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# The Burgeoning “Biorights Movement”: Its Legal Basis, What’s at Stake, and How to Respond

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# THE BURGEONING “BIORIGHTS MOVEMENT”: ITS LEGAL BASIS, WHAT’S AT STAKE, AND HOW TO RESPOND

**Abstract:** The advent of genetic and genomic technologies has the power to transform the understanding, prevention, and treatment of disease on a scale unprecedented in modern medicine. The promise of the era of precision medicine risks being tempered by the emergence of what is increasingly being referred to as the “biorights movement.” Of particular concern is the growing trend of individuals refusing to contribute their biological material to research studies absent some form of monetary compensation. Recently announced, but yet to be implemented, regulations seek to mitigate some of the potentially harmful and progress-impeding positions advanced by the biorights movement. The proposed changes to the legal and regulatory framework, however, do not sufficiently address the opportunities and challenges of the rapidly evolving patient-consumer landscape as it relates to personal genetic testing. Never before have patients been able to know so much about their genetic profile and the potentially valuable information their DNA contains from both a research and commercial perspective. Bolstered by numerous public policy justifications, this Note argues that legislative action needs to be taken that proscribes the ability of individuals to sell their biological material for research purposes.

## INTRODUCTION

Medical research in the United States has long been predicated on the access to and use of human biological samples collected in the course of clinical care.<sup>1</sup> Individuals can contribute their biological materials through participation in formal research projects with informed consent procedures.<sup>2</sup> Additionally, researchers collect blood, tumor pieces, or tissue that would otherwise be discarded as medical waste following a medical or surgical procedure.<sup>3</sup> Samples collected in this manner do not typically require informed consent; however, many institutional consent forms for diagnostic or surgical procedures

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<sup>1</sup> Rina Hakimian & David Korn, *Ownership and Use of Tissue Specimens for Research*, 292 J. AM. MED. ASS’N 2500, 2503 (2004). Until the advent of advanced genetic technologies and increased concerns about genetic privacy, contributions of biological materials for research were considered to advance the public interest. *Id.* Neither the existence nor the use of large sample archives created through altruistic contributions from patients was a matter of public concern or notice. *Id.*

<sup>2</sup> *Id.* at 2501.

<sup>3</sup> See *id.* (noting that hospitals and physicians typically use “extra” or “remaining” portions of excised specimens for research).

include language permitting the institution's use of any extra or remaining biological materials for unspecified future research purposes.<sup>4</sup>

Recent developments in what is being increasingly referred to as the "bio-rights movement" have prompted consideration at the local, state, and federal government levels of whether current collection and consent practices should be permitted to continue.<sup>5</sup> Of particular concern is the growing trend of individuals refusing to contribute their biological material for research absent some form of compensation.<sup>6</sup> At stake is the continued progress of medical

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<sup>4</sup> *Id.*

<sup>5</sup> See Beth Daley & Ellen Cranley, *'Biorights' Rise: Donors Demand Control of Their Samples*, BOS. GLOBE (Oct. 10, 2016), <https://www.bostonglobe.com/metro/2016/10/09/the-rise-biorights-donors-are-demanding-control-and-sometimes-cash-exchange-for-genetic-samples/jCbaQ2E5t6c0Qs1kcITMRM/story.html> [<https://perma.cc/55PB-57UT>] (describing how patients are asserting rights to their biological material collected in the course of medical treatment). For example, a Boston-area woman suffering from a potentially fatal heart condition refused to provide a blood or saliva sample to medical researchers who would not in exchange promise her the results of their work or offer compensation for her sample. *Id.* The patient, instead, gave the sample to a medical start-up company, DNASimple, that offered her \$50 for a saliva sample and additional compensation for any future samples needed. *Id.* The patient was quoted as saying, "Innovation and progress will save lives eventually, but there has been an over-assumption and a gross expectation of patient altruism." *Id.* DNASimple was founded in 2015 and has signed up almost four thousand people to date. *Id.* The startup promotes itself as a way to double the pace of genetic research while allowing its donors to receive fair compensation for the valuable information they provide. *How DNASimple Works*, DNASIMPLE, <https://www.dnasimple.org/about> [<https://perma.cc/S268-P6LF>]. The company's founder, twenty-eight-year-old Olivier Noel, was recognized by Forbes Magazine as a 2017 member of its "30 Under 30 in Science" distinction. Alex Knapp, *30 Under 30 in Science 2017: Olivier Noel*, FORBES (Jan. 3, 2017), <https://www.forbes.com/pictures/585c3586a7ea431d601b9572/olivier-noel-28/#709eeaff48b0> [<https://web.archive.org/web/20180409040704/https://www.forbes.com/pictures/585c3586a7ea431d601b9572/olivier-noel-28/#9d17bae491c5>].

<sup>6</sup> Stephanie M. Lee, *These Startups Will Pay You for Your DNA*, BUZZFEED (Dec. 15, 2016), [https://www.buzzfeed.com/stephaniemlee/these-startups-will-pay-you-for-your-dna?utm\\_term=.wbKX0kWwq#.bgrWv9dRI](https://www.buzzfeed.com/stephaniemlee/these-startups-will-pay-you-for-your-dna?utm_term=.wbKX0kWwq#.bgrWv9dRI) [<https://perma.cc/L2GS-HM9Q>]. Genos Research is another prominent startup that offers individuals monetary compensation for donating their biological material. *Id.* Customers send in a saliva sample of their DNA, and for \$499, the San Francisco-based startup will perform a genetic sequencing of the sample. *Id.* Researchers will then use the Genos Research platform to acquire DNA samples for their studies by analyzing the company's database of genetic profiles. *Id.* If the researcher wants to use a participant's sample, the participant will be paid between \$50 and \$200 depending on the study. *Id.* Presently, the company is focusing its research interests on lymphoma, breast and skin cancer, neurological and psychiatric disorders, and a rare type of neurodegenerative disorder known as Prion disease. *Id.* The company has secured a number of high profile advisors such as esteemed geneticists George Church and Dietrich Stephan, a Nobel Prize winning economist, and other technology executives. *Id.* Genos Research has raised \$6 million thus far from NantOmics, a biotechnology company founded by renowned physician and billionaire entrepreneur Patrick Soon-Shiong. *Id.* The company charges pharmaceutical companies more than academic and nonprofit institutions for access to its database. *Id.* In contrast, DNASimple presently charges scientists \$155 for every match, \$50 of which goes to the customer. *Id.* Biological samples like those collected by DNASimple and Genos Research are projected by some estimates to generate \$23 billion in revenue by 2018. Daley & Cranley, *supra* note 5.

research and treatment just as significant advancements in the field of precision medicine are being made.<sup>7</sup>

Medical care and treatment is poised for significant change and acceleration in the coming years due to advances in genetic and genomic technology.<sup>8</sup> It has been more than ten years since the completion of the Human Genome Project, a thirteen-year, three-billion dollar project to sequence the human genome.<sup>9</sup> Remarkably, by 2015, the cost to sequence a human genome had fallen to approximately one thousand dollars.<sup>10</sup> Genome sequencing costs are now in the range of typical sophisticated medical tests allowing clinicians to use genetic technologies to diagnose developmental disorders, cancers, and other diseases.<sup>11</sup> Additionally, researchers have used these technologies to better understand the genetic basis of thousands of diseases and conditions and to develop medical therapies, such as drug regimens, to treat these illnesses.<sup>12</sup>

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<sup>7</sup> Daley & Cranley, *supra* note 5. Human DNA derived from biological samples is in high demand as the pharmaceutical industry, government agencies, and academic medical centers seek to translate genetic discoveries to medical treatments and therapies. *Id.* For example, in the field of cancer genomics, an insufficient quantity of tissue samples is considered a “rate-limiting step” to the progress of the field’s research. Hakimian & Korn, *supra* note 1, at 2500.

<sup>8</sup> Susan Young Rojahn, *A Decade of Advances Since the Human Genome Project*, MIT TECH. REV. (Apr. 12, 2013), <https://www.technologyreview.com/s/513666/a-decade-of-advances-since-the-human-genome-project/> [<https://perma.cc/4QE9-QF2N>].

<sup>9</sup> *Id.*

<sup>10</sup> *The Cost of Sequencing a Human Genome*, NAT’L HUM. GENOME RES. INST., <https://www.genome.gov/sequencingcosts/> [<https://perma.cc/6T9F-E4D9>]. The reduction in cost does not appear likely to slow. *Id.*

<sup>11</sup> Rojahn, *supra* note 8. Genetic sequencing holds tremendous promise in aiding in the diagnosis of disease. See Carl Zimmer, *What’s Behind Many Mystery Ailments? Genetic Mutations, Study Finds*, N.Y. TIMES (Mar. 15, 2018), <https://www.nytimes.com/2018/03/15/health/genetic-mutations-diagnosis.html> [<https://perma.cc/WD6F-9FG7>] (describing the results of a study that analyzed the electronic health records and DNA samples of over twenty-one thousand patients). The researchers determined that almost 4% of patients carried a Mendelian disease-linked genetic mutation. *Id.* Further, the study posited that as many as 4.5% of cases of seemingly non-genetic diseases, such as infertility or kidney failure, are the result of these mutations. *Id.*

<sup>12</sup> Edward D. Esplin et al., *Personalized Sequencing and the Future of Medicine: Discovery, Diagnosis and Defeat of Disease*, 15 PHARMACOGENOMICS 1771, 1771 (2014). Many of these much-anticipated pharmacogenomic therapies are just beginning to come to market. See, e.g., Jeannie Baumann, *AstraZeneca Drug Approved for Targeted Breast Cancer Therapy*, BLOOMBERG BNA LIFE SCI. L. & INDUSTRY REP. (Jan. 19, 2018) (describing approval of a drug therapy to treat patients with metastatic breast cancer who have a BRCA gene mutation). The Food and Drug Administration’s (FDA) approval of AstraZeneca’s Lynparza marked the first time the agency approved any drug to treat certain patients with metastatic breast cancer patients that carry a BRCA gene mutation. *Id.* Lynparza can be seen as exemplary of a precision medicine approach to tailoring disease prevention and treatment. See *id.* (“This approval demonstrates the current paradigm of developing drugs that target the underlying genetic causes of a cancer, often across cancer types.”) In order to be treated with Lynparza, patients suffering from metastatic breast cancer undergo a diagnostic blood test to detect BRCA mutations. *Id.* By treating patients with this particular genetic mutation, a more effective, targeted, and precise therapy can be delivered. *Id.* This is particularly significant as patients with BRCA-related metastatic breast cancer are often younger than other breast cancer patients, and their disease is more aggressive and harder to successfully treat. *Id.* The FDA has also recently approved a

Of significant promise is the prospect that genomic technologies can be utilized to predict and prevent disease.<sup>13</sup> At present, clinicians utilize these technologies to treat diseases as they emerge, using invasive methods and procedures that are often expensive and have a high morbidity.<sup>14</sup> Genomic technology offers a future of medicine where disease can be prevented if patients and medical providers are armed with an individual's personal genomic profile.<sup>15</sup> This information can be used to inform surveillance and lifestyle choices, as well as to develop preemptive pharmacogenomic therapies.<sup>16</sup>

The promise and transformational value of these genetic technologies is dependent on researchers and clinicians having access to large numbers of human biological samples.<sup>17</sup> There has been a marked increase in demand for

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drug, Merck's Keytruda, for cancer patients whose tumors share a certain genetic profile, regardless of the tumor's location in the body. See Gina Kolata, *Cancer Drug Proves to Be Effective Against Multiple Tumors*, N.Y. TIMES (June 8, 2017), <https://www.nytimes.com/2017/06/08/health/cancer-drug-keytruda-tumors.html> [<https://perma.cc/GAQ9-XJTG>] (noting that this is the first time the FDA has approved such a drug). Treatment with Keytruda represents a departure from the traditional clinical approach to cancer therapy. *Id.* Clinicians typically categorize cancers by their location in the body, instead of the underlying genetic mutation causing the cancerous tumors. *Id.* The drug, and the associated diagnostic test to identify the particular genetic mutation, has been used for treatment of lung, melanoma, and bladder tumors. *Id.*

<sup>13</sup> Esplin et al., *supra* note 12, at 1787.

