer hat off and let's have a sight at the looks of it."

Down rippled the brown cascade.

"Twenty dollars," said Madame, lifting the mass with a practised hand.

"Give it to me quick," said Della.

— O. Henry, *The Gift of the Magi*<sup>1</sup>

**WE LIVE IN** a time of remarkable technological advancement that holds with it the promise of great benefit to mankind. One need only look at daily headlines to see evidence of this advancement and the direct and potential advantage to human health. In particular, medical science is beginning to take the knowledge learned about the basic human genome and apply it to treating debilitating diseases.<sup>2</sup> Often, in what may seem to be science fiction, the source of these great benefits is the human body itself, including portions of the body that may be diseased.<sup>3</sup>

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1. O. HENRY, *The Gift of the Magi*, in *THE BEST SHORT STORIES OF O. HENRY* 1, 3 (Ben-nett A. Cerf & Van H. Cartmell eds., Random House, Inc. 1945) (1899).

2. See *FDA Clears Study to Inject Gene in Parkinson's Patients*, N.Y. TIMES, Oct. 11, 2002, at A30.

3. See *Cancer Vaccine Test Has Promising Result*, N.Y. TIMES, Oct. 14, 2002, at C7 (describing how a cancer vaccine harnesses the patient's own immune system to fight the disease).

As the body becomes the stuff of which products are made, the issue of its ownership becomes paramount. To date, the most widely significant authority on the subject is the California Supreme Court case *Moore v. Regents of the University of California*.<sup>4</sup> That controversial, and influential, decision held that use by researchers of cells removed from a patient's body did not support an action for conversion—the wrongful taking and use of another's property.<sup>5</sup> The court stated that a patient who unknowingly has cells harvested does not retain a property interest in those cells.<sup>6</sup>

In reaching this decision, the highly divided court seemed keenly aware of the policy considerations that would emerge, and advised that such matters are “more appropriately the subject of legislative deliberation and resolution.”<sup>7</sup> Indeed, the breadth of the policy issues related to the ownership of human tissues is illustrated in cases that rely on *Moore*. These cases deal with issues as diverse as whether survivors maintain a quasi-property right in a decedent's tissue,<sup>8</sup> whether a patient has any property rights over cells used in routine diagnostic procedures,<sup>9</sup> whether a researcher must disclose an intention to seek a patent on his genetic disorders research,<sup>10</sup> whether a stillborn fetus is “tissue” that may be dissected,<sup>11</sup> and whether a party may own the right to commercialize a “cell line” from cells used in research.<sup>12</sup>

There has been significant academic comment on the *Moore* decision, much of it centering on whether a person should have the right to sell his own tissue. Some have argued that the very language of a

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4. 793 P.2d 479 (Cal. 1990).

5. *See id.* at 493.

6. *See id.* at 489.

7. *Id.* at 488, 493.

8. *See* *Bauer v. N. Fulton Med. Ctr.*, 527 S.E.2d 240, 243 (Ga. Ct. App. 1999) (holding that appellant family member maintained a quasi-property right in tissue taken from deceased's body).

9. *See* *Cornelio v. Stamford Hosp.*, No. CV 960155779, 1997 Conn. Super. LEXIS 1928, at \*23–26 (Conn. Super. Ct. Jul. 17, 1997) (holding that a patient did not have property rights in tissue taken for use in diagnostic test).

10. *See* *Greenberg v. Miami Children's Hosp. Research Inst.*, 208 F. Supp. 2d 918, 923 (N.D. Ill. 2002) (holding no personal jurisdiction in a case where plaintiff alleged damages from not being informed of physician's intent to seek patent on research based on samples provided by plaintiff).

11. *See* *Janicki v. Hosp. of San Raphael*, 744 A.2d 963, 970 (Conn. Super. Ct. 1999) (holding that there was a greater duty of care in handling a fetus than in handling human tissue).

12. *See* *Miles v. Scripps Clinic & Research Found.*, 810 F. Supp. 1091, 1095 (S.D. Cal. 1993) (holding that there exists a right to commercialization of a cell line).

property analysis is insufficient and improper for this issue.<sup>13</sup> Others counter that the fairest approach is the predictable and practical law of property.<sup>14</sup>

One commentator, Charlotte Harrison, has recently tried to achieve some middle ground in the debate.<sup>15</sup> Her approach, based on a liability rule of compensation for human tissue, suggests that neither the pure market nor a complete proscription of alienability of tissue is the answer to this complex problem.<sup>16</sup> Rather, Harrison proposes a model of compensation predicated on the perceived justice in compensating tissue donors when their contribution has led to a commercially successful endeavor.<sup>17</sup>

Absent a clear national policy, this Comment suggests that the approach taken by Harrison, though flawed, may hold the seeds of a just methodology for managing this significant issue. Use of a partial liability rule, in which a collective valuation model replaces the pure market, may in fact address many of the concerns of those who fear a market driven exchange of human tissue. However, this Comment parts with Harrison and argues that fairness demands such a valuation take place at the time of tissue donation, not only if a product achieves commercial viability. Part I of the Comment reviews the holding in *Moore* and related cases in order to give perspective on the problem. Part II looks at the response to *Moore* and suggests that such issues be discussed with regard to three general areas: the need to protect individuals from being unduly influenced to donate tissue, the need to protect clinical research from any "chilling effect," and the larger impact on society of the choice to permit the "commodification" of human tissue. Part III introduces the approach taken by Harrison and her attempt to find a middle ground.

Part IV, while critiquing the assumptions underlying the Harrison model, suggests that her approach contains the groundwork for a more just methodology. Part V addresses which components must exist in such a model and recommends next steps.

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13. See Richard Gold, *Owning Our Bodies: An Examination of Property Law and Biotechnology*, 32 SAN DIEGO L. REV. 1167, 1171 (1995) (arguing that property discourse is insufficient for discussing the values attached to the human body and its parts).

14. See William Boulier, Note, *Sperm, Spleens, and Other Valuables: The Need to Recognize Property Rights in Human Body Parts*, 23 HOFSTRA L. REV. 693, 701 (1994) (recommending that the law of property is best suited for protecting the rights in one's own body).

15. See Charlotte H. Harrison, *Neither Moore nor the Market: Alternative Models for Compensating Contributors of Human Tissue*, 28 AM. J.L. & MED. 77, 78 (2002).

16. See *id.*

17. See *id.* at 93.

## I. Background: The *Moore* Decision and Beyond

In *Moore v. Regents of University of California*,<sup>18</sup> the plaintiff had been receiving treatment for leukemia at the defendant's hospital. A researcher, a research institute, a major pharmaceutical company, and the plaintiff's physician were also named as defendants. All of the defendants were aware that the plaintiff's blood and other tissue contained substances that were of potentially great commercial value in developing viable treatments. The defendant physician also had a consulting relationship with the Genetics Institute. Without disclosing either the commercial potential or the business relationships to Moore, and under the rubric of treatment, the defendants harvested Moore's spleen and blood cells and created a "cell line" from some of these key blood components.<sup>19</sup> The defendants then applied for a patent on the cell line.

