

# In the Wake of Henrietta Lacks: Current U.S. Law and Policy on Control and Ownership of One's Body Tissues Used in Medical Research

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**Abstract:** Oprah Winfrey's recent adaptation of Rebecca Skloot's book *"The Immortal Life of Henrietta Lacks"*, has reinvigorated interest in the story of an African-American tobacco farmer from Southern Virginia who was diagnosed with cervical cancer when she was 30, and who died in 1951. Lacks would have lived and died in relative anonymity, but for a scientist at Johns Hopkins University Hospital, who removed a tissue sample from Lacks and created what has been deemed the first "immortal human cell line". Lacks' story is not only compelling in terms of human drama, but continues to raise questions regarding the societal and economic value of human tissue. The law has attempted to address the attendant legal and moral questions; for example, through the informed consent requirements of the Common Rule and jurisprudence and legislation that avoids designating human tissue and its byproducts as "property". Nevertheless, as this review of the law proposes, there is potential for unsettled legal issues involving ownership of one's body tissues used in medical research to be raised.

**Keywords:** *Henriette Lacks, Common Rule, Informed Consent, Human Subjects, Research, Human Tissues*

## I. INTRODUCTION

United States' laws avoid designating human tissue and its byproducts as "property"; however, their economic value is significant in drug and therapy development. The approximately \$133 billion biotechnology industry<sup>1</sup> requires volunteer human subjects and often the voluntary use of their tissue samples to test and validate research. In some cases, there is nominal consideration for their use. In many cases, subject altruism and/or their desire to assist in the development of effective therapies for specific medical conditions are their motivation for participation.

Researchers do not necessarily know what advances they might discover from a single human biologic specimen or a group of biologic specimens. This has created the potential to raise legal and moral questions, which gained popular attention through the story of Henrietta Lacks, an African-American tobacco farmer from Southern Virginia who was diagnosed with cervical cancer when

<sup>1</sup> "Biotechnology industry - Statistics & Facts," Statista, accessed March 12, 2017, <https://www.statista.com/topics/1634/biotechnology-industry>.

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she was 30, and who died in 1951.<sup>2</sup> Lacks would have lived and died in relative anonymity, but for a scientist at John Hopkins University Hospital, who removed a tissue sample from Lacks and created what has been deemed the first “immortal human cell line.”

For reasons not yet understood, Lacks’ cells never died.<sup>3</sup> The cells, code-named “HeLa” (derived from the first two letters of Lacks’ name), have since been widely propagated in culture and have become invaluable to medical research over decades, including the development of the polio vaccine, and experiments involving cloning, gene mapping, and *in vitro* fertilization.<sup>4</sup> Lacks’ story, which was brought to public attention in the a book-account by journalist Rebecca Skloot,<sup>5</sup> would be remarkable if only for the medical and scientific value of her cells, particularly when you consider the routine manner in which they were originally obtained. Consider that clinical pathology as a scientific discipline originated as early as the Middle Ages, and microscopic analysis of patient tissue samples has been a usual diagnostic practice for more than 100 years.<sup>6</sup>

Lacks’ story, however, is also remarkable because it foreshadowed subsequent legal controversies involving patients’ control and ownership rights over the use of their tissue samples in medical research, driven largely by advances in biotechnology. Traditionally, tissues removed from patients were used for diagnostic purposes, and subsequently discarded. Occasionally they would have value beyond diagnosis in teaching or study; however, even then, any record of them would be limited to paper files, photographs in medical journals or textbooks, or fixed microscope slides buried in laboratory archives. As noted by Skloot in a 2010 interview, this may have led to general acceptance in society that once tissues were removed from one’s body they could be used without regard to the wishes of their host. She comments:

So much of science today revolves around using human biological tissue of some kind. For scientists, cells are often just like tubes or fruit flies – they’re just inanimate tools that are always there in the lab. The people behind those samples often have their own thoughts and feelings about what should happen to their tissues, but they’re usually left out of the equation.<sup>7</sup>

In fact, the law has evolved to acknowledge patients’ “thoughts and feelings” regarding the disposition of their tissues by imposing a duty of informed consent upon researchers. What complicates this issue is that the patients’ “thoughts and feelings” regarding the use of his or her body tissues may also include dollar signs. The medical advances derived from them certainly benefit society; nevertheless, their economic value has not been lost on human subjects and their families who have pursued claims for damages under various legal theories.