<sup>14</sup> *Id.* The FDA has recently approved the first ever gene therapy available in the United States. Denise Grady, *F.D.A. Approves First Gene-Altering Leukemia Treatment, Costing \$475,000*, N.Y. TIMES (Aug. 30, 2017), <https://www.nytimes.com/2017/08/30/health/gene-therapy-cancer.html> [<https://perma.cc/ZKC6-9YVZ>]. Novartis's Kymria is used for an aggressive and previously resistant to treatment type of leukemia. *Id.* Gene therapies, such as Kymria, entail the removal of a patient's white blood cells or T cells from their bloodstream, which are then shipped to Novartis for genetic engineering, and the reintroduction of the manipulated cells back into the patient's bloodstream—effectively turning the patient's cells into a “living drug” that is trained to recognize and attack cancer cells. *Id.* The FDA also recently approved a gene therapy treatment for a rare, genetic form of blindness. Jeannie Baumann, *Gene Therapy Cost ‘Sparks’ Debate About Pricing Future Therapies*, BLOOMBERG BNA LIFE SCI. L. & INDUSTRY REP. (Jan. 19, 2018). Spark Therapeutics, Inc.'s (“Spark”) Luxturna essentially cures blindness in those born with a certain rare genetic mutation. *Id.* More gene therapies are likely to be approved in the future as more than five hundred types of gene therapy are currently being studied. Grady, *supra*. Spark, for instance, is currently working on a gene therapy for hemophilia, a rare, genetic disorder that causes blood clots. Baumann, *supra*. Pharmaceutical giant, Pfizer, announced in 2016 that it plans to become an “industry leader” in gene therapy, initially focusing on gene therapies for ALS. *Id.*

<sup>15</sup> Esplin et al., *supra* note 12, at 1787; see Kate Crawford & Jason Schultz, *Big Data and Due Process: Toward a Framework to Redress Predictive Harms*, 55 B.C. L. REV. 93, 102 (2014) (describing how technological advancement and more sophisticated health data can improve diagnostic predictions and treatment suggestions).

<sup>16</sup> Esplin et al., *supra* note 12, at 1787. Surveillance, in this context, refers to the ongoing and systematic collection and analysis of a person's health data with the purpose of using that information to prevent or control a disease. *Medical Definition of Disease Surveillance*, MEDICINET.COM, <https://www.medicinenet.com/script/main/art.asp?articlekey=26702> [<https://perma.cc/ZF9N-QMWF?type=image>].

<sup>17</sup> Kayte Spector-Bagdady, *The Privacy Debate Over Research with Your Blood and Tissue*, CONVERSATION (Jan. 25, 2017), <https://theconversation.com/the-privacy-debate-over-research-with-your-blood-and-tissue-71523> [<https://perma.cc/U7D3-MCVT>]. Personalized medicine requires con-

human biological material in recent decades, with no reason to suspect the demand will soften in the foreseeable future.<sup>18</sup> Consequently, restrictions or additional barriers on access to the necessary biosamples risk the continued progress and development of this promising field.<sup>19</sup>

Part I of this Note outlines the legal framework in which any asserted biorights operate.<sup>20</sup> Part I focuses specifically on the judicial decisions and regulations that guide the biomedical research enterprise in the United States.<sup>21</sup> Part II addresses the updated regulations regarding biomedical research set to go

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ducting large-scale comparisons of data from thousands of biosamples to identify relationships between genetic variation, medical outcomes, and health behavior. *Id.* In 2015, the Obama administration announced a \$215 million research initiative to collect biosamples from more than a million volunteers who would provide biosamples and associated health data. *FACT SHEET: President Obama's Precision Medicine Initiative*, WHITE HOUSE OFF. PRESS SECRETARY (Jan. 30, 2015), <https://obamawhitehouse.archives.gov/the-press-office/2015/01/30/fact-sheet-president-obama-s-precision-medicine-initiative> [<https://perma.cc/68YR-T64Y>]. The Precision Medicine Initiative “[t]hrough collaborative public and private efforts . . . will leverage advances in genomics, emerging methods for managing and analyzing large data sets while protecting privacy, and health information technology to accelerate biomedical discoveries.” *Id.* Biologically valuable human samples are typically stored in biobanks throughout the country to which researchers can obtain access. Daley & Cranley, *supra* note 5. For example, in Boston, Partners Healthcare, a \$12 billion healthcare system, is seeking to build a biobank with samples from over one hundred thousand volunteers for use by the system’s six thousand researchers. *Id.*; *Partners HealthCare Reports 2016 Financial Results*, PARTNERS HEALTHCARE, <http://www.partners.org/Newsroom/Press-Releases/Financial-Statement-Q42016.aspx> [<https://perma.cc/NX2Q-4FAH>]. The need for large numbers of genetically profiled samples is also a concern for developers of genetic sequencing tests and diagnostic tools. Jeannie Baumann, *FDA Posed to Finalize Advanced Genetic Diagnostics Guidance*, BLOOMBERG BNA LIFE SCI. L. & INDUSTRY REP. (Jan. 19, 2018). Traditional diagnostic tests detect only a single or a limited number of substances to diagnose a condition; however, next generation sequencing technologies identify approximately three million genetic variants an individual may possess. *Id.* The current FDA approval and validation process for these tests, which would review each of the three million data points, is impractical. *Id.* Therefore, the FDA is expected to issue guidance that modernizes the way it approves and validates genetic sequencing tests and diagnostic tools. *Id.* One such guidance would permit developers to rely on certain approved databases to support the clinical effectiveness and interpretation of their tests—essentially “crowdsourcing” the supporting evidence from a large number of genetically and clinically profiled samples. *Id.*

<sup>18</sup> See Hakimian & Korn, *supra* note 1 (describing the increased demand for biosamples); Specter-Bagdady, *supra* note 17 (describing the ambitious goals of precision medicine and the need for large numbers of biosamples).

<sup>19</sup> Daley & Cranley, *supra* note 5. Leading professional organizations, such as the Association of American Universities and the National Academies of Science, Engineering, and Medicine, oppose changes to the current collection system out of concern that restrictions on access and high costs would stifle medical advances. *Id.* The emergence of this issue has prompted commentary and attention throughout the medical, scientific, and bioethics communities. See Akanksha Jayanthi, *In ‘Biorights’ Movement, Patients Seek Compensation for Providing Genetic Samples*, BECKER HOSP. REV. (Oct. 11, 2016), <http://www.beckershospitalreview.com/healthcare-information-technology/in-biorights-movement-patients-seek-compensation-for-providing-genetic-samples.html> [<https://perma.cc/Q45D-U258>] (demonstrating that the issue has catalyzed debate among bioethicists, as well as the healthcare and scientific research communities); *‘BioRights’ Rise: Donors Demand Control of Their Samples*, BIOETHICS RES. LIBR., GEO. LIBR. (Oct. 10, 2016), <https://bioethics.georgetown.edu/2016/10/biorights-rise-donors-demand-control-of-their-samples> [<https://perma.cc/YS66-Q5D8>] (same).

<sup>20</sup> See *infra* notes 25–90 and accompanying text.

<sup>21</sup> See *infra* notes 25–90 and accompanying text.

into effect in 2018.<sup>22</sup> Part III provides an analysis of the updated regulations and argues that the regulations do not go far enough to sufficiently prevent the harmful consequences of the positions advanced by the biorights movement.<sup>23</sup> Specifically, regulations need to be enacted that explicitly prevent individuals from selling their biological material for research purposes.<sup>24</sup>

## I. THE LEGAL BASIS FOR ASSERTING ONE'S BIORIGHTS

The emergence of the biorights movement is at its core an expression of personal autonomy.<sup>25</sup> In a healthcare context, autonomy is particularly important.<sup>26</sup> A respect for autonomy means allowing patients to make informed decisions about their medical treatment and care.<sup>27</sup> Treating people as autonomous agents with rights of self-determination also includes their ability to participate in medical research and to “donate” their biological material for research purposes.<sup>28</sup> The term donation implies some form of a property or ownership right in the biological material.<sup>29</sup> The law, however, is unclear in regard to the ownership rights of human biological materials.<sup>30</sup>

This Part outlines the legal framework guiding any asserted rights to one's biological material.<sup>31</sup> Section A discusses the judicial decisions that shape the outer boundaries of ownership or property rights to one's biological material as they relate to participation in medical or scientific research.<sup>32</sup> Section B explores the current statutory and regulatory framework that governs the manner in which human subject research is conducted.<sup>33</sup>

### *A. An Individual's Right to Their Biological Material Extends Only So Far*

In the absence of any abundant clarity, “researchers and institutions have assumed they retain the right to collect, study, store, transfer, or dispose of tis-

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<sup>22</sup> See *infra* notes 91–137 and accompanying text.

<sup>23</sup> See *infra* notes 138–219 and accompanying text.

<sup>24</sup> See *infra* notes 138–219 and accompanying text.

<sup>25</sup> See Kristin E. Schleiter, *Donors Retain No Rights to Donated Tissue*, 11 *AMA J. ETHICS* 621, 621 (2009) (describing autonomy as the quality or state of self-governing).

<sup>26</sup> *Id.*

<sup>27</sup> *Id.*

<sup>28</sup> *Id.*

<sup>29</sup> *Id.* To “donate” means to give (property or money) without receiving consideration for the transfer. *Donate*, BLACK'S LAW DICTIONARY (10th ed. 2014).

<sup>30</sup> Schleiter, *supra* note 25, at 621.

<sup>31</sup> See *infra* notes 34–90 and accompanying text.

<sup>32</sup> See *infra* notes 34–52 and accompanying text.

<sup>33</sup> See *infra* notes 53–90 and accompanying text.

sue specimens and the associated patient data.”<sup>34</sup> Such assumptions have been challenged in three noteworthy cases.<sup>35</sup>

In what remains the seminal case on the issue, in 1990, in *Moore v. Regents of University of California*, the Supreme Court of California held that individuals do not retain an ownership interest in their cells after the cells are removed from their bodies.<sup>36</sup> Plaintiff John Moore brought suit against his physician and University of California, Los Angeles Medical Center after they failed to disclose to him that his spleen tissue and other biological material collected, in what Moore assumed was the course of standard clinical care, were being used for commercially lucrative research purposes.<sup>37</sup> The court ultimately found that a cell line derived from the cells of Moore’s surgically excised spleen was a product of invention and, therefore, not the property of the donor.<sup>38</sup> Even if the cells initially belonged to Moore, those cells were legally and factually distinct from the resulting research product.<sup>39</sup> Although technically only binding in California, the decision was hugely influential in shaping

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<sup>34</sup> Schleiter, *supra* note 25, at 621.