The plaintiff sued on a theory of conversion claiming, *inter alia*, that he maintained a property interest in the harvested cells, that the interest had been tortiously converted, and that he had a proprietary interest in any product created from his cells.<sup>20</sup> Importantly, Moore also claimed that the defendant physician had breached a fiduciary duty to the plaintiff by failing to disclose the nature and extent of his research or his economic interests in that research.<sup>21</sup> It was on this latter theory that the court found for the plaintiff, holding that "a physician who is seeking a patient's consent for a medical procedure must, in order to satisfy his fiduciary duty and to obtain the patient's informed consent, disclose personal interests unrelated to the patient's health, whether research or economic, that may affect his medical judgment."<sup>22</sup>

With regard to the issue of conversion, however, the court found for the defendant. They reasoned that there were two significant policy considerations that must be balanced—the right of patients to make medical decisions and the ability of researchers to engage "in socially useful activities."<sup>23</sup> The court suggested that the former is well protected by the concept of informed consent and fiduciary responsi-

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18. 793 P.2d 479 (Cal. 1990).

19. As the court explains in footnote two, a cell line consists of cells that are taken from the body and cultured or supported in reproduction outside of the body. This process allows for the acquisition of certain genetic knowledge, as well as making cells available for research over time. *See id.* at 481, 482 n.2.

20. *See id.* at 487.

21. *See id.* at 483.

22. *Id.* at 485.

23. *Id.* at 493.

bility,<sup>24</sup> and that allowing a tort of conversion would clearly threaten the latter by imposing a burden on researchers and the biotechnology industry.<sup>25</sup> Accordingly, the court held that “the use of excised human cells in medical research does not amount to a conversion.”<sup>26</sup>

The majority’s opinion is strongly supportive of the researchers’ interest and rejects legal arguments that might impede beneficial progress of research on a host of diseases.<sup>27</sup> Indeed, in what might have been an unwittingly accurate turn of phrase, the court recognized the enormous policy implications of the situation by suggesting that to allow a cause of action for conversion “will hinder research by restricting access to the *necessary raw materials*.”<sup>28</sup>

It is important to note that this divided court struggled, at times eloquently, with the difficult moral and philosophical questions that attend this issue. For example, in a concurring opinion, Justice Arabian recoiled from the concept of a sale of some portion of the human body for profit, saying of the plaintiff: “He entreats us to regard the human vessel—the single most venerated and protected subject in any civilized society—as equal with the basest commercial commodity. He urges us to commingle the sacred with the profane. He asks much.”<sup>29</sup>

Similarly, in the dissent, Justice Broussard articulated the unresolved policy issues associated with this subject. In particular, the majority’s holding that the plaintiff did not maintain an interest in cells that had been excised, did not change the fact that it is the patient who maintains the right to determine the uses of his body parts *prior* to their removal.<sup>30</sup> Further, and most important for this discussion, Justice Broussard noted that the concerns regarding the deleterious effects of a commodification of the human body were not addressed by the court’s decision:

Far from elevating these biological materials above the marketplace, the majority’s holding simply bars *plaintiff*, the source of the cells, from obtaining the benefit of the cells’ value, but permits *defendants*, who allegedly obtained the cells from plaintiff by improper means, to retain and exploit the full economic value of

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24. *See id.*

25. *See id.*

26. *Id.*

27. *See id.* at 494.

28. *Id.* (emphasis added).

29. *Id.* at 497 (Arabian, J., concurring).

30. *See id.* at 499 (Broussard, J., dissenting).

their ill-gotten gains free of their ordinary common law liability for conversion.<sup>31</sup>

This theme is carried on in another dissent by Justice Mosk, who noted that in scientific research, donors, while not clearly participating in the invention of a product, are "providing the researchers with unique raw materials" that make the invention itself possible.<sup>32</sup> To permit researchers "to freely mine or harvest valuable physical properties of the patient's body" would allow for the exploitation of research subjects, the consequent degradation of their bodies, and the potential unjust enrichment of the researchers at the expense of the donor.<sup>33</sup> This last concern becomes clearest when considering that the parties—researcher and patient—are not in equal bargaining positions.<sup>34</sup>

While *Moore* has not resolved these key issues, its influence has been significant. Notably, in a case that involved a dispute between researchers over the right to commercialize a cell line from donated cells, one federal district court found that there was such a right to be protected, but that an action for conversion does not provide the appropriate remedy.<sup>35</sup> The court repeated concern for the chilling impact that actions for conversion might have on scientific development.<sup>36</sup> However, they noted that the concern is less when the property is in the hands of researchers: "[T]he chilling effect on medical research that the *Moore* court feared is not identical here since the parties developing the cell lines are sophisticated researchers capable of protecting themselves legally, not patients who may be unaware of the economic uses for discarded body parts."<sup>37</sup>

## II. Discussion

The issues presented by *Moore* are multifaceted. Both the majority<sup>38</sup> and the dissents<sup>39</sup> noted the complexity of the policy issues, and suggested that the judiciary was not the proper place for their resolution.<sup>40</sup>

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31. *Id.* at 506 (Broussard, J., dissenting).

32. *Id.* at 512 (Mosk, J., dissenting).

33. *Id.* at 516.

34. *Id.*

35. *Miles v. Scripps Clinic*, 810 F. Supp. 1091, 1098 (S.D. Cal. 1993).

36. *See id.* at 1097.

37. *Id.*

38. *See Moore v. Regents of the Univ. of Cal.*, 793 P.2d 479, 493 (Cal. 1990).

39. *See id.* at 498–523.

40. *See id.* at 493; *see also id.* at 498 (Broussard, J., dissenting).

These larger policy concerns cluster around three issues: the protection of the individuals whose tissue may be involved, the preservation of the integrity of clinical research, and the larger, societal interests that relate to the issue of alienability or commodification of human tissue. This section of the Comment will look at each of these areas and discuss the arguments raised.

### A. Protecting the Individual

The *Moore* majority, acknowledging the treating physician's potentially competing interests, suggested that forcing disclosure of that conflict to the patient "may corrupt the patient's own judgment by distracting him from the requirements of his health."<sup>41</sup> There is a concern based on the potential vulnerability of people who may become either the subjects of research or, for other reasons, choose to transfer some portion of their body to another.