Years after Lacks’ death, her family, which had been mostly impoverished, learned about the HeLa cells and contemplated a claim against John Hopkins University for financial compensation. While there is no record that Lacks’ family filed suit or was ever remunerated, the matter is not yet resolved. At least for the family, the matter is not resolved. A report in February 2017 indicated that Lawrence Lacks, the eldest son of Henrietta Lacks, wants compensation from Johns Hopkins University and possibly others for the unconsented and unauthorized use of the cells in research that led to decades of medical advances.<sup>8</sup> This article reviews the legal developments in the area of ownership and control of human tissues since Lacks’ Case, including changes of key legislation and case law. The article will also examine what remedies might be available to Lacks’ family today and in what ways the laws related to control and ownership of one’s body tissues remain unsettled. In addition, this article emphasizes the critical onus on medical researchers to obtain proper and enforceable informed consent from human subjects in research. Discussed below, in 2004, the members of the Havasupai Tribe filed a \$25 million lawsuit against Arizona State University, i.e., the Arizona Board of Regents and three professors for damages related to unauthorized studies of blood samples taken from members of the tribe between 1990 and 1994.<sup>9</sup> The case eventually settled with \$700,000 being paid to 41 members of the tribe.<sup>10</sup> In addition, the article also reviews case

<sup>2</sup> Sarah Zielinski, “Henrietta Lacks’ ‘Immortal’ Cells,” Smithsonian.com, January 22, 2010, accessed Dec. 10, 2017, <http://www.smithsonianmag.com/science-nature/Henrietta-Lacks-Immortal-Cells.html>.

<sup>3</sup> Ibid.

<sup>4</sup> Ibid.

<sup>5</sup> Rebecca Skloot, *The Immortal Life of Henrietta Lacks* (New York: Random House, 2010).

<sup>6</sup> Darlene Berger, “A Brief History of Medical Diagnosis and the Birth of the Clinical Laboratory,” *Medical Laboratory Observer* 31 no. 7 (July 1999): 28-40

<sup>7</sup> Zielinski, “Henrietta Lacks’ ‘Immortal’ Cells.”

<sup>8</sup> Andrea K. McDaniels, “Henrietta Lacks’ Family Wants Compensation for her Cell,” *The Baltimore Sun*, February 15, 2017, accessed Dec. 10, 2017, <http://www.baltimoresun.com/health/bs-hs-henrietta-lacks-johns-hopkins-20170213-story.html>.

<sup>9</sup> Larry Hendricks, “Havasupai File \$25M Suit at ASU,” *Arizona Daily Sun*, February 28, 2004.

law on the patentability of intellectual property derived from human tissues. This raised the policy question whether private enterprises should be able to claim proprietary rights over human cells and their genetic components, and thus own a monopoly on medical knowledge and resources that could benefit society at large.

## II. REVIEW OF LEGAL PRINCIPLES ADDRESSING HUMAN TISSUE AS PROPERTY

U.S. law carefully avoids designating human body parts as “property,” a common law legal definition of which includes “everything that has an exchangeable value, or which goes to make up wealth or estate.”<sup>11</sup> Under the federal law, “it shall be unlawful for any person to knowingly acquire, receive, or otherwise transfer any human organ for valuable consideration for use in human transplantation if the transfer affects interstate commerce.”<sup>12</sup>

Both U.S. jurisprudence and legislation seem to be in agreement that human subjects in research are owed a duty of informed consent in regard to the manner in which their tissues will be used in research.<sup>13</sup> This position has been strengthened with recent revisions to the “Federal Policy for Protection of Human Research Subjects,” also known as the “Common Rule,”<sup>14</sup> which governs research with human subjects conducted or supported by 15 federal departments and agencies. The Common Rule, the revised version of which is due to be effective January 19, 2018, is based on the Belmont Report, a statement of basic ethical principles and guidelines to assist in resolving the ethical problems that surround the conduct of research with human subjects by the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research.<sup>15</sup>

However, in spite of the general moral and policy consensus, via operation of law, these issues hinge on a patchwork of court opinions and legislation. *Moore v. University of California*<sup>16</sup> is a seminal case addressing control and ownership of a patient’s body tissue. The issues addressed in *Moore* remain to be “first impression” in a number of state and U.S. district courts, assuming that they do not evade judicial review. For example, the state of Arizona had an opportunity to address these issues in the aforementioned case filed by the Havasupai Tribe; however, the particular case settled before the state appellate court has an opportunity to rule on the substantive legal issues.

In sum, regulation of informed consent in human research is addressed by the Common Rule, which was revised in 2017 with changes going into effect in 2018. Both the Common Rule and *Moore* promote the idea that medical researchers owe a duty of informed consent to research subjects, including how their tissues will be used. The underlying policy basis for the Common Rule is the Belmont Report, which summarized the basic ethical principles that should underlie the conduct of biomedical and behavioral research involving human subjects – including the principle of patient autonomy – and to develop guidelines which should be followed to assure that such research is conducted in accordance with those principles.<sup>17</sup>

However, the problem is that the recent revisions to the Common Rule allow broad consent for the secondary research use of identifiable biologic specimens. Consistent with the current rule, researchers will not have to obtain consent for studies on non-identified bio-specimens. Henrietta Lacks’ immortal cells, by definition, are identified; however, the Common Rule was not enacted until 1981. The policy for the basis of the *Moore* decision regarding a patient’s right of informed consent is not entirely clear, and appears to provide less protection to patients than does the Common Rule.