<sup>35</sup> See *Wash. Univ. v. Catalona*, 490 F.3d 667, 676–77 (8th Cir. 2007) (holding that individuals who provide biological samples for research do so as irrevocable inter vivos gifts retaining no property rights to request the return or transfer of the samples to another party); *Moore v. Regents of Univ. of Cal.*, 793 P.2d 479, 493–95 (Cal. 1990) (holding that individuals do not retain an ownership interest in their cells after the cells are removed from their bodies); *Greenberg v. Miami Children’s Hosp. Research Inst., Inc.*, 264 F. Supp. 2d 1064, 1076 (S.D. Fla. 2003) (holding that voluntarily donating biosamples is done absent a contemporaneous expectation of return even though a commercial benefit may accrue). The invention at issue in *Moore* was a cell line, a common but also valuable biological research tool. *Cell Line*, BIOLOGY ONLINE, [https://www.biology-online.org/dictionary/Cell\\_line](https://www.biology-online.org/dictionary/Cell_line) [<https://perma.cc/EW5V-FZKR>]. Specifically, a cell line is a cell culture, or a cultivation of cells grown outside their natural environment in a laboratory, that is immortalized and will proliferate indefinitely given the appropriate laboratory conditions. *Id.*; *Cell Culture*, BIOLOGY ONLINE, [https://www.biology-online.org/dictionary/Cell\\_culture](https://www.biology-online.org/dictionary/Cell_culture) [<https://perma.cc/K5PQ-SAE9>]. See generally Jean-Pierre Gillet, *The Clinical Relevance of Cancer Cell Lines*, 105 J. NAT’L CANCER INST. 452 (2013) (discussing the value but also limitations of using cell lines in cancer research).

<sup>36</sup> 793 P.2d at 493–95. In *Moore*, the plaintiff, John Moore, sought treatment from the University of California, Los Angeles Medical Center (“UCLA”) for a rare form of leukemia. *Id.* at 481. Moore’s physician removed his spleen for therapeutic purposes but used the spleen tissue for research purposes. *Id.* He did not disclose such a fact to Moore. *Id.* Moore continued to return to UCLA for several years after the procedure under the guise of medical necessity, when in fact the research team needed to collect additional samples. *Id.* The researchers were eventually able to develop and patent a cell line from Moore’s samples that was worth approximately three billion dollars. *Id.* at 482. Moore sought to recover a share of the proceeds of the patented cell line bringing claims of conversion and breach of physician disclosure obligations. *Id.* at 482–83. Although the court rejected Moore’s conversion claim, it recognized a physician’s duty to disclose economic or research interests to patients when seeking consent for a medical procedure. *Id.* at 493–95.

<sup>37</sup> *Id.* at 481–82.

<sup>38</sup> *Id.* at 492–93.

<sup>39</sup> *Id.* In refusing to impose conversion liability, the court placed significant emphasis on the policy considerations of not wanting to impede medical research and the derivative social benefits. *Id.*



jurisprudence in this area of law and was the only decision on the issue of ownership of biological samples for more than a decade.<sup>40</sup>

Similarly, in 2003, in *Greenberg v. Miami Children's Hospital Research Institute, Inc.*, the U.S. District Court for the Southern District of Florida held that individuals have no property rights in their body tissue and genetic material donated for research.<sup>41</sup> Unlike in *Moore*, however, the biological material in *Greenberg* was donated voluntarily and knowingly for research and not obtained during the course of clinical care.<sup>42</sup> In *Greenberg*, the plaintiff approached a physician-scientist to help identify the genes associated with a rare and fatal genetic disease common in the plaintiff's Ashkenazi Jewish community.<sup>43</sup> The plaintiff provided researchers with access to biological samples, financial support, and helped recruit other Ashkenazi Jewish individuals to participate in the research project.<sup>44</sup> The court ultimately concluded that the materials at issue were voluntarily donated without a contemporaneous expectation of return even though a commercial benefit accrued.<sup>45</sup>

Much of the *Greenberg* court's reasoning was echoed by the U.S. Court of Appeals for the Eighth Circuit, in 2007, in *Washington University v. Catalo-*

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<sup>40</sup> See Hakimian & Korn, *supra* note 1, at 2502 (describing how no other state or federal court ruled on the ownership of tissue samples in research for more than a decade following *Moore*, which was noteworthy given the burgeoning biotechnology industry of the time); Osagie K. Obasogie, *Your Body, Their Property*, BOS. REV. (Sept. 30, 2013), <http://bostonreview.net/us/obasogie-gene-patent-myriad-moore> [<https://perma.cc/9SP6-HV85>] (“[*Moore*] enshrined a principle in property law that . . . patients have virtually no property interest in most of the non-reproductive cells or tissues taken from them, even when these materials turn out to be profitable to researchers and institutions. This conclusion by the California Supreme Court has been followed by almost every jurisdiction.”). The Supreme Court also denied a Petition for Writ of Certiorari. *Moore*, 793 P.2d 479, *cert. denied*, 499 U.S. 936 (1991).

<sup>41</sup> 264 F. Supp. 2d at 1074–75. The plaintiff, Daniel Greenberg, had initially approached Reuben Matalon, MD, PhD, to request his assistance in discovering the genes associated with Canavan disease, a rare and fatal genetic disease frequently occurring in the Ashkenazi Jewish population. *Id.* at 1068. Greenberg and others supplied Matalon with blood, urine, and tissue samples to help in the development of a prenatal test that would screen for the disease. *Id.* With the support of Miami Children's Hospital Research Institute (“MCH”), Matalon was able to isolate and clone the gene associated with Canavan disease. *Id.* MCH obtained a patent on the gene and related applications generating annual royalties of approximately \$375,000. *Id.* Greenberg filed suit claiming that the defendants had a duty to disclose any information that might influence a prospective subject's decision to participate in the research, including the desire to seek a patent and commercial benefit from the research. *Id.* The commercial benefit derived in this case from a patented gene would no longer be realized since the U.S. Supreme Court decision to strike down the validity of gene patents. *Ass'n for Med. Pathologists v. Myriad Genetics*, 569 U.S. 576, 580 (2013). In *Myriad Genetics*, the Court held that naturally-occurring human genes are not patentable. *Id.* A naturally-occurring DNA segment is a product of nature and is not patent-eligible merely because it has been isolated. *Id.*

<sup>42</sup> *Greenberg*, 264 F.Supp.2d at 1067–68.

<sup>43</sup> *Id.*

<sup>44</sup> *Id.*

<sup>45</sup> *Id.* at 1076. The court looked to the reasoning in *Moore* in declining to extend conversion liability to body tissue and genetic material donated for research, as well as Florida state court decisions that limit property rights attached to body tissue. *Id.* at 1075–76.

na.<sup>46</sup> There, the court held that individuals who provided biological samples for research did so as inter vivos gifts and retained no property rights that would allow them to request the return of the samples or the transfer to a third party.<sup>47</sup> The court determined that the research participants voluntarily donated the samples for research, and once the donative transfer was completed, the gift was irrevocable.<sup>48</sup>

The aforementioned cases demonstrate that while individuals have the right to donate bodily tissues for research purposes, the right to own and retain control of donated tissues is extinguished once those tissues leave the body.<sup>49</sup> Such a loss encompasses any claim of commercial benefit acquired through the development of products derived from the tissue.<sup>50</sup> Courts have consistently expressed concern that if patients were able to retain ownership rights over their biosamples, research could not be performed efficiently or effectively.<sup>51</sup> Patients remain free, however, to enter into legal contracts prior to the removal of their biological material that allow them to retain certain property rights in that material.<sup>52</sup>

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<sup>46</sup> *Catalona*, 490 F.3d at 676–77. In *Catalona*, a physician-scientist’s patients signed consent forms contributing their biological samples to a biorepository at the researcher’s institution of Washington University. *Id.* at 670–71. When the researcher requested the transfer of the samples to a private research laboratory and later to another academic medical center, Washington University refused to authorize the transfer of the samples despite the patients requesting as such. *Id.* The patients sued claiming ownership rights to their tissue, which included the ability to transfer the tissues to another institution. *Id.* at 672–73. An inter vivos gift is a gift of personal property made during the donor’s lifetime and delivered to the donee with the intention of irrevocably surrendering control over the property. *Inter vivos gift*, BLACK’S LAW DICTIONARY (10th ed. 2014).

<sup>47</sup> *Catalona*, 490 F.3d. at 676–77.

<sup>48</sup> *Id.*

<sup>49</sup> See Carlo Petrini, *Ethical and Legal Considerations Regarding the Ownership and Commercial Use of Human Biological Materials and Their Derivatives*, 2012 J. BLOOD MED. 87, 92 (describing how the aforementioned cases indicate that case law is generally oriented towards recognizing certain assertions regarding ownership).

<sup>50</sup> *Id.*

<sup>51</sup> See *Moore*, 793 P.2d at 492–93 (placing significant emphasis on encouraging the burgeoning biotechnology industry at the time and the desire to not impede societally valuable medical and scientific research); *Greenberg*, 264 F. Supp. 2d at 1076 (warning that imposing conversion liability on research institution for use of donated biosamples would cripple medical research); see also Sarah Dry et al., *Stuck Between a Scalpel and a Rock, or Molecular Pathology and Legal-Ethical Issues in Use of Tissues for Clinical Care and Research*, 137 AM. J. CLINICAL PATHOLOGY 346, 350 (2012) (noting that “courts consistently have rejected the idea that patients are the owners of their removed biosamples that are used for research purposes” as ownership could further frustrate the research process).

<sup>52</sup> Dry et al., *supra* note 51, at 350. An influential article on the tissue-industrial complex appeared in a 2006 issue of *The New York Times Magazine*. Rebecca Skloot, *Taking the Least of You*, N.Y. TIMES MAG. (Apr. 16, 2006), <http://www.nytimes.com/2006/04/16/magazine/taking-the-least-of-you.html> [https://perma.cc/DJ9J-THSQ]. The article describes how in the 1970s, Ted Slavin, upon learning that his blood contained highly valuable Hepatitis B antibodies, sold his blood to laboratories and companies in what was an unusual arrangement at the time. *Id.* Hepatitis B is a liver infection caused by the Hepatitis B virus that is transmitted when blood, semen, or another body fluid from a

### B. Confusion Abounds in Statutory and Regulatory Framework

Human subject research in the United States that is conducted or supported by federal agencies is governed by federal regulations.<sup>53</sup> Although technically only research that is federally funded or conducted by federal agencies must adhere to the applicable federal regulations, in practice, many institutions require all research proposals to adhere to federal regulation standards.<sup>54</sup> Additionally, state or local laws may impose additional forms of research subject protection.<sup>55</sup>

Federal policies on human research are specified in the Code of Federal Regulations in what has been termed the Common Rule.<sup>56</sup> The Department of Health and Human Services' ("HHS") Office for Human Research Protections is responsible for the interpretation and oversight of the Common Rule.<sup>57</sup> The Food and Drug Administration (FDA) provides an additional regulatory framework for some types of human subject research.<sup>58</sup> Subsection 1 of this Section outlines the regulatory framework governing issues of consent for human subjects research.<sup>59</sup> Subsection 2 of this Section describes the regulatory guidelines that address issues of ownership of human biological material.<sup>60</sup>

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person infected with the Hepatitis B virus enters the body of someone who is not infected. *Hepatitis B Information*, CTNS. FOR DISEASE CONTROL & PREVENTION, <https://www.cdc.gov/hepatitis/hbv/> [<https://perma.cc/P99T-YTAT>]. This can happen through sexual contact, sharing needles, syringes, or other drug-injection equipment, or from mother to baby at birth. *Id.* A test for Hepatitis B, a multi-billion-dollar market, required a significant supply of the antibodies in Slavin's blood. Skloot, *supra*. Slavin's blood was also used to help uncover the link between Hepatitis B and liver cancer and the first Hepatitis B vaccine. *Id.* Slavin later created a company that recruited other people with valuable blood. *Id.* The difference between Slavin and the plaintiff in *Moore* was not that Slavin owned his tissues and the plaintiff in *Moore* did not. *Id.* It was that Slavin was told his tissues were valuable to researchers and was able to control the use of them before they left his body. *Id.*

<sup>53</sup> See 45 C.F.R. § 46.101 (2016) (outlining which types of human subjects research are subject to federal regulations).