That there should be such concern for vulnerable patients is no surprise. The informed consent approach seen in Western clinical research is based on philosophic traditions that value patient autonomy.<sup>42</sup> Such an emphasis may be seen as an understandable response to the horrors of excesses and abuses in the research setting. For example, in the mid-20th century, Nazi physicians engaged in horrific experimentation on human beings.<sup>43</sup> Closer to home, the infamous Tuskegee Syphilis experiment was a long-term study of the natural history of syphilis in which study participants, all African-Americans, were denied information or treatment in order to compare the treated disease with the untreated natural history of syphilis.<sup>44</sup> Perhaps even more heinous, a study of hepatitis among profoundly impaired, institutionalized children in New York allowed for their deliberate infection.<sup>45</sup>

Outside the realm of clinical research, a similar concern has been raised as to the vulnerability of those who might be induced to sell some portion of their bodies. Researchers have looked at impoverished kidney donors in India who sought to escape poverty by selling

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41. *Id.* at 484.

42. See Laura A. Siminoff, *Money and the Research Subject: A Comment on Grady*, 1 *AM. J. BIOETHICS* 65, 65 (2001).

43. See ROBERT J. LIFTON, *THE NAZI DOCTORS: MEDICAL KILLING AND THE PSYCHOLOGY OF GENOCIDE* 269-70 (Basic Books 1986).

44. See JAMES H. JONES, *BAD BLOOD: THE TUSKEGEE SYPHILIS EXPERIMENT 1-2* (Maxwell MacMillan International 1993).

45. See JONATHAN D. MORENO, *UNDUE RISK: SECRET STATE EXPERIMENTS ON HUMANS* 249-50 (W.H. Freeman 2000).

their organs.<sup>46</sup> Noting the failure of those who donated, to receive what they had been promised, one researcher underscored that the problem is one of the poor being induced to sell their organs, a situation that would not be the same for those who were not poor or desperate.<sup>47</sup>

Clinical research provides very few guidelines, but a rich discussion of the ethics of paying research participants may provide insights into this issue. There are two key ethical arguments against paying research subjects: first, to do so would take advantage of a person's particular vulnerability, and second, the participant may already be receiving a benefit from the study.<sup>48</sup> Both of these arguments are theoretically applicable to the issue of tissue donation and deserve a more detailed investigation here.

## B. The Vulnerable Patient

Key to the discussion of patient vulnerability is whether the factors that bear on a patient's choice to participate in clinical research may be subject to undue influence.<sup>49</sup> Indeed, federal regulations governing human research forbid both coercion and the exercise of undue influence.<sup>50</sup> What makes an influence *undue* is a matter of great dispute. It has been suggested that any influence that is excessive or inappropriate diminishes a person's autonomous choice to participate and could be considered undue.<sup>51</sup>

Thus, the undue influence analysis may hinge upon whether the person so influenced has a decreased choice with regard to voluntary participation. For example, does such a person find the participation unwelcome, but because of the irresistible nature of the inducement, find himself unable to refuse?<sup>52</sup> This concern takes on greater significance when the participant is potentially more vulnerable because she

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46. See Madhav Goyal et al., *Economic and Health Consequences of Selling a Kidney in India*, 288 JAMA 1589, 1589 (2002) (describing study in which poor people sold a kidney, used proceeds to pay off debts and then, on average, saw their family income decline).

47. See *id.* See also Eric Nagourney, *Rx Money: When People Sell Their Kidneys*, N.Y. TIMES, Oct. 8, 2002, at F6.

48. See Neal Dickert & Christine Grady, *What's the Price of a Research Subject? Approaches to Payment for Research Participation*, 341 NEW ENG. J. MED. 198, 198 (1999).

49. See Christine Grady, *Money for Research Participation: Does It Jeopardize Informed Consent?*, 1 AM. J. BIOETHICS 40, 40 (2001).

50. See 45 C.F.R. § 46.111 (1991) (stating the requirements for informed consent in clinical research including the goal of minimizing the risk of "coercion or undue influence").

51. See Dickert & Grady, *supra* note 48, at 198.

52. See *id.*

is ill.<sup>53</sup> This argument posits that a researcher has an obligation to protect an unhealthy study participant from being unduly influenced, i.e., finding the inducement to participate so excessive or inappropriate that the subject would not properly attend to the necessary choices about her health.<sup>54</sup>

It is undoubtedly this fear of exploiting a person's vulnerability that underlies the discussion of undue influence and distinguishes it from other examples of compensation. An attempt to influence a person's behavior by remuneration—even seemingly excessive remuneration—is normally not rejected in other contexts. For example, there is no argument against using money to attract workers to do dangerous jobs. "Most people accept financial compensation for dangerous work, such as construction, mining, and deep sea diving."<sup>55</sup> However, inducing a person to choose a particular treatment for a serious disease or to donate a portion of their own body gives us pause in a way that inducing healthy people to engage in a particular line of work does not.

There are at least two understandable reasons for this hesitancy when it comes to issues of health. First, the horrific examples of exploitation of vulnerable human subjects discussed above are within our collective memory and should stay there as a warning against any such future behavior. Second, and perhaps more germane, is the realization of how easily an ill patient can be influenced to make a choice of a treatment option. At least one physician has noted the inordinate ability to shape a patient's choice that lies within his power:

I could get most of my patients to participate in almost any kind of clinical study. They would swallow new drugs, receive infusions of calcium or glucagon, or even embrace esophageal or rectal catheters because they had faith in my goodwill or, I now fear, because they wanted to please me.<sup>56</sup>

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53. See David B. Resnick, *Research Participation and Financial Inducements*, 1 AM. J. BIOETHICS 54, 55 (2001) (This article discusses, *inter alia*, the differences in expectations between healthy volunteers and those who are ill. Resnick suggests that there is a problem known as the "therapeutic misconception" in which a patient, despite proper informed consent, perceives there will be a benefit from participation in a trial whether or not the belief is reasonable.)

54. See *id.*

55. Julian Savulescu, *The Fiction of "Undue Inducement": Why Researchers Should Be Allowed to Pay Participants Any Amount of Money for Any Reasonable Research Project*, 1 AM. J. BIOETHICS 2 (2001).

56. Jesse A. Goldner, *Dealing with Conflicts of Interest in Biomedical Research: IRB Oversight as the Next Best Solution to the Abolitionist Approach*, 28 J. L. MED. & ETHICS 379, 392 (2000).