### A. The Uniform Commercial Code and Human Tissue

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<sup>10</sup>Amy Harmon, “Indian Tribe Wins Fight to Limit Research of Its DNA,” *The New York Times*, April 21, 2010, accessed Dec. 10, 2017, <http://www.nytimes.com/2010/04/22/us/22dna.html?hp=&pagewanted=all>.

<sup>11</sup> Black’s Law Dictionary 846 (6th ed. 1990).

<sup>12</sup> 42 U.S.C. § 274(e) – Prohibition of Organ Purchases in U.S. Code (2000).

<sup>13</sup> *The Belmont Report*, Office of the Secretary Ethical Principles and Guidelines for the Protection of Human Subjects of Research, The National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, April 18, 1979, <https://www.hhs.gov/ohrp/regulations-and-policy/belmont-report/index.html>.

<sup>14</sup> *Federal Policy for the Protection of Human Subjects*, 82 Fed. Reg. 7149, 7274 (Jan. 19, 2017) (to be codified at 45 C.F.R. part 46).

<sup>15</sup> 42 U.S.C. § 274(e)

<sup>16</sup> *Moore v. Regents of University of California*, 271 Cal.Rptr. 146, 51 Cal.3d 120 (1990).

<sup>17</sup> 42 U.S.C. § 274(e)

The Uniform Commercial Code (U.C.C.) is a comprehensive code addressing most aspects of commercial law which has been enacted with some local variation in all 50 states including the District of Columbia and the Virgin Islands.<sup>18</sup> Article 2 of the U.C.C. addresses sales transactions in goods and specifically notes that any transaction subject to this article is also subject to any applicable statute of the particular state applicable to the transaction, such as a statute dealing with the transfer of human blood, blood products, tissues, or parts.<sup>19</sup>

Excluding blood and tissues from the legal characterization as “goods” insulates transactions in these materials from the implied warranty provisions of the U.C.C., as illustrated, for example, in Massachusetts’s version of Article 2 of the U.C.C., which specifically provides: The “implied warranties of merchantability and fitness shall not be applicable to a contract for the sale of human blood, blood plasma or other human tissue or organs from a blood bank or reservoir of such other tissues or organs. Such blood, blood plasma or tissue or organs shall not for the purposes of this Article be considered commodities subject to sale or barter, but shall be considered as medical services.”<sup>20</sup>

### B. *Moore v. University of California*

In *Moore v. University of California*,<sup>21</sup> Plaintiff John Moore “visited UCLA [the University of California, Los Angeles] Medical Center on October 5, 1976, shortly after he learned that he had hairy-cell leukemia.”<sup>22</sup> *Moore* is binding only on the California courts; however, it is an important case. Aspects of the *Moore* have been cited as persuasive authority in U.S. District and circuit court opinions, and in case law in 12 other states, including Arkansas,<sup>23</sup> Colorado,<sup>24</sup> Connecticut,<sup>25</sup> Florida,<sup>26</sup> Illinois,<sup>27</sup> Indiana,<sup>28</sup> Minnesota,<sup>29</sup> New Mexico,<sup>30</sup> New York,<sup>31</sup> Pennsylvania,<sup>32</sup> Texas,<sup>33</sup> and Washington.<sup>34</sup> The facts in *Moore*, as summarized by the court below, are reminiscent of Henrietta Lacks and her “immortal cells”:

After hospitalizing Moore and “withdr[awing] extensive amounts of blood, bone marrow aspirate, and other bodily substances... At this time all defendants ... were aware that “certain blood products and blood components were of great value in a number of commercial and scientific efforts” and that access to a patient whose blood contained these substances would provide “competitive, commercial, and scientific advantages.”<sup>35</sup>

Unlike the physicians who treated Lacks, it appears that Plaintiff Moore’s doctor became quickly aware of the value of his patient’s cell. A patented cell line derived from Moore’s tissues deemed the “Mo-cell line” proved to have great commercial value to one of Moore’s physicians and to the University of California. In his complaint, Plaintiff Moore raised 13 causes of action, including

<sup>18</sup> “What is the UCC?” *Uniform Commercial Code (UCC)*, Duke Law Library, accessed Dec. 10, 2017, <http://www.law.duke.edu/lib/researchguides/ucc>.

<sup>19</sup> Uniformed Commercial Code § 2-108 (2005).

<sup>20</sup> Mass. Gen. Laws ch. 106 § 2-316-5 (2010), accessed Dec. 10, 2017, <http://law.onecle.com/massachusetts/106/2-316.html>.

<sup>21</sup> Hendricks, “Havusupai File \$25M Suit at ASU.”

<sup>22</sup> *Moore*, 51 Cal.3d, at \*125.

<sup>23</sup> *Wilson v. Adkins*, 57 Ark. App. 43, 941 S.W.2d 440 (Ark. App. 1997).

<sup>24</sup> *Spoor v. Serota*, 852 P.2d 1292 (Colo. App. 1992).