<sup>54</sup> See R. HAKIMIAN ET AL., NAT'L CANCER INST. CANCER DIAGNOSIS PROGRAM, 50-STATE SURVEY OF LAWS REGULATING THE COLLECTION, STORAGE, AND USE OF HUMAN TISSUE SPECIMENS AND ASSOCIATED DATA FOR RESEARCH 90 n.3 (2004), <https://ntrl.ntis.gov/NTRL/dashboard/searchResults/titleDetail/PB2006100582.xhtml> [<https://perma.cc/N2FN-4T4J>] ("While the Common Rule only applies to human subjects research that is federally funded or conducted, many research institutions have agreed to subject all of their research activities to its requirements.").

<sup>55</sup> Dry et al., *supra* note 51, at 351.

<sup>56</sup> *Federal Policy for the Protection of Human Subjects ('Common Rule')*, U.S. DEP'T HEALTH & HUM. SERVS., <https://www.hhs.gov/ohrp/regulations-and-policy/regulations/common-rule/index.html> [<https://perma.cc/U4B2-3RBD>] (describing how the Federal Policy for the Protection of Human Subjects or Common Rule was published in 1991 and codified in separate regulations by fifteen federal agencies, with the applicable Department of Health and Human Services ("HHS") regulations located in 45 C.F.R. Part 46).

<sup>57</sup> Hakimian & Korn, *supra* note 1, at 2501.

<sup>58</sup> See 21 C.F.R. § 50.1 (2016) (stating that the FDA's purview extends to clinical investigations involving drugs or biological products for human use).

<sup>59</sup> See *infra* notes 61–82 and accompanying text.

<sup>60</sup> See *infra* notes 83–90 and accompanying text.

## 1. Informed Consent Standards

Informed consent serves many purposes.<sup>61</sup> In a clinical context, it serves to permit patients to make informed choices about the appropriate options for their care.<sup>62</sup> Informed consent is often viewed as a rejection of the notions of paternalism often pronounced in medicine.<sup>63</sup> In therapeutic research, such as participation in a clinical trial, informed consent serves a similar function to that in clinical care with the notable exception that the experimental option could be ineffective or even harmful, necessitating the need for more thorough consent procedures.<sup>64</sup> Nontherapeutic research, however, offers no prospect of direct benefit to the subject.<sup>65</sup> The benefit, if any, may accrue to the individual in the future or to others in society.<sup>66</sup>

Appropriate consent guidelines vary according to the purpose for which human biological material is collected.<sup>67</sup> For instance, a biological sample collected in the course of therapeutic treatment, like a biopsy, has different consent considerations than for what is collected as “surgical leftovers.”<sup>68</sup> Additionally, samples collected for one purpose may be subsequently used for others.<sup>69</sup> Consent practices also need to be tailored to each type of intervention.<sup>70</sup> Consequently, general consent guidelines are infeasible.<sup>71</sup> Consent standards

<sup>61</sup> Jeffrey R. Botkin, *Informed Consent for the Collection of Biological Samples in Household Surveys*, in 12 CELLS AND SURVEYS: SHOULD BIOLOGICAL MEASURES BE INCLUDED IN SOCIAL SCIENCE RESEARCH 276, 277–78 (Caleb E. Finch et al. eds., 2001) (describing how the emergence of informed consent parallels the consumer rights movement in society more broadly).

<sup>62</sup> *Id.* at 278.

<sup>63</sup> *Id.*

<sup>64</sup> *Id.*

<sup>65</sup> *Id.* at 278–79.

<sup>66</sup> *Id.* Some of the most egregious examples of abuse in U.S. biomedical research have involved nontherapeutic research projects, some even involving federal agencies, such as the Tuskegee syphilis experiments and human radiation experiments. *Id.* Such incidences are widely considered to have driven the development of informed consent requirements and other research participant protections. *Id.*

<sup>67</sup> Petri, *supra* note 49, at 87.

<sup>68</sup> *Id.* A biopsy is a procedure to remove a piece of tissue or a sample of cells from your body so that they can be analyzed in a laboratory. *Biopsy: Types of Biopsy Procedures Used to Diagnose Cancer*, MAYO CLINIC, <http://www.mayoclinic.org/diseases-conditions/cancer/in-depth/biopsy/art-20043922> [https://perma.cc/AV4M-B7MM]. Surgical leftovers refer to the tissue that is removed from patients during an operation as part of their clinical care and that would normally be disposed of as medical waste. *Material Leftover from an Operation*, IMPERIAL C. LONDON, <http://www.imperial.ac.uk/imperial-college-healthcare-tissue-bank/collection-of-tissue/material-leftover-from-an-operation/> [https://perma.cc/87VZ-4TSR].

<sup>69</sup> Petri, *supra* note 49, at 87.

<sup>70</sup> *Id.*

<sup>71</sup> *Id.*; see Christine Grady, *The Changing Face of Informed Consent*, 376 NEW ENG. J. MED. 856, 857 (2017) (“Even those who favor requiring consent for biospecimen research disagree about whether consent should be broad enough or a wide range of future possible research or specific for each use, one-time or ongoing, and opt-in or opt-out.”). See generally Amy L. McGuire & Laura M. Beskow, *Informed Consent in Genomics and Genetic Research*, in 11 ANN. REV. OF GENOMICS & HUM. GE-

and requirements for the collection of human biological material are dictated by the context in which the samples are obtained, as well as the purpose for which the samples are collected.<sup>72</sup>

Responsibility for compliance with federal regulations, including informed consent requirements, is tasked to institutional review boards (“IRBs”).<sup>73</sup> IRBs are internal institutional committees composed of research scientists, regulatory compliance staff, legal experts, and members of the lay public.<sup>74</sup> These boards interpret federal guidelines and apply them to submitted research proposals from their institutions to ensure regulatory compliance.<sup>75</sup>

Informed consent and IRB review are required when researchers obtain from living individuals “identifiable private information” or “data through interaction or intervention with the individual.”<sup>76</sup> Additionally, federal regulations dictate a variety of elements that must be included in obtaining informed consent.<sup>77</sup> Certain types of human subject research, however, can be exempted from the informed consent requirement.<sup>78</sup>

Federal regulations have allowed research use of patient biosamples obtained without informed consent as long as the patient’s identity is unknown; the sample must be anonymized.<sup>79</sup> Further, biosamples not obtained specifically for research use through an intervention or interaction with a living person,

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NETICS (2010) (describing how traditional standards of consent are incompatible with modern research techniques and methodologies as the scope of future research with collected biosamples cannot be foreseen at the time of collection).

<sup>72</sup> Petrini, *supra* note 49, at 87.

<sup>73</sup> See 45 C.F.R. § 46.109 (a) (2016) (stating that “[a]n IRB [Institutional Review Board] shall review and have authority to approve, require modifications in (to secure approval), or disapprove all research activities covered by this policy”).

<sup>74</sup> See *id.* § 46.107 (detailing the requirements for a valid IRB including membership criteria).

<sup>75</sup> *Id.*

<sup>76</sup> Hakimian & Korn, *supra* note 1, at 2501; see 45 C.F.R. § 46.102(f) (defining “human subject” research subject to federal regulation).

<sup>77</sup> See 45 C.F.R. § 46.116 (detailing the informed consent requirements). In the rulemaking process culminating in the enactment of the original version of the Common Rule in 1991, the applicable agencies did address comments that “research that could involve sensitive data could place the subjects at risk, even if information is not recorded in such a manner that human subjects be identified and should not be exempt from provisions of the Policy.” Federal Policy for the Protection of Human Subjects; Notices and Rules, 56 Fed. Reg. 28,002, 28,007 (June 18, 1991) (codified at 45 C.F.R. pt. 46). One comment noted that “one IRB reviews this type of research even if an exemption is permitted by the regulations.” *Id.* The agencies responded that “at a later date” they may consider incorporation of stricter provisions, but “such considerations should not delay publication of basic protections for all human subjects.” *Id.*

<sup>78</sup> See 45 C.F.R. § 46.116. (describing how the IRB may approve a consent procedure which does not include, or which alters, some or all of the elements of informed consent set forth above, or waive the requirement to obtain informed consent).

<sup>79</sup> *Id.* § 46.102(f); Dry et al., *supra* note 51, at 352; *Coded Private Information or Specimens Use in Research, Guidance*, U.S. DEP’T HEALTH & HUM. SERVS. (Oct. 16, 2008), <https://www.hhs.gov/ohrp/regulations-and-policy/guidance/research-involving-coded-private-information/index.html> [<https://perma.cc/FW9N-HP4D>].

such as a diagnostic biopsy, are exempted from informed consent requirements.<sup>80</sup> From a bioethical perspective, samples obtained in the course of clinical care seem distinct from those obtained from formal research studies.<sup>81</sup> Some bioethicists consider the former type of tissue to be “abandoned” by patients.<sup>82</sup>

## 2. Ownership of Human Biological Material

Regulatory ambiguity persists for issues of ownership of biosamples.<sup>83</sup> Typically, when informed consent is obtained to study a sample, consent forms do not address the issue of tissue ownership, either by the individual who is the source of the specimen, the investigator, or the institution.<sup>84</sup> When tissues are collected without informed consent as part of clinical care, issues of ownership are also not considered.<sup>85</sup> Researchers are presently unable to use informed consent language that either confers or curtails individual ownership rights in tissue samples.<sup>86</sup> The FDA prohibits the use of the term “donation” in consent forms because it implies a waiver of ownership.<sup>87</sup> Additionally, no state laws establish individual ownership rights in tissue samples.<sup>88</sup> At present, researchers are afforded a fair degree of latitude in using biosamples for a variety of research purposes, despite a relatively unclear legal and regulatory frame-

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<sup>80</sup> 45 C.F.R. § 46.102(f); *Coded Private Information or Specimens Use in Research, Guidance*, *supra* note 79.

<sup>81</sup> Dry et al., *supra* note 51, at 352. Bioethics is concerned “with the ethics and philosophical implications of certain biological and medical procedures, technologies, and treatments.” *Bioethics*, DICTIONARY.COM, <http://www.dictionary.com/browse/bioethics> [<https://perma.cc/PVC9-CLBE?type=image>].

<sup>82</sup> Dry et al., *supra* note 51, at 352.

<sup>83</sup> Hakimian & Korn, *supra* note 1, at 2501.

<sup>84</sup> *Id.*

<sup>85</sup> *Id.*

<sup>86</sup> See 45 C.F.R. § 46.116 (stating that “[n]o informed consent, whether oral or written, may include any exculpatory language through which the subject or the representative is made to waive or appear to waive any of the subject’s legal rights, or releases or appears to release the investigator, the sponsor, the institution or its agents from liability for negligence”). The unsettled legal framework regarding ownership rights has likely prompted the lack of clarity by federal regulators. Hakimian & Korn, *supra* note 1, at 2501. In 1987, three years prior to the decision in *Moore*, the U.S. Office of Technology Assessment published a study of the legal, economic, and ethical considerations relating to the ownership of human cells and tissues and concluded that there “is great uncertainty about how courts will resolve disputes between the human sources of specimens and specimen users.” *Id.* In 1996, the HHS’ Office of Human Research Protection (“OHRP”) published guidelines that specifically addressed the proscription of consent form language that implies some form of waiving one’s legal rights. *Id.* The guidelines state that asking participants to relinquish any property rights was exculpatory despite the fact that no such legal rights have been established. *Id.* In 2001, the OHRP reiterated its stance when it said that participants could also not be asked to relinquish continuing ownership rights in their tissue. *Id.*

<sup>87</sup> Hakimian & Korn, *supra* note 1, at 2501.