Perhaps the most effective counter argument is that suggested by Christine Grady, who acknowledges that there are times when inducements—for example, a large amount of money offered to a destitute person to participate in a study—may be so great as to unduly influence.<sup>57</sup> She raises a crucial question in response to this issue: “[D]o we protect such people by allowing them to participate in . . . research without receiving money or by not allowing them to participate at all?”<sup>58</sup> She challenges researchers to do more careful analysis of all of the factors that go into a participant giving informed consent and not relying on the elimination of pecuniary reward as a guaranty against undue influence.<sup>59</sup>

Others have echoed this need to look at the question of influence more broadly than by limiting it to the issue of payment. The very context in which research is performed may be the source of many different influences that come to bear on the potential participant. It has been argued that the greatest concern is not that a patient might be induced to enter a study, but that she might be induced to enter a study that lacks the basic safeguards to reduce risks of harm to the participants.<sup>60</sup> Indeed, precluding payments to patients so as to not unduly influence them does not even begin to address the influence that might be brought to bear on the same patient whose physician has been paid to recruit participants for the study.<sup>61</sup> As one researcher has put it:

The ethical duty of the research community is not to be “thought police” guarding against subjects’ making decisions for the “wrong” reasons, but to assure that the research we are asking subjects to consider participating in is not so onerous or so dangerous that participation would seriously threaten their health and safety.<sup>62</sup>

In short, the issue of whether an influence is undue or not is anything but simple. There are no bright lines offered. Rather, the analysis becomes one that includes the nature of the inducement as well as the status of the party being induced. The dollar amount of the offered inducement should be considered to rationally judge whether a person may be unduly influenced. The offer of a large amount of money may simply be one influence among many. Such an offer, how-

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57. See Grady, *supra* note 49, at 42.

58. *Id.*

59. See *id.*

60. See Rebecca Dresser, *Payments to Research Participants: The Importance of Context*, 1 AM. J. BIOETHICS 47, 47 (2001).

61. See *id.*

62. Siminoff, *supra* note 42, at 65.

ever, in the context of extreme poverty, lack of true medical choices (or information), a desperate medical condition, and strong influence of a physician may become part of a total influence that effectively reduces a person's choice to refuse participation. It is hard to imagine a confluence of influences that would similarly diminish the would-be deep-sea diver's ability to refuse an offer of employment. Thus, while the analogy to dangerous employment is strong, it may not be perfectly applicable in the area of research on human subjects.

### C. Patients Already Receiving Benefit

Another issue is the appropriateness of payment when the participant is already receiving a benefit by virtue of participating in the research.<sup>63</sup> The premise of this argument is that a study participant may already be receiving treatment as compensation for any value that he provides to the study, and thus, should not receive further payment. This argument has been criticized on several grounds. First, there are clinical studies in which patients participate and the benefit to them, if any, is unclear.<sup>64</sup> Further, even though a patient may benefit, there is no reason that payment must necessarily be unavailable.<sup>65</sup>

How this issue relates to the alienability of tissue may be seen in a hypothetical involving ongoing clinical research. Consider that a major pharmaceutical company is conducting research of an anti-viral medication for a disease such as HIV/AIDS. The medication being tested is proving effective in the treatment of the disease. The nature of the agreement between the patient and the researching company—as clearly spelled out in the informed consent form—is that the patient will participate in the study, give frequent blood samples in order to monitor the safety and efficacy of the treatment, and receive the indicated treatment for a defined period of time. Thus, the agreement between patient and researcher amounts to an exchange of the patient's time, effort, and willingness to monitor his body's response to treatment for a guarantee of treatment.

However, consider if the research sponsor were doing some related testing. For example, alongside the testing of this treatment they may be interested in determining if there were patients with a particu-

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63. See Dickert & Grady, *supra* note 48, at 198.

64. See *id.* at 198–99.

65. See *id.*

lar genomic sequence<sup>66</sup> who responded well or poorly to this treatment. This sort of data could lead to important information regarding the marketability of the agent under study. It is not, however, directly related to the safety and efficacy of the treatment that the patient is undergoing. Again, what if this or some other information were best obtained by way of a tissue biopsy, for example, a liver or lymph node biopsy?<sup>67</sup> Alternatively, perhaps that tissue is desired by the company for the possibility of some form of testing that does not yet exist. Are these situations, in which tissue is taken for the benefit of the researcher, to be seen in the same light as the tissue used to test the safety and efficacy of the treatment the patient is receiving?

#### D. Protecting the Integrity of Research

The arguments related to the protection of the biotechnology industry are well articulated in the *Moore* decision. The court envisioned the very serious implications of permitting the plaintiff to sue for conversion as “threaten[ing] with disabling civil liability innocent parties who are engaged in socially useful activities.”<sup>68</sup> The majority feared that a researcher could share human cells with another researcher and, in effect, broaden the liability to all researchers, even those not directly involved with the initial harvest.<sup>69</sup>

The court, noting the importance of research in human cells, used dire language to describe a situation that might ensue, suggesting that extending liability for conversion “threatens to destroy the economic incentive to conduct important medical research.”<sup>70</sup>

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66. It is beyond the scope of this Comment to discuss the particulars of clinical research. This reference to genomic medicine highlights the promising, but unknown, future. Genomics is a term used to describe the functions of genes:

The science of genomics rests on direct experimental access to the entire genome and applies to common conditions, such as breast cancer and colorectal cancer, human immunodeficiency virus (HIV) infection, tuberculosis, Parkinson’s disease, and Alzheimer’s disease. These common disorders are also all due to the interactions of multiple genes and environmental factors. They are thus known as multifactorial disorders. Genetic variations in these disorders may have a protective or a pathologic role in the expression of diseases.

Alan E. Guttmacher & Francis S. Collins, *Genomic Medicine—A Primer*, 347 *NEW ENG. J. MED.* 1512, 1512 (2002).

67. “Biopsy” refers to the taking of tissue from a living person for the purposes of diagnosis. This is often performed in clinical research and can be achieved in a variety of fashions, some more intrusive than others. The range of methods for acquiring a biopsy is from a simple taking of a blood sample to the removal of tissue in surgery. *See* *Mosby’s MEDICAL DICTIONARY* 191 (Kenneth N. Anderson, et al. eds. 4th ed. 1994).

68. *Moore v. Regents of the Univ. of Cal.*, 793 P.2d 479, 493 (Cal. 1990).

69. *See id.* at 494.

70. *Id.* at 495.

They suggested that each donation of tissue would require a “pedigree” check, a showing that the tissue used comes from a particular source,<sup>71</sup> and that any researcher that acquires a cell sample “purchases a ticket in a litigation lottery.”<sup>72</sup>

These fears translate into a general concern about the transaction costs involved in the acquisition of human tissue for research. The argument suggests that if a research company had to secure the rights to all samples of tissue it needed for its research, the transaction costs would be prohibitive.<sup>73</sup> It is suggested that the costs go beyond the actual monetary expenses and include the time and effort expended in the actual negotiation over tissue.<sup>74</sup>

This argument is not fully convincing in suggesting that a ban on alienability of tissue is needed to avoid the economic catastrophe feared by the *Moore* majority. Indeed, the dissent makes clear that the contribution of cells is, at best, limited in its claim on economic benefits, and may best be seen as a necessary commodity.<sup>75</sup> Thus, the argument of economic inefficiency may be a bit overblown. As the dissent notes:

[T]he great bulk of the value of a cell line patent and derivative products is attributable to the efforts of medical researchers and drug companies, rather than to the “raw materials” taken from a patient . . . the patient’s damages will be correspondingly limited, and innocent medical researchers and drug manufacturers will retain the considerable economic benefits resulting from their own work.<sup>76</sup>

The concern is, clearly, that any threat of a chilling impact on research not serve as a front for protecting other specific, financial interests of the researchers. The danger is that one motivation can serve as a hidden way of giving benefit to one party over another, often under the guise of benefit.<sup>77</sup>

### E. Protecting Societal Interests—The Cost of Commodification

The issues surrounding the alienability of human tissue have consequences that reach farther than the researchers and those who provide the tissue for medical research. As noted in *Moore*, products that

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71. *Id.* at 496.