<sup>25</sup> *Cornelio v. Stamford Hosp.*, 246 Conn. 45, 717 A.2d 140 (Conn. 1998); *Janicki v. Hospital of St. Raphael*, 46 Conn. Supp. 204, 744 A.2d 963 (Conn. Super. 1999); *DeGennaro v. Tandon*, 89 Conn. App. 183, 873 A.2d 191 (Conn. App. 2005).

<sup>26</sup> *Drew v. Tenet St. Mary's, Inc.*, 35 Fla. L. Weekly D2454, 46 So.3d 1165 (Fla. App. 4 Dist. 2010).

<sup>27</sup> *Neade v. Portes*, 303 Ill.App.3d 799, 710 N.E.2d 418 (Ill. App. 2 Dist. 1999).

<sup>28</sup> *Culbertson v. Mernitz*, 602 N.E.2d 98 (Ind. 1992).

<sup>29</sup> *D.A.B. v. Brown*, 570 N.W.2d 168 (Minn. App. 1997).

<sup>30</sup> *Garcia v. Coffman*, 124 N.M. 12, 946 P.2d 216 (N.M. App. 1997).

<sup>31</sup> *Hecht v. Kaplan*, 645 N.Y.S.2d 51, 221 A.D.2d 100 (N.Y. 1997).

<sup>32</sup> *Duttry v. Patterson*, 565 Pa. 130, 771 A.2d 1255 (Pa. 2001).

<sup>33</sup> *In re University of Texas Health Center at Tyler*, 198 S.W.3d 392 (Tex. App.—Texarkana 2006).

<sup>34</sup> *Whiteside v. Lukson*, 89 Wn. App. 109, 947 P.2d 1263 (Wash. App. Div. 3 1997).

<sup>35</sup> *Moore*, 51 Cal.3d, at \*151.

“conversion,” described by the court as “a tort that protects against interference with possessory and ownership interests in personal property.” The court observed as follows:

Plaintiff Moore theorizes that he continued to own his cells following their removal from his body, at least for the purpose of directing their use, and that he never consented to their use in potentially lucrative medical research. Thus, to complete Moore's argument, defendants' unauthorized use of his cells constitutes a conversion. As a result of the alleged conversion, Moore claims a proprietary interest in each of the products that any of the defendants might ever create from his cells or the patented cell line<sup>36</sup>.

In *Moore*, the court did not disregard notions of equity and fairness attendant to property rights, noting that “there are bountiful benefits, monetary and otherwise, to be derived from human biologics” and that:

[t]here is, however, a third party to the biotechnology enterprise - the patient who is the source of the blood or tissue from which all these profits are derived. While he maybe a silent partner, his contribution to the venture is absolutely crucial; as pointed out above ... but for the cells of Moore's body taken by defendants there would have been no Mo-cell line at all. <sup>37</sup>

That said, ultimately, in *Moore*, we see once again the law's reluctance to recognize property interest in body tissues. The court refused to recognize Moore's claim for conversion, based on several policy arguments, including those related to the advancement of medical science:

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.<sup>38</sup>

The court in *Moore* also based its opinion regarding the plaintiff's conversion claims, among other reasons, on grounds that it conflicted with a statute that addressed disposal of human tissue, observing:

Pursuant to Health and Safety Code section 7054.4, “[n]otwithstanding any other provision of law, recognizable anatomical parts, human tissues, anatomical human remains, or infectious waste following conclusion of scientific use shall be disposed of by interment, incineration, or any other method determined by the state department [of health services] to protect the public health and safety.” Clearly the Legislature did not specifically intend this statute to resolve the question of whether a patient is entitled to compensation for the nonconsensual use of excised cells. A primary object of the statute is to ensure the safe handling of potentially hazardous biological waste materials.

Yet one cannot escape the conclusion that the statute's practical effect is to limit, drastically, a patient's control over excised cells. By restricting how excised cells may be used and requiring their eventual destruction, the statute eliminates so many of the rights ordinarily attached to property that one cannot simply assume that what is left amounts to “property” or “ownership” for purposes of conversion law.<sup>39</sup>

One might ponder the outcome of *Moore* if Plaintiff Moore had the information, foresight, and leverage to have entered into a contractual relationship with the researchers for interest in the “Mo-cell line” in exchange for his consent to harvest the cells. In other words, would such an agreement have provided Moore remedies in contract, given that Anglo-American law is reluctant to set aside a transaction that meets the requirements of a valid and lawful contract?<sup>40</sup> This underscores further that *Moore* raises important questions regarding control and ownership of human body tissues, yet it does not settle them.

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<sup>36</sup> Moore, 51 Cal.3d, at \*135.

<sup>37</sup> Moore, 51 Cal.3d, at \*175.

<sup>38</sup> Moore, 51 Cal.3d, at \*145.

<sup>39</sup> Moore, 51 Cal.3d, at \*141.