<sup>88</sup> *Id.*; see HAKIMIAN ET AL., *supra* note 54, at 7–8 (noting that no state statutes have addressed the ownership of tissue samples, and the few states that have passed statutes addressing ownership of “genetic information” still permit the use and retention of such information when the data is anonymous).

work.<sup>89</sup> Proposed changes to the current system would have done more harm than good, but that by no means is to say that the current system would not benefit from change and modernization.<sup>90</sup>

## II. ALTHOUGH THE PROPOSED CHANGES TO THE COMMON RULE ARE A STEP IN THE RIGHT DIRECTION, THE EXISTING REGULATORY FRAMEWORK DOES NOT PROVIDE ADEQUATE PROTECTION FOR MODERN RESEARCH

Section A of this Part discusses the benefits of the proposed changes to the Common Rule and applauds the regulations for their recognition of the way doing research has evolved in the past thirty years.<sup>91</sup> Section A also notes, however, that the updated regulations remain silent on the issue of ownership, and that they fail to address the issue of offering compensation for biosamples contributed for research purposes.<sup>92</sup> In the absence of any update to the Common Rule that specifically addresses the sale of biosamples for research purposes, this Part explores the legal, regulatory, and economic framework regarding the non-proscribed sale of certain biological material.<sup>93</sup> In regard to the sale of human biological material, the National Organ Transplant Act (the “Transplant Act”) is explicit that the trafficking of vital organs for profit is proscribed.<sup>94</sup> The law is less explicit in regard to the sale of other biological material.<sup>95</sup> Section B addresses the sale of bone marrow.<sup>96</sup> Section C provides a similar analysis for blood and plasma donation.<sup>97</sup>

### *A. Bringing the Common Rule into the Twenty-First Century*

In September 2015, HHS and fifteen other federal agencies published a Notice of Proposed Rulemaking (“NPRM”) in regard to updating the Common Rule.<sup>98</sup> The Common Rule had been in effect since 1991 and was drafted at a

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<sup>89</sup> See *supra* notes 25–88 and accompanying text.

<sup>90</sup> See *infra* notes 91–129 and accompanying text.

<sup>91</sup> See *infra* notes 98–113 and accompanying text.

<sup>92</sup> See *Final Rule*, *infra* note 98 (leaving both of these issues unaddressed).

<sup>93</sup> See *infra* notes 98–137 and accompanying text.

<sup>94</sup> 42 U.S.C. § 274e(c)(1) (2012). The statute states: “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. The preceding sentence does not apply with respect to human organ paired donation.” *Id.* The statute defines a “human organ” as “human (including fetal) kidney, liver, heart, lung, pancreas, bone marrow, cornea, eye, bone, and skin or any subpart thereof” as well as any other human organ specified by the HHS Secretary. *Id.*

<sup>95</sup> See *infra* notes 114–137 and accompanying text.

<sup>96</sup> See *infra* notes 114–121 and accompanying text.

<sup>97</sup> See *infra* notes 122–137 and accompanying text.

<sup>98</sup> *Final Rule Enhances Protections for Research Participants, Modernizes Oversight System*, U.S. DEP’T HEALTH & HUM. SERVS., <https://www.hhs.gov/about/news/2017/01/18/final-rule-enhances-protections-research-participants-modernizes-oversight-system.html> [<https://perma.cc/Z259-4BDB>] [hereinafter *Final Rule*].

time when research was conducted predominantly at a single site by universities and academic medical centers.<sup>99</sup> The NPRM drew more than 2100 comments.<sup>100</sup> In January 2017, the updated regulations, which will largely go into effect in 2018, were released in what has been generally seen as a win for the research community.<sup>101</sup> A widely criticized provision that sought to require consent for use of a study participant's de-identified biosamples was removed from the final rule.<sup>102</sup> The final rule maintains the current practice with respect to de-identified biosamples.<sup>103</sup> The final rule also contains a number of changes to the current regulatory framework relating to other aspects of informed consent.<sup>104</sup> Such changes are largely intended to reduce the administrative bur-

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<sup>99</sup> *Id.* According to the HHS Press Release announcing the final rule: "The new rule strengthens protections for people who volunteer to participate in research, while ensuring that the oversight system does not add inappropriate administrative burdens, particularly to low-risk research. It also allows more flexibility in keeping with today's dynamic research environment." *Id.* The updated regulations sought to account for the fact that human subjects research has dramatically increased in scale and diversity. *Id.* Additionally, much of the data gathered is digital and easily transferrable between research groups and institutions throughout the world. *Id.*

<sup>100</sup> *Id.* Most of the comments focused on whether informed consent should be required before using an individual's de-identified biosample. Spector-Bagdady, *supra* note 17. Approximately 80% of commenters opposed the proposal. *Id.*

<sup>101</sup> See Federal Policy for the Protection of Human Subjects: Delay of the Revisions to the Federal Policy for the Protection of Human Subjects, 83 Fed. Reg. 2885, 2885 (Jan. 22, 2018) (delaying the effective date of the final rule six months from January 19, 2018, to July 19, 2018); Dianne J. Bourque, *Newly Updated Common Rule Is Here—And on Collision Course with 21st Century Cures Act*, NAT'L L. REV. (Jan. 26, 2017), <http://www.natlawreview.com/article/newly-updated-common-rule-here-and-collision-course-21st-century-cures-act> [<https://perma.cc/TA7J-QC2C>] (describing the challenges associated with harmonizing the Common Rule with the 21st Century Cures Act); Scott Jaschik, *U.S. Issues Final Version of 'Common Rule' on Research Involving Humans*, INSIDE HIGHER EDUC. (Jan. 19, 2017), <https://www.insidehighered.com/news/2017/01/19/us-issues-final-version-common-rule-research-involving-humans> [<https://perma.cc/4L5E-S87A>] (describing the final rule as a win for research universities). The Association of American Universities and the Association of Public Land-Grant Universities were largely supportive of the final rule. Jaschik, *supra*. Shortly after the announcement of the final rule, the organizations issued a joint statement noting that requiring universities and scientists to obtain consent for potentially billions of de-identifiable biosamples would be administratively burdensome and costly, as well as impede vital research initiatives. *Id.* Support for the enhanced consent procedures for de-identified biosamples largely came from the professional anthropological community. *Id.* The American Anthropological Association viewed the consent requirement as a way to protect patients and increase transparency within the research community. *Id.* They advanced a position that additional administrative burdens would not make conducting research impossible, just more protective of patients and participants. *Id.*

<sup>102</sup> *Final Rule*, *supra* note 98.

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

<sup>104</sup> *Id.* In regards to the text requisite in consent forms, for instance, the final rule requires consent forms to include at the beginning of the document a concise explanation of the key information important to a participant such as the research's purpose and its risks and benefits. *Id.* Jerry Menikoff, MD, who directed the regulatory overhaul stated: "Over the years, many have argued that consent forms have become these incredibly lengthy and complex documents that are designed to protect institutions from lawsuits, rather than providing research subjects with information they need in order to make an informed choice about whether to participate in a research study." *Id.*



dens for researchers and research participants.<sup>105</sup> The final rule also helps to harmonize discrepancies between HHS and FDA regulations, conforming with the FDA's policy that explicitly permits the use of leftover de-identified blood and tissue samples for secondary research.<sup>106</sup>

Although safety and privacy for human research participants remains of paramount importance, the final rule recognizes that these needs must be balanced with enabling scientific progress and technological advances.<sup>107</sup> Additionally, there was concern that the proposal would result in fewer available biosamples as smaller institutions would not be able to implement administratively expensive consent processes.<sup>108</sup> This could impact the diversity of samples collected, as community clinics and local hospitals that serve diverse populations would be least well-positioned to implement such consent processes.<sup>109</sup> Large academic medical centers that have the resources to implement such processes typically serve a less diverse community.<sup>110</sup>

The updated regulations, however, remain silent on the issue of ownership, and they fail to address the issue of offering compensation for biosamples contributed for research purposes.<sup>111</sup> Other areas of the legal and regulatory system are also silent on this issue.<sup>112</sup> The federal government's approach to the most analogous situation to selling biosamples for research purposes, selling blood or bone marrow, could be considered to encourage the sale of biosamples and, therefore, offers no recourse that could prevent such a practice.<sup>113</sup>

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<sup>105</sup> *Id.* Additional changes include requiring a single IRB to oversee multi-institutional research studies and creating new exempt categories of research based on the level of risk they pose to participants. *Id.* Some ongoing research studies will not be subject to continuing IRB reviews if the reviews are considered to do little to protect subjects. *Id.*

<sup>106</sup> Bourque, *supra* note 101. The 21st Century Cures Act includes a mandate for HHS and the FDA to harmonize differences between the Common Rule and FDA Human Subject Protection regulations by January 2020. *Id.* The final rule helps further the goal of reducing regulatory duplication and delay. *Id.*

<sup>107</sup> Spector-Bagdady, *supra* note 17.

<sup>108</sup> *Id.*

<sup>109</sup> *Id.* Genetic research already faces significant criticism and concern that it does not represent a sufficiently diverse population. *Id.* African and Hispanic individuals represent only 5% of participants involved in studies that seek to identify associations between gene disruption and disease. *Id.* The lack of diversity in research studies is not limited to genetic research. See Carolyn Plunkett et al., *Worth the Money? Paying to Ensure a Representative Cohort in Precision Medicine Initiative*, HEALTH AFF. (July 30, 2015), <http://healthaffairs.org/blog/2015/07/30/worth-the-money-paying-to-ensure-a-representative-cohort-in-the-precision-medicine-initiative> [<https://perma.cc/GEN6-9NKL>] (noting that between 1993 and 2013, less than 5% of participants in National Institutes of Health supported studies identified as non-white and less than 5% of all studies on respiratory diseases reported the inclusion of members of ethnic and racial minorities).

<sup>110</sup> Spector-Bagdady, *supra* note 17.

<sup>111</sup> See *Final Rule*, *supra* note 98 (leaving both of these issues unaddressed).

<sup>112</sup> See *infra* notes 114–137.

<sup>113</sup> See *infra* notes 114–137.

*B. You Can Sell Your Bone Marrow (but Only Because  
Technology Has Made It Easier to Do So)*

In 2012, in *Flynn v. Holder*, the U.S. Court of Appeals for the Ninth Circuit held that language in the Transplant Act proscribing the sale of bone marrow did not prohibit offering compensation for bone marrow donations by a non-invasive blood-based collection method.<sup>114</sup> In finding so, the court made a distinction between two types of bone marrow.<sup>115</sup> The sale of bone marrow that is the soft, fatty substance within bone cavities, extracted with a needle, is illegal under the Transplant Act.<sup>116</sup> Conversely, bone marrow obtained through a blood-based extraction method is not proscribed under the Transplant Act and, therefore, is acceptable to be exchanged for compensation.<sup>117</sup> The court did recognize that Congress had a rational basis in preventing human body parts being viewed as commodities by prohibiting compensation for the donation of bone marrow.<sup>118</sup> The government also expressed concern—a concern ultimately seen as non-determinative by the court—about the prospect of exploitative market forces should compensation be permitted for bone marrow donation.<sup>119</sup> Although the market for bone marrow stem cells is still in its early stage, there are centers that

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<sup>114</sup> *Flynn v. Holder*, 684 F.3d 852, 857 (9th Cir. 2012). The plaintiffs brought an equal protection challenge to the ban on compensation for bone marrow transplants. *Id.* at 856. Plaintiffs included, among others, the parents of leukemia and anemia-stricken children who need bone marrow transplants, the parent of a mix raced child, and a California-based nonprofit that sought to offer \$3,000 scholarships, housing allowances, or charitable gifts to predominantly mixed race or minority bone marrow donors. *Id.* at 857. Deep genetic compatibility is critical in blood marrow transplants. *Id.* All donations, except from one's identical twin, create a graft-versus-host disease. *Id.* Consequently, the more diverse one's genetic background, the rarer the match. *Id.* This makes finding donors for mixed race individuals incredibly difficult, so the nonprofit plaintiff sought to mitigate this matching problem by creating financial incentives to donate bone marrow. *Id.* at 858. The plaintiffs argued that bone marrow harvesting was not materially different than blood, sperm, and egg harvesting which was not proscribed under the Transplant Act. *Id.* Advances in bone marrow harvesting had created a method no different than donating blood; the process just took hours longer and required that the blood pass through a machine that separates out the desired bone marrow stem cells. *Id.* This process, referred to as peripheral blood cell apheresis, was not in existence when the Transplant Act was passed and bone marrow donation required an in-patient procedure where a large needle was used to extract marrow directly from within a donor's hipbone. *Id.* at 856; *see supra* note 94 (describing the specific prohibitions of the Transplant Act).