72. *Id.* at 495–96.

73. See Harrison, *supra* note 15, at 87.

74. See *id.*

75. See *Moore*, 793 P.2d at 505 (Broussard, J., dissenting).

76. *Id.*

77. See Guido Calabresi & A. Douglas Melamed, *Property Rules, Liability Rules, and Inalienability: One View of the Cathedral*, 85 HARV. L. REV. 1089, 1115 (1972).

have been developed through biotechnology have had an enormous impact on many different human diseases.<sup>78</sup> If, as the majority suggests, there is a chilling effect on research, its reach would be far.

It has also been suggested that the “commodification” of humans—the treating of human body parts as fungible articles of commerce—can be degrading to the human spirit.<sup>79</sup> The long-term societal impact of commodification has been explored and found frightening in some instances. For example, one commentator has suggested that allowing the sale of fetal tissue would have an exploitative effect on Black women, given their likelihood to participate in such a market,<sup>80</sup> and thus, should not be permitted.<sup>81</sup>

The appropriateness to speak of the body as property or as a commodity has been questioned. Indeed, it has also been argued that the very language of property law analysis is grossly insufficient to capture the magnitude of value that humans impart to the body.<sup>82</sup> The concept of allowing one to profit from the sale of the human body has raised great opposition.<sup>83</sup>

Often, the suggested approach to dealing with the ills that would flow from a free commodification of human tissue is to preclude the practice and insist that the tissue, when conveyed to another, be donated.<sup>84</sup> When the economic analysis of the probable pricing and availability of fetal tissue leads to an analysis that one segment of the population would be adversely impacted, the suggested response is to ban that practice.<sup>85</sup> This is, essentially, what the *Moore* court did in disallowing the plaintiff a property interest in his excised cells.

However, it has been argued that the debate over the commercialization of the human body is mistakenly based on the fiction that markets in human tissue do not exist.<sup>86</sup> Indeed, Mahoney claims that not only do such markets exist, but they are extensive and necessary.<sup>87</sup>

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78. See *Moore*, 793 P.2d at 494.

79. See *id.* at 497 (Arabian, J., dissenting).

80. See Khiara M. Bridges, *On the Commodification of the Black Female Body: The Critical Implications of the Alienability of Fetal Tissue*, 102 COLUM. L. REV. 123, 124–25 (2002) (arguing that market forces would cause Black women to be exploited while denying them the benefits, if any, that would accrue from the donation of fetal tissue).

81. See *id.*

82. See Richard Gold, *Owning Our Bodies: An Examination of Property Law and Biotechnology*, 32 SAN DIEGO L. REV. 1167, 1171 (1995).

83. See Julia Mahoney, *The Market for Human Tissue*, 86 VA. L. REV. 163, 164–65 (2000).

84. See Bridges, *supra* note 80, at 127.

85. See *id.* at 123–25.

86. See Mahoney, *supra* note 83, at 166.

87. See *id.* at 208.

Donated tissue has value added to it at every step of the process toward its intended developmental goal. The only part of the process denied valuation is the original donation.<sup>88</sup>

When one recognizes the impact of this fiction, arguments that speak of the horrors that will occur if patients or research subjects are reimbursed—either for their participation or their tissue—seem thin, at best. For example, it has been argued that the reimbursement of patients for participation in research will lead to a “tradesman morality” and impair the relationship that ought to exist between the subject and the rest of society.<sup>89</sup> However, these arguments are based on the premise that the study participant *ought* to be motivated by altruism, but impose no such similar moral obligation on the practitioner conducting the research.

### III. Harrison: A Middle Ground?

In *Neither Moore nor the Market: Alternative Models for Compensating Contributors of Human Tissue*, Charlotte Harrison argues that one reason no clear policy has emerged on the issue of compensating donors may be that the legal models used to analyze the issue are inadequate.<sup>90</sup> The ethical and practical complications flowing from a free market property analysis and the harshness of a complete proscription of compensation, following *Moore*, all fail to satisfy the interests at stake.<sup>91</sup> Instead, she argues that an intermediate approach, drawing on other successful models of compensation, may move us toward an effective policy.<sup>92</sup>

In essence, Harrison acknowledges that many of the arguments against both a free market approach and an approach of complete inalienability have merit. She offers a model that accepts parts of both of the competing views. For example, she suggests that most instances of human tissue transfers continue to be treated as donations.<sup>93</sup> However, in those circumstances in which the donated tissue proves to be “unusually valuable” in the development of a commercially valuable product, compensation would be in order.<sup>94</sup> Central to her model is that such remuneration would be achieved “through a transparent,

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88. *See id.*

89. Tod Chambers, *Participation as Commodity, Participation as Gift*, 1 AM. J. BIOETHICS 48, 48 (2001).

90. *See* Harrison, *supra* note 15, at 78.

91. *See id.*

92. *See id.*

93. *See id.* at 93.

94. *Id.*

collectively-guided process conducted at a distance from the original contribution."<sup>95</sup>

Harrison's approach is based on the concept of a liability rule, which she suggests occupies the middle ground between property rights and inalienability.<sup>96</sup> The concept is described in a classic work by Calabresi and Melamed,<sup>97</sup> that argues when one has a property right in some thing, another may appropriate that right by means of a voluntary transaction.<sup>98</sup> However, while society may deem that these parties have a property right, it says nothing about the value of the thing in question—that is decided in the marketplace.<sup>99</sup> An inalienability rule is even simpler in that the state simply determines that the thing is inalienable, that the parties cannot transact an exchange, and thus, value is not an issue.<sup>100</sup> A liability rule permits the exchange, but value is determined by an objective third party, not by the parties involved.<sup>101</sup> There are many reasons why a liability rule might be preferable to a strict property rule. As Calabresi and Melamed note, a liability rule is often the most economically efficient method when "the cost of establishing the value of an initial entitlement by negotiation is so great that even though a transfer of the entitlement would benefit all concerned, such a transfer will not occur."<sup>102</sup> While offering eminent domain and accident compensation as examples of situations in which pre-transaction negotiations would be impossible or impractical, the authors suggest that any situation in which a "market valuation of the entitlement is deemed inefficient"<sup>103</sup> is one in which a liability rule or "collective valuation"<sup>104</sup> might be superior.