<sup>40</sup> Lawrence Dick, “Meeting the Challenge of Innovation in Government” (presentation, The Innovation Journal Innovation Conference, March 1, 2001), available at <http://www.innovation.cc/archives/news/innovation-conference/new-paradigm.pdf>.

In 2007, the Eighth Circuit Court of Appeals was “asked to determine the ownership of biological materials contributed by individuals for the purpose of genetic cancer research and currently housed on the campus of Washington University (WU).”<sup>41</sup> In this case, Dr. Catalona, a urologist, surgeon, and researcher employed by WU from 1976 to 2003 had collected samples of biological materials to be used later for prostate cancer research and was instrumental in establishing the world’s largest storage facility for biological samples for prostate cancer research. After leaving WU, he sought a declaration that the contributing subject could direct the transfer of their biological materials to him, and he moved for an order prohibiting WU from utilizing, disseminating, transferring, or destroying the biological materials at issue. The court affirmed the district court holding that WU owns the biological materials and that neither Dr. Catalona nor any contributing individual has any ownership or proprietary interest in the disputed biological materials. The court decided that the subjects who provided biospecimens (such as blood or tissue) for genetic cancer research did so as *inter vivos* gifts and thus retained no property rights that would allow them to request the return of the biospecimens or the transfer of the biospecimens to a third party.

The ruling conferred property rights of the biospecimens to WU. Ostensibly, this restricted Dr. Catalona’s ability to continue his genetic cancer research using these tissues. One might ask if this was an example of “socially useful activities” that the *Moore* court would protect from “disabling civil liability” by avoiding the classification of human tissue as property.

Biobanks that permit access to biospecimens to qualified researchers would promise to avoid this kind of dispute, and the revised Common Rule<sup>42</sup> has the provision intended to facilitate the creation of biobanks for future research. These include two new exemption categories that will allow an investigator to obtain “broad consent” from a subject for participation in a biobank that involves the storage, maintenance, or use of identifiable private information or identifiable biospecimens for future secondary research.<sup>43</sup>

### C. The Duty of Informed Consent

While the court refused to recognize the plaintiff’s claim for conversion, the court in *Moore* upheld his cause of action for “breach of the physician’s disclosure obligations,”<sup>44</sup> i.e., “breach of fiduciary duty and lack of informed consent.” The court, however, weighs patient autonomy against the cost to future medical research in its holding:

This policy weighs in favor of providing a remedy to patients when physicians act with undisclosed motives that may affect their professional judgment. The second 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. To reach an appropriate balance of these policy considerations is extremely important. In its report to Congress ... the Office of Technology Assessment emphasized that “[u]ncertainty 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.”<sup>45</sup>

In short, *Moore* recognizes that medical researchers owe a fiduciary duty of informed consent to their patients, but expresses a need to protect “socially useful activities” from “disabling civil liability.” In doing so, *Moore* seems to suggest a balancing test that weighs fiduciary duty to the patient against the social value of medical research provided by his tissues.

Here, the importance of the policy basis for the outcome becomes apparent. As noted by one legal commentator, John Hopkins University Hospital’s conduct in the case of Henrietta Lacks’ situation would have clearly violated the Common Rule,<sup>46</sup> which, unlike

<sup>41</sup> Washington University v. Catalona, 409 F.3d 667 (8th Cir. 2007).

<sup>42</sup> The Federal Policy for the Protection of Human Subjects, 82 Fed. Reg. 7149, 7274.

<sup>43</sup> “Attachment C - Recommendations for Broad Consent Guidance” Guidance on Broad Consent under the Revised Common Rule, U.S. Department of Health and Human Services, Recommendation Approved by SACHRP July 26, 2017, accessed Dec. 10, 2017, <https://www.hhs.gov/ohrp/sachrp-committee/recommendations/attachment-c-august-2-2017/index.html>.

<sup>44</sup> Moore, 51 Cal.3d, at \*147.

<sup>45</sup> Moore, 51 Cal.3d, at \*143.

<sup>46</sup> Laurie T. Baulig, “Are There Property Rights in Human Tissue? The Law “Lacks” Definitive Answers,” *The Journal of Lancaster General Hospital* 87 (Fall 2010), accessed Dec. 10, 2017, <http://www.jlgh.org/JLGH/media/Journal-LGH-Media-Library/Past%20Issues/Volume%205%20-%20Issue%203/baulig53.pdf>

*Moore*, is unequivocal in asserting a duty of informed consent to human research subjects. The specific language addressing the requirements for informed consent within the Common Rule, as in §46.116 General Requirements for Informed Consent, read:

(a) Basic elements of informed consent. Except as provided in paragraph (c) or (d) of this section, in seeking informed consent the following information shall be provided to each subject:

(1) A statement that the study involves research, an explanation of the purposes of the research and the expected duration of the subject's participation, a description of the procedures to be followed, and identification of any procedures which are experimental...<sup>47</sup>