<sup>115</sup> *Flynn*, 684 F.3d at 857.

<sup>116</sup> *Id.*

<sup>117</sup> *Id.*

<sup>118</sup> *Id.* at 859.

<sup>119</sup> *Id.* In drafting the Transplant Act, the court recognized that Congress had valid public policy reasons for prohibiting compensation for organ donation. *Id.* at 860. Congress could have rightly been concerned about poorer individuals being exploited by richer individuals into incurring excessive risk, pain, or disability. *Id.* Donees could exact "your money or your life" offers from those in need. *Id.* Compensation for organs might degrade the quality of the organ supply as donors might be inclined to lie about their medical histories increasing the risk of serious medical complications. *Id.* The court also recognized that philosophically there is aversion to the removal of one's flesh for use by another and the commodification of one's bodily tissue. *Id.*

will pay up to eight-hundred dollars for a single donation.<sup>120</sup> It remains unclear, however, if there is sufficient interest and demand for such arrangements.<sup>121</sup>

### C. *You Can Sell Your Blood and Plasma, but There Might Not Be a Buyer*

There are no laws proscribing the sale and purchase of blood.<sup>122</sup> The applicable FDA regulations only require that blood from paid donors be labeled as such.<sup>123</sup> In practice, however, most hospitals and medical providers refuse to accept blood that is paid for out of concern that doing so creates a riskier patient population and a higher chance of contaminated and potentially dangerous blood.<sup>124</sup> There is also a concern that by providing compensation to prospective donors, donors might be more inclined to lie about their health or risk behaviors.<sup>125</sup>

In contrast, there is a healthy market for blood plasma obtained through compensation arrangements.<sup>126</sup> There is no labeling requirement indicating a paid donor status for plasma.<sup>127</sup> Unlike in a simple blood donation, plasma is not necessarily transfused into another person; instead, it can be broken down into its components for usage in pharmaceutical products.<sup>128</sup> Concerns that providing payment for blood plasma encourages people to lie about their

<sup>120</sup> JoNel Aleccia, *Hutch Pays Up to \$800 for Blood Stem Cell Donations, but Donors Are Hard to Find*, SEATTLE TIMES (Jan. 1, 2016), <http://www.seattletimes.com/seattle-news/health/a-different-kind-of-blood-donation-hutch-seeks-cells-for-science/> [<https://perma.cc/U2PH-C4XY>].

<sup>121</sup> See *id.* (noting that finding enough donors can often be a challenge despite the financial incentive).

<sup>122</sup> See 42 U.S.C. § 274e(c)(1) (2012) (failing to include blood as one of the human organs that cannot be sold).

<sup>123</sup> See 21 C.F.R. § 606.121 (2016) (specifying that container labels must include “paid donor” if applicable); Requirements for Blood and Blood Components Intended for Transfusion or for Further Manufacturing Use, 80 Fed. Reg. 29848 (May 22, 2015) (codified at 201 C.F.R. pt. 606) (“FDA regulations do not preclude paid donations for blood for transfusion or for further manufacture.”)

<sup>124</sup> Elizabeth Preston, *Why You Get Paid to Donate Plasma but Not Blood*, STAT NEWS (Jan. 22, 2016), <https://www.statnews.com/2016/01/22/paid-plasma-not-blood/> [<https://perma.cc/KUD7-YXQD1>]; see Karen Brown, *How Medical Advances Have Affected the Blood Bank Industry*, WBUR (Feb. 14, 2017), <http://www.wbur.org/commonhealth/2017/02/14/blood-economy> [<https://perma.cc/VJE7-TMD2>] (describing the financial strain blood banks are experiencing as hospitals increasingly perform more minimally invasive surgeries so as to rely less on blood transfusions and the associated risks of infection).

<sup>125</sup> Preston, *supra* note 124. For instance, the concern of deception on the part of donors is particularly relevant to the American Red Cross which was recently fined \$10 million by the FDA for a number of violations, including the ineffective screening of donors. Lena Groeger, *\$10 Million Fine on Red Cross Highlights Its Troubled History of Blood Services*, PROPUBLICA (Feb. 2, 2012), <https://www.propublica.org/article/10-million-fine-on-red-cross-highlights-its-troubled-history-of-blood-servi> [<https://perma.cc/4EX5-SPF6>].

<sup>126</sup> Preston, *supra* note 124. During a plasma donation, blood is drawn from the arm and channeled through an automated machine that collects plasma from the blood and returns the remaining blood components. *Plasma Donation*, AM. RED CROSS, <http://www.redcrossblood.org/donating-blood/types-donations/plasma> [<https://perma.cc/VHG6-C7RB>].

<sup>127</sup> Preston, *supra* note 124.

<sup>128</sup> *Id.*

health or risk behaviors are mitigated, as the plasma is subject to stringent screening and processing that removes or kills any blood-based viruses.<sup>129</sup> There is a substantially lessened risk of infection being transmitted through the plasma.<sup>130</sup>

The market for plasma donation in the United States is quite robust with plasma obtained from paid donors making up approximately seventy percent of plasma collections worldwide.<sup>131</sup> The number of donations has also increased substantially in recent years, with more than twenty-three million donations recorded in 2011, up from twelve million in 2006.<sup>132</sup> The compensation offered for a donation is approximately fifty dollars for the first few donations and then sixty dollars per week if two donations are made in that period.<sup>133</sup>

In addition to the proposed updates to the Common Rule failing to address the issue of exchanging compensation for biosamples, there are no other statutory or regulatory mechanisms for proscribing such sales.<sup>134</sup> In fact, the current system for donating blood does not explicitly proscribe providing compensation, even if such a practice has not been adopted by the blood bank industry.<sup>135</sup> Additionally, the exchange of plasma or bone marrow is not proscribed by the legislature or regulatory agencies and is even sanctioned by the judiciary.<sup>136</sup> Therefore, the current system provides no avenue of recourse to prevent the significant problems created by allowing the exchange of compensation for biosamples.<sup>137</sup>

### III. THE REGULATIONS NEED TO GO FURTHER TO ADDRESS THE CRUCIAL ISSUE OF COMPENSATION FOR BIOSAMPLE DONATION

The recently announced updates to the Common Rule are widely seen as a win for the research community.<sup>138</sup> The requirement to obtain consent for the collection of de-identified biosamples threatened to hinder a valuable resource

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<sup>129</sup> *Id.*

<sup>130</sup> *Id.*

<sup>131</sup> Darryl Lorenzo Wellington, *The Twisted Business of Donating Plasma*, THE ATLANTIC (May 28, 2014), <http://www.theatlantic.com/health/archive/2014/05/blood-money-the-twisted-business-of-donating-plasma/362012/> [<https://perma.cc/3ANL-P886>]. Since 2008, the plasma therapeutics market has grown from \$4 to \$11 billion. *Id.*

<sup>132</sup> *Id.*

<sup>133</sup> *Id.*

<sup>134</sup> See *supra* notes 98–133 and accompanying text.

<sup>135</sup> See *supra* notes 122–125 and accompanying text.

<sup>136</sup> See *supra* notes 114–133 and accompanying text.

<sup>137</sup> See *supra* notes 98–133 and accompanying text.

<sup>138</sup> Jocelyn Kaiser, *Update: U.S. Abandons Controversial Consent Proposal on Using Human Research Samples*, SCIENCE (Jan. 18, 2017), <http://www.sciencemag.org/news/2017/01/update-us-abandons-controversial-consent-proposal-using-human-research-samples> [<https://perma.cc/MY5D-BXP8>]. Some view the outcome though as an inevitable consequence of disparate lobbying power between powerful research institutions and patient advocacy groups. *Id.*

for medical and scientific discovery.<sup>139</sup> Allowing the current collection and usage practices of these samples to remain in effect allows the research community to utilize advances in genetic and genomic technologies to develop treatments, diagnostic tools, and personalized medical and health care from which all members of society can benefit.<sup>140</sup> The passage of the updated regulations, although still subject to revision or alteration prior to their implementation, counter the potentially harmful consequences of the burgeoning biorights movement.<sup>141</sup>

The updated regulations, however, do not go far enough to ensure the continued advancement and progress of scientific and medical research and to help realize the tremendous promise of personalized medicine.<sup>142</sup> This Part argues that additional legislative and regulatory action is needed to ensure the realization of such promise.<sup>143</sup> Specifically, legislative action is needed to proscribe the ability of an individual to contribute their biological material for research purposes in exchange for compensation.<sup>144</sup> Section A describes the convergence of factors and developments that have created a potentially significant impedance to the progress of scientific and medical research.<sup>145</sup> Additionally, the Section describes how the current legal and regulatory framework provides no adequate recourse to address this problem.<sup>146</sup> Section B presents the strongest counter-arguments and considerations against the proscription of receiving compensation for biological material contributed for research purposes.<sup>147</sup> Finally, Section C argues that public policy considerations ultimately justify the suggested legislative action.<sup>148</sup>

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<sup>139</sup> *Id.* The proposed change would have imposed significant costs on research institutions in setting up processes that facilitated obtaining consent during clinical care, as well as additional systems that tracked the consent data. *Id.* Additionally, there was concern that creating a link between the biosamples and consent forms created enhanced privacy risks. *Id.* Such concerns, however, overlook a much larger privacy risk inherent in the collection of a large number of biosamples and the sophistication of genetic sequencing technologies. Dry et al., *supra* note 51. A biosample that has been extensively sequenced can be identifiable regardless of how many patient identifiers are removed. *Id.*

<sup>140</sup> See Kaiser, *supra* note 138 (stressing the concerns of the biomedical research community that the proposed regulations would inhibit scientific and medical research); F. Randy Vogenberg et al., *Personalized Medicine Part I: Evolution and Development into Therapeutics*, 35 PHARMACY & THERAPEUTICS 560, 560 (2010) (describing how precision medicine can tailor medical therapy to provide the most effective effect in a safe manner ensuring better patient care).

<sup>141</sup> Kaiser, *supra* note 138.

<sup>142</sup> See *infra* notes 149–219 and accompanying text.

<sup>143</sup> See *infra* notes 149–219 and accompanying text.

<sup>144</sup> See *infra* notes 149–219 and accompanying text.

<sup>145</sup> See *infra* notes 149–178 and accompanying text.

<sup>146</sup> See *infra* notes 149–178 and accompanying text.

<sup>147</sup> See *infra* notes 179–189 and accompanying text.

<sup>148</sup> See *infra* notes 190–219 and accompanying text.