Harrison applies this reasoning to the issue of compensation for tissue donation. Having noted that one of the major concerns of the *Moore* and other courts was the transaction costs associated with a property rights approach, she suggests that one way to deal with this would be to allow the setting of value to be done by an objective third party.<sup>105</sup> Thus, in general, an inalienability rule would apply and tissue

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95. *Id.*

96. *See id.* at 94.

97. *See* Calabresi & Melamed, *supra* note 77, at 1089.

98. *See id.* at 1092.

99. *See id.*

100. *See id.*

101. *See id.*

102. *Id.* at 1106.

103. *Id.* at 1110.

104. *Id.* at 1109.

105. *See* Harrison, *supra* note 15, at 97.

would need to be donated freely and voluntarily.<sup>106</sup> However, in those circumstances where a researcher would have created something of commercial viability, an independent tribunal would assess the appropriate compensation for those who donated tissue to the development of the product.<sup>107</sup>

One benefit that would flow from such a model, according to Harrison, is the decreased transaction costs associated with the tracing and notification of tissue donors.<sup>108</sup> The research company or academic researcher would not have to trace or record all tissue donations, only those associated with an attempt to commercialize a proven product.<sup>109</sup> Further, with regard to the cost to the developer, companies would benefit from pricing predictability, as opposed to a price that is set on the open market.<sup>110</sup> Similarly, potential tissue donors would benefit. There would be no need to engage in pre-donation negotiation or even be aware of the potential for commercial development.<sup>111</sup>

To summarize, Harrison's proposal begins with maintaining a ban on the private sale of tissue by the donor to the researcher but allows for remuneration if the donation leads to the development of a commercially viable product.<sup>112</sup> At the time that a commercial entity is preparing a product for going to market, it would be required to report the use of any human tissue to an agency or "tribunal" that would adjudicate the proper compensation.<sup>113</sup> Donors would then be traced, notified, and compensated where possible.<sup>114</sup> By donor choice, or in cases where tracing the donors was not possible, the collecting agency or some other entity, such as a patient advocacy group, could be designated to receive the remuneration.<sup>115</sup>

#### IV. Critique of Harrison's Model

The model proposed by Harrison is an attempt to move along policy with regard to the use of human tissue in research. Indeed, her efforts seem designed to deal with the fact that since the *Moore* deci-

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106. *See id.*

107. *See id.*

108. *See id.* at 99.

109. *See id.* at 97.

110. *See id.*

111. *See id.* at 87.

112. *See id.* at 97.

113. *See id.*

114. *See id.*

115. *See id.* at 98-99.

sion, and in "twelve years of controversy, no professional consensus or concerted public policy response has emerged."<sup>116</sup> Further, her assessment that the central problem involved may be related to the legal models used is a bold attempt to open up discussion on this issue.

The suggestion that a liability rule may be appropriate in this situation is particularly appealing. As the review of objections to the property rule approach show, even if the transfer of tissue is allowed as property, one of the key problems is assigning an appropriate value to tissue. A free market may produce prices that are exorbitantly high and thereby may lead to coercion.<sup>117</sup> Further, the price offered may not be just and there is no assurance it will be paid.<sup>118</sup> As Harrison noted, the "true" value of a given tissue may simply be unknowable at the time of donation given the uncertainty of commercial development or even the nature of the proposed research.<sup>119</sup> Perhaps opening a free, unregulated market in human tissue is too great a burden on society.<sup>120</sup> The difficulty in fairly assigning value seems to make tissue transfer a dilemma in which a liability rule, or some variation on that, might be appropriate. As noted by Calabresi and Melamed, this is the sort of circumstance in which society has turned to a liability rule.<sup>121</sup> At the very least, this situation represents a moment in which society might make a choice as to the best method to achieve the goals of economic efficiency and just distribution, deciding whether "market transactions or collective fiat is most likely" to bring this about.<sup>122</sup>

There are, however, at least two key problems with the Harrison approach, both of which involve the time when the tissue donor may be recompensed. First, in choosing to assign value to a donated tissue only after the researcher has created a commercially viable product, she fails to acknowledge the value of the donation prior to that fortuitous moment. Second, the argument that transaction costs would be substantially lower if compensation were only allowed at the time of commercial success is based on flawed assumptions.

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116. *Id.* at 78.

117. *See* Bridges, *supra* note 80, at 123.

118. *See* Goyal, *supra* note 46, at 1591.

119. *See* Harrison, *supra* note 15, at 87.

120. *See* Mahoney, *supra* note 83, at 168 (citing reasons that society shrinks from permitting an unregulated market in human tissue); *see also* Gold, *supra* note 13, at 1246 (suggesting the market is an insufficient tool for dealing with this issue).

121. *See* Calabresi & Melamed, *supra* note 77, at 1106-07.

122. *Id.* at 1097.

The choice to assign value at the moment that a donation has “commercially utility”<sup>123</sup> suggests that Harrison supports, at least partially, the claim made by the plaintiff in *Moore* that he should have a proprietary interest in any ultimate product that is derived from his donation.<sup>124</sup> It most certainly rejects the minority approach, which suggests that the tissue can be seen as the “raw material” in the process of development.<sup>125</sup> At the very least, her insistence on maintaining a mandatory donative approach at the outset assures a system that, as Mahoney suggested, prohibits only the original donor from commodifying the tissue—yet, all others in the process may do so.<sup>126</sup>

This problem becomes clearer if one understands that the value of the donation to the researcher may not be measured only by the ultimate commercial success of the endeavor. For example, returning to the hypothetical AIDS research situation discussed above, consider that the tissue extracted from the study patients by biopsy has shown that there is a particular genomic profile that will respond poorly to the proposed treatment, and that best estimates are that the product being developed, though effective in some circumstances, will not be effective broadly enough in the population to be commercially viable. This knowledge will not translate directly into profit earned by the researcher, which could be shared with those who donated tissue. Rather, this knowledge will result in loss. However, this knowledge is not without enormous value to the company that can use it to suspend the expensive work of development and shift to another tactic. In short, this new information enables the company to avoid greater losses.

Similarly, in situations where a company or researcher is unsure of the full purpose or nature of the intended research, the donated tissue may still have some value—even if that value is difficult to assign. The question becomes whether the researcher should have to pay for this tissue upon serendipitously uncovering a use for it. Thus, the researcher that froze the biopsy sections for the possibility of future testing has acquired the ability to do that testing whether or not it ultimately produces a commercially viable product. Moreover, following Harrison’s approach, the researcher has acquired the needed raw materials without any cost to himself.

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123. See Harrison, *supra* note 15, at 96–97.