### III. THE CASE OF THE HAVASUPAI INDIANS

Conduct similar to both John Hopkins University in the matter of Henrietta Lacks and the University of California in *Moore* formed the factual basis of the above-referenced 2004 lawsuit brought by the Havasupai Indians against Arizona State University Board of Regents. In 1989, two members of the tribe members approached an Arizona State University (ASU) faculty member, asking for help to stem the tribe's high incidence of diabetes.<sup>48</sup> As alleged in a complaint filed in Arizona state superior court, an ASU researcher originally presented her project to the tribal council as consisting of three elements: (1) "diabetes education," (2) "collecting and testing blood samples from individual members to identify diabetics or persons susceptible to diabetes," and (3) "genetic testing to identify an association between certain gene variants and diabetes" among Havasupai.<sup>49</sup>

The plaintiffs alleged that the researcher did not inform them that she was pursuing a grant to study schizophrenia among the Havasupai. Nor were they subsequently told that the research caused her assistant to surreptitiously examine their medical charts for schizophrenia after operating hours of the local health clinic. The complaint alleged that the defendants authored 15 publications dealing with schizophrenia, inbreeding, and theories about ancient human population migrations from Asia to North America – secondary uses of the samples to which the Havasupai would not have consented.<sup>50</sup>

The complaint, which requested the court to hold the defendants jointly and severally liable for \$25,000,000 in compensatory damages and \$25,000,000 in punitive damages, listed six causes of action, several of which were similar to the *Moore* case, including lack of informed consent and conversion. Further, plaintiffs requested that the court enjoin any further research activity or publication involving the blood samples and to prohibit the defendants "from committing similar acts in the future."<sup>51</sup>

The trial court dismissed the case on summary judgment against the plaintiffs because it concluded they failed to comply with Arizona's "notice-of-claim asked" statute. The Arizona state court of appeals reversed the summary judgment in an unpublished opinion, and remanded the matter back to the trial court.<sup>52</sup>

The parties settled the matter for \$700,000 before the substantive issues could be tried. The settlement might have benefitted the tribe financially; however, the substantive issues of the suit were never adjudicated at the trial or appellate level, leaving one to speculate how the Arizona courts would have ruled in this matter. According to at least one legal commentator, however, the strength of the tribe's claim of lack of informed consent might have rested with the "Common Rule", which, as noted, is the regulatory regime that governs federally-funded human subject research. Again, the Common Rule states that researchers must seek to obtain informed consent from participants. The participants that are uninformed cannot provide valid consent and, thus, their rights as subjects are violated."<sup>53</sup>

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<sup>47</sup> 45CFR690.116 (1991).

<sup>48</sup> Lori Andrews, "Havasupai Tribe Sues Genetic Researchers," *Law and Bioethics Report* 10 (Winter 2004), accessed Dec. 10, 2017, <http://www.kentlaw.edu/islat/pdf/HavasupaiTribeSues.pdf>.

<sup>49</sup> *Moore*, 51 Cal.3d, at 10.

<sup>50</sup> *Moore*, 51 Cal.3d, at 11.

<sup>51</sup> *Ibid*.

<sup>52</sup> *Havasupai Tribe of Havasupai Reservation v. Arizona Board of Regents*, Nos. 1 CA-CV 07-0454, 1 CA-CV 07-0801 (unpublished 2008), accessed Dec. 10, 2017, <http://caselaw.findlaw.com/az-court-of-appeals/1425062.html>.

<sup>53</sup> Dan Vorhaus, "The Havasupai Indians and the Challenge of Informed Consent for Genomic Research," *Genomics Law Report*, April 21, 2010, accessed Dec. 10, 2017, <http://www.genomicslawreport.com/index.php/2010/04/21/the-havasupai-indians-and-the-challenge-of-informed-consent-for-genomic-research/>.

#### IV. PATENT RIGHTS OVER GENES

Biotechnology firms also compete for ownership and control interests in human tissues and their derivative intellectual property. In May 2009, the Association for Molecular Pathology, American College of Medical Genetics, American Society for Clinical Pathology, and 17 other plaintiffs (including medical researchers and cancer survivors) brought a claim against 12 defendants including Myriad Genetics. Myriad Genetics had obtained patent rights over BRCA1 and BRCA2 genes, as well as the United States Patent and Trademark Office, the federal agency authorized to grant patent rights. According to the complaint, filed in the United States District Court, Southern District of New York, the gene patents that “are challenged in this case are patents covering the BRCA1 and BRCA2 genes, which relate to an increased risk of breast and/or ovarian cancer.” Furthermore, the complaint asserted that “[e]ase of access to genomic discoveries is crucial if basic research is to be expeditiously translated into clinical laboratories that benefit patients in the emerging era of personalized and predictive medicine.”<sup>54</sup>