### A. People Will Increasingly Demand Compensation for Their Biosamples

At present, individuals can refuse to allow their biological material to be used for research studies.<sup>149</sup> Individuals have no obligation to participate in research projects and cannot be compelled to participate in research studies.<sup>150</sup> Consequently, much of the motivating force driving the donation of biosamples is rooted in altruism and a societal encouragement to participate in research that could eventually benefit society at-large.<sup>151</sup> The biosample collection systems currently in place also function quite purposefully with a level of opaqueness and outside people's knowledge or recognition.<sup>152</sup> For example, by allowing hospitals and medical centers to collect leftover biological material without requiring informed consent, collection practices often go unnoticed by patients.<sup>153</sup> Additionally, current collection practices benefit from the imposing nature of the environment in which the samples are collected.<sup>154</sup> Even if people were aware, for instance, that their biological material would be collected for research purposes following surgery, they might be disinclined to refuse to contribute their biological material given the imposing nature and imbalance of power inherent in interactions with medical and healthcare institutions.<sup>155</sup> The current biosample collection system operates on trust in the altruistic nature of individuals and the research and medical community at-large, but such trust is being increasingly strained due to a variety of economic, political, and social factors.<sup>156</sup>

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<sup>149</sup> Dry et al., *supra* note 51.

<sup>150</sup> *Id.*

<sup>151</sup> Hakimian & Korn, *supra* note 1, at 2503.

<sup>152</sup> *See id.* (cautioning that people's altruism could be tempered by knowledge of commercial benefit).

<sup>153</sup> *See* Michelle Meyer, *No, Donating Your Leftover Tissue to Research Is Not Like Letting Someone Rifle Through Your Phone*, FORBES (Dec. 13, 2015), <https://www.forbes.com/sites/michellemeyer/2015/12/31/no-donating-your-leftover-tissue-to-research-is-not-like-letting-someone-rifle-through-your-phone/#4fa727222240> [<https://web.archive.org/web/20180404201350/https://www.forbes.com/sites/michellemeyer/2015/12/31/no-donating-your-leftover-tissue-to-research-is-not-like-letting-someone-rifle-through-your-phone/>] (describing how by informing people that their leftover biological material may be used for research, there is a greater risk of them not allowing the samples to be donated).

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

<sup>155</sup> *See* Brian McKinstry, *Paternalism and the Doctor-Patient Relationship in General Practice*, 340 BRIT. J. GEN. PRAC. 342, 342 (1992) (describing how issues of paternalism are common in medical practice and influence patient and doctor relationships and decision making); Meyer, *supra* note 153 (noting how patients are often unaware of the consequences of donating biological material for research purposes and are susceptible to participating or refusing to participate based on incomplete or insufficient knowledge).

<sup>156</sup> Hakimian & Korn, *supra* note 1, at 2503; *see* Robert J. Blendon et al., *Public Trust in Physicians—U.S. Medicine in International Perspective*, 371 NEW ENG. J. MED. 1570, 1572 (2014) (describing that despite how the rising cost of healthcare has weakened people's trust in the healthcare system, people largely still trust their doctors and other medical practitioners). Public sentiment toward the pharmaceutical and biotechnology industry is quite negative, particularly with the skyrocketing costs of prescription drugs, medical devices, and diagnostic tests. Jim Norman, *Americans' Views*

Although there has not been a recorded, marked increase in people refusing to contribute their biological material absent compensation, it is clear that people are less inclined to do so when they know financial or commercial gain is accruing to parties who utilize their material.<sup>157</sup> Additionally, the emergence and accessibility of personal genetic testing has created the opportunity for people to know whether they carry any unique or scientifically valuable genetic signatures.<sup>158</sup> For instance, the public has never before been so easily and inexpensively able to discover if they have a rare genetic mutation that would be valuable to the biomedical research community.<sup>159</sup> Through utilizing per-

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*of Pharmaceutical Industry Take a Tumble*, GALLUP (Sept. 14, 2015), <http://www.gallup.com/poll/185432/americans-views-pharmaceutical-industry-tumble.aspx> [<https://perma.cc/FQ7F-E34V>]. There is undoubtedly going to be growing unease as genomic technologies are incorporated into people's lives. See Lena H. Sun, *Employees Who Decline Genetic Testing Could Face Penalties Under Proposed Bill*, WASH. POST (Mar. 11, 2016), [https://www.washingtonpost.com/news/to-your-health/wp/2017/03/11/employees-who-decline-genetic-testing-could-face-penalties-under-proposed-bill/?utm\\_term=.b208b0ffa2e7](https://www.washingtonpost.com/news/to-your-health/wp/2017/03/11/employees-who-decline-genetic-testing-could-face-penalties-under-proposed-bill/?utm_term=.b208b0ffa2e7) [<https://perma.cc/37PA-AAR5>] (describing a bill recently introduced in Congress that would allow employers access to people's personal genomic profiles as part of workplace wellness programs). If employees refused to contribute that information, employers could penalize employees with charges of up to thirty percent of the total cost of the employee's health insurance. *Id.* The proposed legislation has been highly criticized by a number of consumer, health, and medical advocacy groups, but the legislation represents the unease that can be cultivated as genomic technologies become more mainstream. *Id.*

<sup>157</sup> Daley & Cranley, *supra* note 5. Survey evidence demonstrates that people are less inclined to help researchers when they know that researchers stand to recognize a commercial gain from their contributions. *Id.* Approximately 68% percent of people are willing to let researchers use their biosample for any purpose. *Id.* When people know that their sample could be used to develop patents and generate monetary gain for commercial enterprises, however, support declines to 55%. *Id.* This is of particular concern given the increasingly close relationships and arrangements between nonprofit academic medical centers and for-profit biotechnology, pharmaceutical, and health data institutions. Deborah Josefson, *Human Tissue for Sale: What Are the Costs?*, 173 W. J. MED. 302, 303 (2000). Academic hospitals, for instance, have long been sending leftover pathology specimens to biotechnology companies. *Id.* Although hospitals routinely stored clinically rare tumor tissues, for instance, those tissues were frequently analyzed in-house or shared within the hospital or other research institutions. *Id.* Legal, financial, and ethical issues are now raised when such samples are used to directly increase a hospital's revenue by selling such samples to for-profit institutions. *Id.*

<sup>158</sup> Lee, *supra* note 6. By proving a simple saliva sample, personal genetic testing kits offer tremendous insight into one's family history and health risk profile. Peter Pitts, *The Privacy Delusions of Genetic Testing*, FORBES (Feb. 15, 2017), <https://www.forbes.com/sites/realspin/2017/02/15/the-privacy-delusions-of-genetic-testing/#26a94a5b1bba> [<https://web.archive.org/web/20180210190420/https://www.forbes.com/sites/realspin/2017/02/15/the-privacy-delusions-of-genetic-testing/>]. Global sales of genetic testing are expected to reach \$10 billion. *Id.* Direct-to-consumer companies, like 23andMe and Genos, are experiencing substantial consumer interest, selling tens of thousands at-home testing kits every year. *Id.* The worldwide genetic testing market is estimated to expand from \$4.6 billion in 2017 to \$5.8 billion in 2022. Sramana Mitra, *Billion-Dollar Unicorns: 23andMe in High Gear*, SEEKING ALPHA (Dec. 5, 2017), <https://seekingalpha.com/article/4129881-billion-dollar-unicorns-23andme-high-gear> [<https://perma.cc/SS7Q-AHRX>]. Such growth is fueled by an aging population, increased awareness and incidences of genetic diseases, and technological advancements. *Id.*

<sup>159</sup> Pitts, *supra* note 158. For instance, 23andMe has sold access to its database to at least thirteen outside pharmaceutical firms. *Id.* One buyer, Genentech, paid \$10 million for the genetic profiles of

sonal genetic testing services, individuals can obtain access to their genetic information by simply mailing away a saliva sample.<sup>160</sup> With the advent of genetic sequencing technology and the greater accessibility of personal genetic testing, people can more readily know if they harbor either a protective or pathogenic genetic variation that would be of significant research or commercial value.<sup>161</sup> We are currently in the early stages of the convergence of an individual's ability to know if they harbor a genetically valuable and potentially lucrative mutation with a demonstrated societal unwillingness to contribute such material absent compensation if others stand to economically benefit.<sup>162</sup>

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people suffering from Parkinson's disease. *Id.* Another prominent player in this space, AncestryDNA, recently announced a lucrative data-sharing partnership with the biotechnology company Calico. *Id.*

<sup>160</sup> Sarah Buhr, *Genetics Startup Genos Wants to Pay You for Your DNA Data*, TECHCRUNCH (Nov. 1, 2016), <https://techcrunch.com/2016/11/01/genetics-startup-genos-wants-to-pay-you-for-your-dna-data/> [<https://perma.cc/Y56T-ZB52>]. At present, direct-to-consumer genetics companies like 23andMe, Genos, Color Genomics, Helix, and Veritas will provide exome sequencing of your DNA for as little as \$199. *Id.* Exome sequencing is not as intensive as whole genome or next-generation sequencing, as it only covers what are referred to as the "protein coding genes." *Id.* Exome sequencing is still useful in discovering diseases caused by rare genetic variants. *Id.* As next-generation sequencing is adopted more uniformly across the industry, individuals will have a more thorough understanding of their genetic map, which researchers could use to better understand, prevent, and treat disease. *Id.*

<sup>161</sup> *Personal Genomics: The Future of Healthcare?*, YOURGENOME.ORG, <http://www.yourgenome.org/stories/personal-genomics-the-future-of-healthcare> [<https://perma.cc/XYS6-8LK3>]. A complaint was recently filed in U.S. District Court of Nevada by a couple who developed a drug to treat a rare neurological disease that they claim was improperly misappropriated by a drug developer. Complaint and Demand for Jury at 2, *Hempel v. Cydan Dev., Inc.*, No. 18-cv-00008 (D. Nev. Jan. 5, 2018). The couple's twin daughters suffered from Niemann-Pick disease, Type C ("NPC"), a rare, progressive, and fatal neurological genetic disease. *Id.* Spurred by their daughters' illness, the couple, relying on \$3 million of their personal funds, outside donations, and pro-bono expertise by physicians, developed a treatment for the disease, which was granted preliminary approval by the FDA, as well as "Orphan Drug Status" which provided certain exclusivity rights for developers. *Id.* at 2–3. The couple alleged breach of contract and fiduciary duty claims, among others, by drug developer Cydan which used confidential information shared by the couple to develop a competing drug. *Id.* at 4–5. Of note, however, is that the complaint specifically alleges that given the only five-hundred known cases of NPC worldwide and the one-hundred in the United States, the twins "are the only known identical twins in the world living with NPC, making their medical information highly valuable." *Id.* at 2.

<sup>162</sup> See Christina Farr, *Should You Get Paid for Your DNA*, FAST COMPANY (Mar. 12, 2016), <https://www.fastcompany.com/3057732/should-you-get-paid-for-your-dna> [<https://perma.cc/GS3G-23BF>] (describing how the development of a class of promising cholesterol lowering drugs known as PCSK9 inhibitors was catalyzed by the discovery of two patients who carried an extremely rare genetic mutation that resulted in them having exceedingly low cholesterol levels). Clinical trials of this recently discovered class of drugs are promising and could be quite profitable for pharmaceutical companies. *Id.* According to Gregory Curfman, MD, Editor-in-Chief of Harvard Health Publications: "Every so often a medical advance comes along that rewrites the script for treating a disease or condition. After today's announcements of impressive results of a new type of cholesterol-lowering drug, that scenario might just happen in the next few years." Gregory Curfman, *PCSK9 Inhibitors: A Major Advance in Cholesterol Lowering Drug Therapy*, HARV. HEALTH PUB. (Mar. 15, 2015), <http://www.health.harvard.edu/blog/pcsk9-inhibitors-a-major-advance-in-cholesterol-lowering-drug-therapy-2015-03157801> [<https://perma.cc/NQC4-VELP>]. Such an approach to drug development—finding people who are impervious to heart disease for instance—is a significant advancement and "can open a door



Although there has not been, as of yet, a marked increase in people refusing to contribute their biological material absent compensation, it is unlikely the status quo can be maintained into the foreseeable future.<sup>163</sup>

The most analogous situation to selling one's biological material for research purposes is the sale of bone marrow or plasma.<sup>164</sup> In *Flynn v. Holder*, the Ninth Circuit narrowed the definition of bone marrow in the Transplant Act to permit the sale of marrow, recognizing that modern technologies made the process easier and less risky.<sup>165</sup> Doing so is demonstrative of a societal indication that we are not completely opposed to paying people for their biological material, absent the strong disapproval towards the most pronounced forms of organ trafficking and harvesting.<sup>166</sup> It is also not an overly forward assertion that the market for blood donation could be quite robust if not for the fact that likely purchasers of the blood have adopted industry wide practices and internal policies that prevent the market from developing.<sup>167</sup> By looking to the

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to letting the rest of the population share their genetic luck." Gina Kolata, *Rare Gene Mutations Inspire New Heart Drugs*, N.Y. TIMES (May 24, 2017), <https://www.nytimes.com/2017/05/24/health/heart-drugs-gene-mutations.html> [<https://web.archive.org/web/20170827071444/https://www.nytimes.com/2017/05/24/health/heart-drugs-gene-mutations.html>].