124. See *Moore v. Regents of the Univ. of Cal.*, 793 P.2d 479, 482 (Cal. 1990).

125. See *id.* at 494.

126. See Mahoney, *supra* note 83, at 174–75.

This leads to the second flaw in Harrison's model—the issue of transaction costs. Her model seems to accept the argument of the majority in *Moore* that all researchers who deal with human tissue should do a “pedigree” check on the tissue to avoid a charge of conversion.<sup>127</sup> This argument also fails if one allows for a model in which the donation is seen as “raw material” and not as conveying a proprietary interest to the donor. Following the “raw material” line of reasoning, the transaction costs could be dealt with at the time of donation. Indeed, it is arguably a more efficient process to assign value at the time of donation and transact a deal that includes a waiver of any claim of proprietary interest. Then, whatever value the researcher, company, or inventor added to the donation would clearly belong to that entity and one need not expend the energy or cost involved in “tracking down” those who might have contributed—a situation that Harrison acknowledges is replete with difficulties.<sup>128</sup>

Indeed, a practical matter that makes the model suggested by Harrison problematic is the time involved. She acknowledges that justice may demand remuneration for donors of tissue.<sup>129</sup> However, to suggest that such remuneration is not appropriate until commercial viability is proved—especially in the cases where such tissue is derived from patients who are participating in clinical trials and are ill—increases the possibility that those patients will be neither found nor compensated, as many may have died by that time.

Harrison's answer to this problem suggests that, as in punitive damages in torts, the company, to avoid unjust enrichment, should be forced to share profits with some third party—an aggregate or patient advocacy group.<sup>130</sup> However, this is removed from the transaction that seems most just, and will most likely increase transaction costs by forcing determinations as to whom the compensation should rightly go. In short, the laudable effort of avoiding unjust enrichment creates a potentially significant increase in the transaction costs involved in the management of this issue.

Lastly, Harrison's recommendation of how to implement her proposal suggests that the proper regulatory body to carry out such a program may already exist. She proposes both the Patent and Trademark Office and the Food and Drug Administration as organizations that are currently involved and may be able to monitor the donation of

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127. See *Moore*, 793 P.2d at 496.

128. See Harrison, *supra* note 15, at 99.

129. See *id.*

130. See *id.* at 99.

tissue and compensation of patients.<sup>131</sup> Analyzing the propriety of selecting one government agency for such a task is beyond the scope of this Comment. However, the key is to identify the proper stakeholders and ensure their representation in the process. Whether that could happen with an existing governmental agency is an open question.

## V. Suggestions for Another Model

One of the benefits of a liability rule is that it can be helpful when valuation of an entitlement is either impossible or extremely difficult.<sup>132</sup> Further, such a rule is often used “because it facilitates a combination of efficiency and distributive results which would be difficult to achieve under a property rule.”<sup>133</sup> It is this difficulty in assessing the value of human tissue that is at the heart of many of the problems that have been discussed thus far.

For example, the unpredictability of supply and demand can lead to fears that impoverished organ donors or socially disadvantaged fetal tissue donors may be exploited or degraded. The uncertainty of the eventual success of biotechnological advances makes it impossible to know whether one donated tissue sample will be involved in the creation of a miracle treatment, while another may become medical detritus. Indeed, the inability of researchers to know with any certainty the cost of their “raw material”—either at the time of acquisition or litigation over a charge of conversion—leads to the “chilling effect” feared by the *Moore* court.

At least at some level, this argument is not one of *whether* there ought to be any compensation for human tissue. In fact, Mahoney’s arguments that there are already thriving tissue markets are persuasive.<sup>134</sup> The question, instead, is *who* is to be paid and *how much* he will be paid. Another open question, as evidenced by criticisms of Harrison’s model, is *when* parties ought to be paid for the donated tissue.

Harrison suggests that an independent agency or tribunal should determine a “contributor’s eligibility for compensation and the appropriate amount or percentage of profits to be awarded.”<sup>135</sup> This Comment recommends implementation of a policy by which all donations of human tissue are to be compensated in some form—either by direct remuneration or by services. Thus, such compensation would be

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131. *Id.* at 98.

132. *See* Calabresi & Melamed, *supra* note 77, at 1106–07.

133. *Id.* at 1110.

134. *See* Mahoney, *supra* note 83, at 174.

135. Harrison, *supra* note 15, at 88.

come standard and the attendant transactions costs would be predictable and capable of being budgeted.

The remaining issue for such a regulatory body would then be the appropriate compensation for the donated tissue. It is well beyond the scope of this Comment to suggest the exact mechanism by which such prices or payments would be reached. Unraveling the complexities of arguments regarding methods and models of compensation is beyond the simple goal of this paper—to provide a suggested approach.<sup>136</sup> This Comment suggests that a simple concept of fairness—a weighing of competing valuations—may be sufficient to guide the process.

A simple example of a liability rule is the doctrine of eminent domain, where a governmental body attempts to simulate market forces in assessing value of the condemned or appropriated property.<sup>137</sup> The interests of the parties, the homeowner, and the government, are clear. Also, the difficulty in approximating a market value is not great—one can look at the market value of comparable properties and translate it to a figure for the property in question.

The issue of tissue donation, particularly in the context of clinical research, is not so simple. There are, as we have seen, many different stakeholders or interested parties. Each may apply a completely distinct method of valuation to the tissue in question. Nor is there “comparable property” that can be used as a guide, particularly in the area of creative, groundbreaking research.

Thus, the goal of a disinterested, objective, third party charged with the valuation of human tissue should be to blend the various interests represented in as fair and just a manner possible, while maintaining fundamental protections in the three areas that have been outlined. Individuals should be protected against exploitation. The integrity of the research process should be protected against a chilling effect that could cripple it. Moreover, society should be protected against the excesses of commodification.

#### A. Protection of Individuals

A first concern that ought to be considered in assessing the value of tissue donation is the nature of that donation itself. Here, regula-

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136. See Margaret Jane Radin, *Compensation and Commensurability*, 43 DUKE L.J. 56, 57 (1993) (comparing models of compensation in tort law); see also Neil Duxbury, *Law, Markets and Valuation*, 61. BROOKLYN L. REV. 657, 663–74 (1995) (critiquing, *inter alia*, Radin’s arguments against commodification).

137. See Calabresi & Melamed, *supra* note 77, at 1106–07.

tors should consider the intrusiveness of the procedure of acquiring the tissue, the impact of such an acquisition on the donor, and, perhaps, the frequency of donation. For example, the impact on the patient of a tissue donation that consisted of a simple, single blood draw would be compared to a donation that called for an invasive and painful procedure—for example, a bone marrow donation—on a frequent basis. Perhaps experts in health care and in research could even devise some sort of scale or formula by which the comparative impact of procedures could be measured. That measure, then, could serve as one factor in the overall assessment of value.