The importance of the subject matter was underscored by the interest of the biotechnology sector, researchers and patients, and the United States Supreme Court’s willingness to hear patent cases on *certiorari*. The causes of action in the complaint challenged the patent on several intellectual property law grounds, which were highly technical. The policy issues, however, were more straightforward. Commenting on the suit in a website blog post that was written – not surprisingly – by Rebecca Skloot,<sup>55</sup> who cited research that challenges the restrictive licensing and monopolization of clinical-testing services caused by gene patents:

In a survey done a few years ago, 53 percent of laboratories had stopped offering or developing a genetic test because of patent enforcement, and 67 percent felt patents interfered with medical research. It costs \$25,000 for an academic institution to license the gene for researching a common blood disorder, hereditary haemochromatosis, and up to \$250,000 to license the same gene for commercial testing. At that rate, it would cost anywhere from \$46.4 million (for academic institutions) to \$464 million (for commercial labs) to test a person for all currently-known genetic diseases.<sup>56</sup>

The *Myriad* case was decided on March 29, 2010. The court held that the composition patents were invalid, essentially because they are “products of nature.”<sup>57</sup>

To overcome this, Myriad would have had to establish that the “isolated” and “purified” DNA segments in question had markedly different characteristics, or were fundamentally distinct, from what was found in nature. Like the court in *Moore*, the plaintiffs in *Myriad* argued that biomedical advances should not be hindered by control or ownership interests. In *Myriad* plaintiffs raise concern that life-saving therapies might not be widely available if an *entity* could own the genomic discoveries. In *Moore*, the court suggests that biomedical advances could be hindered in the first place by giving *patients* unlimited control and/or ownership of their tissues. The common thread is the notion that handing control and ownership of human tissue and their byproducts, to a patient or a biotechnology enterprise, has potential to stifle medical advancement. If this is the case, does it offer any sympathy – let alone recourse – for Henrietta Lacks, but for whose cells the development of the polio vaccine might have been hindered?

#### V. HARMONIZATION OF ETHICS WITH PREVAILING POLICY AND LAW

Prevailing U.S. policy and law appear to be aligned with the ethical principles of the Belmont Report. Henrietta Lacks’ family continues to question if she should be entitled to compensation for the unauthorized use of her cells in research that led to decades of medical advances. Setting aside the question of the family’s interest in compensation and focusing on the ethical violations by modern standards, Henrietta Lacks was denied “respect for persons”, pursuant to the Belmont Report. She was not presented with the opportunity to consent voluntarily to the use of her tissues and apprised of the risks involved. She was also deprived of efforts to maintain confidentiality of her tissues and, of course, her privacy. Her life history, illness, and her family are now well known.

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<sup>54</sup> Association for Molecular Pathology, et. al. v. United States Patent and Trademark Office, et al., Complaint filed in the United States District Court, Southern District of New York, accessed Dec. 10, 2017, [http://www.aclu.org/files/images/asset\\_upload\\_file939\\_39568.pdf](http://www.aclu.org/files/images/asset_upload_file939_39568.pdf).

<sup>55</sup> Rebecca Skloot, “Enough with Patenting the Breast Cancer Gene,” *Slate*, May 15, 2009, accessed Dec. 10, 2017, <http://www.doublex.com/section/health-science/enough-patenting-breast-cancer-gene>.

<sup>56</sup>Jon F. Merz et. al, “Diagnostic Testing Fails the Test,” *Nature* 415 (7 February 2002): 577-579, accessed Dec 1, 2017, doi: 10.1038/415577a

<sup>57</sup> Association for Molecular Pathology, et. al. v. United States Patent and Trademark Office.

In the wake of Henrietta Lacks, it would seem that the ethical principle of respect for persons is neatly aligned with the policy of informed consent process, via the Common Rule. Today, the patients regularly consent to the use of tissues biopsies for assays to gauge the results of companion studies and other tests, with ample notice of the risks, and are promised protection of confidentiality and privacy.

Furthermore, if we associate “respect for persons” with the moral basis of the 13<sup>th</sup> amendment of the Constitution,<sup>58</sup> which bars slavery in the U.S., we might consider that proscribing human tissue as property insulates the moral use of human organs and tissues from claims pursuant to the takings’ clause of the 5<sup>th</sup> Amendment while the use may be applied to the states under the 14<sup>th</sup> Amendment. In *Horne et al. v Department of Agriculture*,<sup>59</sup> the U.S. Supreme Court ruled that the 5<sup>th</sup> Amendment’s takings clause extends to takings of personal property. While it sounds as if it would occur in a dystopian state, one might imagine that, if government deemed samples of someone’s tissue of vital social value to advance medical research, the individual may refuse to consent to its use.

Despite those corporate managers who exclaim that “our employees are our greatest assets,” human beings have not appeared on a balance sheet in the U.S. since the 1860s. Both the duty of informed consent and the proscription of human tissue as property extend this guarantee that neither our organs nor our tissues be accounted for in such a manner. However, our society which places great value on autonomy drives our expectations that our organs and tissues, something of value to others, should be compensated unless we donate it voluntarily, i.e., making a gift. Henrietta Lacks’ cells proved to be highly valuable, and there is a moral argument grounded in fairness that she and her heirs should be compensated in some way for the benefits she unwittingly conferred to medical science and society.

On the other hand, prevailing policy and law prioritizes the utilitarian philosophical value. The policy that biomedical advances should not be hindered by control or ownership interests is aligned, arguably, with the ethical principle of distributive justice as also stated in the Belmont Report:

Who ought to receive the benefits of research and bear its burdens? This is a question of justice, in the sense of “fairness in distribution” or “what is deserved.” An injustice occurs when some benefit to which a person is entitled is denied without good reason or when some burden is imposed unduly. Another way of conceiving the principle of justice is that equals ought to be treated equally. However, this statement requires explication. Who is equal and who is unequal? What considerations justify departure from equal distribution?<sup>60</sup>

Human tissue as property encourages economic and market forces to govern its access and use. Individuals in economic distress might be likely to bear a disproportionate burden of research that requires human tissue, and perhaps less likely to benefit from it. Nevertheless, as we see in *Moore*, not every human subject subscribes to the contested value of utilitarianism if their tissues had significant economic value. Theoretically, there are other ways a subject might benefit from the value of his or her tissue without claiming property rights. One can imagine a scenario in which a patient or human research subject learns that certain cells in his or her body have properties that would make them tremendously valuable to medical science, and is asked for permission to use them as such. If the subject were to enter into a valid contract with researchers to retain some control of those cells and/or the derivative biotechnology, as well as economic claims to therapies and other valuable advancements thereof, it is conceivable that the courts would uphold its validity of that agreement, based on the common law contract law theory, in the absence of code or statute that would make such agreements void *ab initio* (as a matter of public policy). Indeed, human subjects are routinely offered compensation as inducement to agree to participate in research studies.

## VI. CONCLUSION

In near future, many disease processes from infection to recovery will be understood and thus new therapies can be suggested, which requires for medical science to need more human biospecimens. Meanwhile, the advances in medical technology that allow human organs and tissues to be used might make difficult ethical dilemmas related to control and ownership of human organs and tissues. The key legal development protecting the rights of patients such as Henrietta Lacks are the informed consent provisions of the Common Rule. It addresses many of the ethical concerns raised by her family. In brief, the prevailing law seems to agree that

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<sup>58</sup> U.S. Const. 13th Amend.

<sup>59</sup> *Horne v. Dept. of Agriculture*, 135 S. Ct. 1039 (U.S. 2015).

<sup>60</sup> *The Federal Policy for the Protection of Human Subjects*, 82 Fed. Reg. 7149, 7274.

traditional legal theories of personal property rights in human tissue are disfavored, with *Moore* remaining a widely cited source of common-law guidance on property rights in human tissue. The question remains if the courts would be able, or even inclined, to apply *Moore* in every case in which a human subject, researcher, or commercial enterprise claims property interest in body tissues, as in the case of *Washington University v. Catalona*?

Another question remains regarding remuneration for use of body tissues, either consented or, in the case of Henrietta Lacks, unconsented. Remuneration for participation in research and the donation of body tissues is available, although most of these exchanges are not governed by property law. The National Organ Transplant Act's ban on the sale of organs does not apply to all bodily products (e.g., blood, sperm, or ova) and does not prohibit all forms of compensation (e.g., NOTA allows reasonable compensation for the organ procurement procedures but prohibits compensation for the bodily source product).<sup>61</sup>

Again, while hypothetical, if both Henrietta Lacks and the medical scientific community understood the value of her cells prior to consenting to their use in research, could they have negotiated an arrangement for significant compensation, despite the prohibitions on human tissue as property? Informed consent, by definition, is voluntary, and not an infallible process. Might someone be able to enforce rights to remuneration via contract or equitable principles such as unjust enrichment, outside of claiming property rights?

This might beg the question whether there is a need for a uniform act as a model statutory framework to govern control and ownership of human tissue obtained for research. Such a model could be presented for ratification by the legislators in each state, rather than be subject to common-law jurisprudence. Among the advantages of this proposal is that it could provide another opportunity for the medical and medical ethics community to work alongside legal scholars, including the National Conference of Commissioners on Uniform State Laws and the American Law Institute to shape important legislation.

Perhaps in the manner that the U.C.C. harmonized business and commercial transactions between the states and created a consistent national regulatory framework, a uniform code governing patients' and subjects' control and ownership over their tissues would avoid these matters being governed under the state common law contract theory. It might also provide another forum for ethicists, legal scholars, and academic and industry stakeholders of medical research to guide the future development of regulation of the use of human tissue and its derivatives.

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<sup>61</sup> Jennifer K. Wagner, "Property Rights and the Human Body," *Genomics Law Report* (June 11, 2014), accessed Dec. 11, 2017, <https://www.genomicslawreport.com/index.php/2014/06/11/property-rights-and-the-human-body/>.

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