A second consideration would be the nature of the context in which the tissue is sought. Here, the focus is on whether there is some other benefit accruing to the donor of the tissue. Thus, a healthy volunteer receiving no benefit from a study might be compared with an ill patient who is receiving treatment in the context of a clinical trial, such as in the hypothetical noted above. These issues are very difficult, if not impossible, to quantify. Indeed, it is that very difficulty which gives support to the use of a liability rule. However, the issue that regulators would focus on here is whether or not the donation of tissue exceeds the value of the benefit being received. If the tissue donation were to serve in the monitoring of the safety and efficacy of the original trial, perhaps there would be no call for compensation. On the other hand, if the donation were for some other purpose, which accrues some benefit to the researcher beyond the original bargained for exchange, it would support some level of compensation.

Perhaps the most basic issue with regard to the protection of the individual is the safety of the process. This is based on the concern that a patient can be unduly influenced to do something that is perhaps harmful. Here, a regulatory body needs to be assured by the Food and Drug Administration that the very nature of the research is not one that would be harmful to human subjects. That said, there are various risks that attend to the acquiring of human tissue and the participation in clinical research. The nature of these risks could be yet another factor in assessing just compensation.

## **B. Protection of Research**

In discussing the protection of research, the focus changes from the potential donor to the potential payer. If the *Moore* court's concern about the "chilling" of an industry is to be heeded, then the na-

ture of the industry itself must be considered.<sup>138</sup> Generally, considerations should include whether or not a potential human tissue user is engaged in purely commercial research or in basic scientific inquiry, or some hybrid. Here, though, the boundaries are often not clear—the division is often between academic institutions, whose inquiry may be more basic science in nature, and for-profit commercial enterprises, whose focus is decidedly the generation of profit.

Furthermore, there are differences among the commercial entities themselves. Some, be they small start-up or large pharmaceutical companies, may be engaged in groundbreaking, innovative research that involves significant financial risk. Others may simply wait on the sidelines, watching the progress of the innovators and, when they see the right moment, engage in “me too” research by which they can “pick the low hanging fruit.” All of these factors can be considered in setting the appropriate amount for compensation or the price of the “raw materials.” Innovators can be rewarded by being asked to shoulder less of the overall burden, while those who seek to leverage others’ work into their own profit can be “taxed” by making requirements for a greater financial contribution. The nature of the exchange of this information, among and between research organizations, should be considered. Indeed, the *Moore* court noted that biological materials are often shared among researchers.<sup>139</sup> Thus, the nature of the institution’s use of the tissue and its willingness to share are factors that can influence the decision as to a just assessment. For example, a purely commercial entity, maintaining exclusive control over the materials, may be asked to pay more than an organization that plans to make the information gained from the donated material publicly available.

### C. Protection of Societal Interests

The key role for any regulatory body is to consider those aspects of human tissue transfer that have lasting impacts on the greater society. Here, the issues associated with commodification drive the discussion. Certainly, no single regulatory agency has the power to protect society against base human instincts. However, Justice Arabian’s warning about commingling “the sacred with the profane”<sup>140</sup> needs to be addressed.

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138. A full examination of all of the factors to be considered is beyond the scope of this Comment.

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

140. *Id.* at 497 (Arabian, J., concurring).

First, any regulatory entity must begin by acknowledging that human tissue is, in fact, regularly commodified.<sup>141</sup> The issue becomes one of whether we as a society wish to preclude all commodification of tissue or whether we are content to simply preclude some commodification of tissue. Were we to pursue the former approach, the impact would be enormous and would include a “chilling” effect on research of a magnitude much greater than that feared by the *Moore* court.<sup>142</sup> To suggest that the evils of commodification are completely avoided by a proscription on donor compensation are simplistic at best and disingenuous at worst.

The potential impact of the commodification of tissue on vulnerable populations is perhaps best dealt with by a keen awareness of the issues of supply and demand. Concerns that relative unavailability of a type of tissue would drastically increase its price and exert undue influence on vulnerable populations<sup>143</sup> might be ameliorated by control of the price. Here, it would be the regulation of the market that provides the protection against the excesses rather than a proscription of sales. Such regulation can also serve to protect the distribution of rare tissue by “imitat[ing] the policy followed in more conventional cases of monopoly power by permitting sales but regulating prices so that they reflect the marginal costs and risks borne by the donor.”<sup>144</sup>

A final issue is who should do this work. Harrison’s suggestions of the Patent and Trademark Office or the Food and Drug Administration seem based in a desire to leverage an already existing structure to reduce costs associated with adopting her proposal.<sup>145</sup> Perhaps the more important issue is whether an agency or tribunal is sufficiently representative of the stakeholders in the process. It should be remembered that the basis of using a liability rule is the belief that in certain circumstances both the economic efficiency argument and the distributional goals of society are best served by a collective valuation and not one determined only by negotiation of the parties.<sup>146</sup>

This review of the issues involved in the transfer of human tissue for research should, if nothing else, make clear that the stakeholders in this transaction are many. Thus, any body that would aim to regu-

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141. See Mahoney, *supra* note 83, at 163, 174.

142. See *id.* at 196–200 (describing the impact of a true noncommodification regime on all aspects of the research and development of medical products).

143. See Bridges, *supra* note 80, at 142.

144. Susan Rose-Ackerman, *Inalienability and the Theory of Property Rights*, 85 COLUM. L. REV. 931, 949 (1985).

145. See Harrison, *supra* note 15, at 97.

146. See Calabresi & Melamed, *supra* note 77, at 1102–04 .

late this arena should strive to be representative. All phases of the industry need to be fully represented—the academic researchers, the entrepreneurial companies, and the large pharmaceuticals. Patients and other potential tissue donors must also find representation, perhaps through the participation of patient advocacy groups and other such representatives. The healthcare industry and professionals, too, should have input into the process. Lastly, it would be foolish to suggest that such an agency attempt to set value without the input of economists and others who are able to ascertain trends, both nationally and internationally, that would have impact on this issue.

### **Conclusion**

This Comment has explored the policy issues that flow from the decision reached in *Moore v. Regents of the University of California* to deny property rights to human tissue donors. Until recently this subject has focused only on the issue of whether donors should be compensated or not. A recent suggestion has been made that the use of a liability rule approach might provide for a more just allocation of resources.

This suggestion, however, suffers from the flaws outlined above. In particular, forcing donors to initially donate tissue continues the injustices that attend to that practice, and mistakenly implies that such a donation is without value. Further, the problems associated with postponing the assigning of value until such time as a research product has proved commercially viable have been explored.

Finally, using the liability rule model might allow for a more just valuation of donated tissue at the time the donation is made. A regulatory body that is representative of all of the potential stakeholders could assign value and protect the process from the potentially damaging components of market forces.