<sup>163</sup> See Farr, *supra* note 162 (noting the emergence and increasing popularity of personal genetic testing services). New private-sector models are increasingly demonstrating the monetary value of one's DNA. *Id.* Direct-to-consumer genetics companies, like 23andMe, operate by selling people's health data to pharmaceutical companies in bulk. *Id.* One such arrangement between 23andMe and pharmaceutical company, Genentech, involved analyzing genetic data from three thousand 23andMe customers with Parkinson's disease in order to identify genes that Genentech could use to then develop drugs to treat the neurodegenerative disorder. Francie Diep, *23andMe to Sell Customers' Genetic Data to Biotech Company*, POPULAR SCI. (Jan. 7, 2015), <http://www.popsci.com/23andme-inks-deal-sell-customers-genetic-data-biotech-company> [<https://perma.cc/2QNY-87QQ?type=image>]. The arrangement may be worth up to \$50 million according to some reports. *Id.* 23andMe is reported to have sold more than two million of its at-home testing kits. Mitra, *supra* note 158. 23andMe's growth is particularly noteworthy; the eleven-year-old company is valued as high as \$1.75 billion. *Id.* 23andMe's growth is even more spectacular given that the company was ordered by the FDA in 2013 to stop selling its genetic health tests. *Id.* But, in 2015, the FDA authorized the company to market its tests for detecting a genetic variant associated with Bloom syndrome, a rare disorder associated with increased cancer risk. *Id.* In April 2017, the FDA authorized the company to market a test for ten genetic diseases including Alzheimer's and Parkinson's diseases. *Id.*

<sup>164</sup> See *infra* notes 165–170 and accompanying text.

<sup>165</sup> 684 F.3d 852, 857 (9th Cir. 2012).

<sup>166</sup> *Id.* at 861.

<sup>167</sup> See Preston, *supra* note 124 (explaining how hospitals and other medical providers refuse to use blood from paid donors out of concern that compensation encourages people to lie about their health and risk behaviors, thereby increasing the possibility of using contaminated or infected blood); Deborah Zabarenko, *The Nation Has A Major Blood Shortage*, ABC NEWS (Sept. 19, 2016), <http://abcnews.go.com/Health/story?id=117954&page=1> [<https://perma.cc/T6AZ-5DJM>] (describing how the Red Cross and America's Blood Centers, which represent the vast majority of U.S. blood banks, routinely report shortages that require emergency appeals to the public). In situations such as these, it is likely that a market-based solution to the problem would entail providing compensation to prospective donors. Zabarenko, *supra*. A recent crisis was so severe that thirty-two of the Red Cross's thirty-six regions had less than a day's supply of blood available or an inadequate supply to meet hospital

plasma donation market, it becomes clear that such a market could similarly develop for blood donation.<sup>168</sup> Selling one's biological material for research purposes could operate in a similar manner to the plasma or bone marrow market.<sup>169</sup> It is unlikely that researchers would suddenly begin to refuse to utilize scientifically valuable materials just because they were acquired in exchange for compensation, a situation distinct from that of blood donations.<sup>170</sup>

The relevant regulatory framework, including the proposed regulations set to go into effect in 2018, are silent as to the issue of compensation for biological materials contributed for research purposes.<sup>171</sup> The current legal framework for the sale of other types of biological materials also offers no mechanism to prevent the sale of biological material for research purposes.<sup>172</sup>

Therefore, action needs to be taken to amend the Transplant Act to include a provision that expressly proscribes the ability of an individual to sell their biological material for research purposes.<sup>173</sup> Action on the administrative agency level, such as amending the Common Rule, is insufficient as it would fail to prevent the types of actions that are currently taking in place, such as people selling their biological materials to private companies that might not be governed by the Common Rule.<sup>174</sup> This proposal would allow current collection practices to con-

demand. *Id.* The Red Cross needs eighty thousand units on hand daily, but during this crisis, it had only about thirty-six thousand. *Id.*

<sup>168</sup> See Wellington, *supra* note 131 (describing how there is an established market for compensation for contributing blood plasma, as there is a substantially reduced risk of contamination and infection when the plasma is used to make pharmaceuticals).

<sup>169</sup> See *id.* (noting the robust market for blood plasma compensation to donors).

<sup>170</sup> See Preston, *supra* note 124 (noting that there is not a concern of researchers to receive infected blood samples as the blood will not be transfused into another individual and researchers are more concerned with the genetic markers contained in the blood).

<sup>171</sup> See *Final Rule*, *supra* note 98 (leaving unaddressed the issue of compensation for biosample contribution).

<sup>172</sup> See, e.g., 42 U.S.C. § 274e(a)–(c) (2012) (omitting from the Transplant Act any proscription against providing compensation for biosamples contributed for research purposes).

<sup>173</sup> *Id.* It would be difficult to amend the definition of “human organ” under the Transplant Act to include biosamples used for research purposes as the Transplant Act is concerned with “human transplantation,” rather than research purposes. *Id.* § 247e(a). An amendment to the Transplant Act, however, could specifically proscribe the ability of individuals to receive “valuable consideration” for the contribution of biological material for research purposes. See *id.* § 247e(c)1(2) (defining valuable consideration as “not include[ing] the reasonable payments associated with the removal, transportation, implantation, processing, preservation, quality control, and storage of a human organ or the expenses of travel, housing, and lost wages incurred by the donor”).

<sup>174</sup> See 45 C.F.R. § 46.101(a) (2016) (stating that the Common Rule “applies to all research involving human subjects conducted, supported or otherwise subject to regulation by any federal department or agency which takes appropriate administrative action to make the policy applicable to such research”). A private organization, such as DNASimple, is not a federal agency and might not be the recipient of federal funding; therefore, it might not be subject to the Common Rule. *Id.*; see *supra* note 5 and accompanying text (describing DNASimple’s business model and operational practices). It is possible, however, that such a private organization would likely fall under the purview of the Common Rule as such an organization might be performing research “otherwise subject to regulation by any federal department.” 45 C.F.R. § 46.101(a); see *id.* § 46.102(e) (describing “[r]esearch subject

tinue unchanged, in that hospitals or other research institutions could still collect de-identified biosamples collected during the course of clinical care without obtaining consent.<sup>175</sup> Given that the proposal only addresses providing compensation for research, not therapeutic or clinical, purposes, it would also allow current practices regarding bone marrow, blood, and plasma donation to go unchanged.<sup>176</sup> The current system could operate in such a manner as that of blood donations to blood banks with the addition of a law that specifically proscribes the exchange of monetary compensation.<sup>177</sup> The nuances of such a proposal are beyond the scope of this Note, but I offer the outline of a legislative solution to a potentially harmful practice while causing the least amount of disruption as possible to the current legal and regulatory framework.<sup>178</sup>

*B. Is That Even A Problem? Shouldn't People Be Encouraged to Seek Compensation for What Is Theirs?*

A common argument advanced in support of the proposition that people are rightfully entitled to compensation for their genetically valuable biological material is one rooted in some sense of equity or fairness.<sup>179</sup> It seems facially unfair to allow researchers, biotechnology or pharmaceuticals companies, or even hospitals to financially profit from that which is derived from the indi-

to regulation” as “encompass[ing] those research activities for which a federal department or agency has specific responsibility for regulating as a research activity (for example, Investigational New Drug requirements administered by the [FDA]”); *supra* note 163 (describing how direct-to-consumer genetics company, 23andMe, is subject to regulation by the FDA).

<sup>175</sup> See 45 C.F.R. § 46.102(e) (stating that informed consent is not needed when researchers obtain de-identified patient information or when there is no intervention or interaction with the individual for research purposes). My proposal would also prevent the exchange of compensation for biosamples even when informed consent is not required. *Id.*

<sup>176</sup> See *supra* notes 114–121 and accompanying text (examining how current practices regarding bone marrow donation are the consequence of judicial reinterpretation of “bone marrow” under the Transplant Act which governs organ donation or transplantation). Given that my proposal is focused on the donation of biological materials for research purposes, rather than clinical or therapeutic purposes, the current practice regarding bone marrow, blood, and plasma are unaltered by my proposal. See *supra* notes 122–125 and accompanying text (describing the process of donating blood to blood banks for clinical or therapeutic purposes); *supra* notes 126–133 and accompanying text (describing how plasma donations are used for the manufacture of pharmaceutical products).

<sup>177</sup> See *supra* notes 122–125 and accompanying text (describing the process of donating blood to blood banks and the industry practice of not accepting blood from paid donors despite there being no regulation preventing such a practice); *infra* notes 202–203 and accompanying text (describing how nominal forms of compensation, such as gift cards or coupons, can provide a sufficient incentive to donate biosamples, as is the current practice for altruistic blood donation).

<sup>178</sup> See *supra* notes 173–177 and accompanying text.

<sup>179</sup> Farr, *supra* note 162. As DNA becomes more monetarily valuable as a revenue-producing commodity, many patient advocates are calling for a portion of that revenue. *Id.* According to Sharon Terry, founder and CEO of Genetic Alliance, a nonprofit organization that advocates on behalf of people with genetic diseases: “I think there may be an economy emerging in which we might want to include donors in the commerce that is taking place around clinical recruitment.” *Id.*

vidual.<sup>180</sup> Physicians, for instance, are typically compensated for recruiting people into clinical trials and other research projects.<sup>181</sup> If not for the individual, research and scientific discoveries and their resultant commercial applications would never have materialized.<sup>182</sup> Those individuals are deserving of some form of compensation or equity in the resulting commercial application.<sup>183</sup>

Such arguments have been strengthened in recent years by a number of high-profile incidents that have generated public discussion on the matter.<sup>184</sup> Of note has been the media coverage of the story of Henrietta Lacks.<sup>185</sup> In 1951, Lacks, an impoverished, African American mother of five, died of cervical cancer and her cells, unbeknownst to her or her family, were used to create the HeLa cell line, which has subsequently generated billions of dollars in economic activity and is credited for fueling a proliferation of medical and scientific discoveries over the past decades.<sup>186</sup> In 2013, Lacks' descendants formed an agreement with the National Institutes of Health (NIH) that would require researchers to apply for and obtain permission to use Lacks' genomic data.<sup>187</sup> Two members of the Lacks family will be required to serve on the NIH panel responsible for reviewing such applications and any resulting publications should acknowledge the Lacks family.<sup>188</sup> Although issues of compensation were not part of the considerations between the NIH and the Lacks family, the situation prompted a broader societal discussion of what people should be enti-

<sup>180</sup> *Id.*

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

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

<sup>183</sup> *Id.* The assertion that such individuals should be compensated for contributing their biological material is strengthened by the massive revenues drug companies derive from the resultant therapies. See Baumann, *supra* note 14 (noting that Spark's Luxturna blindness gene therapy costs \$850,000 for both eyes); Grady, *supra* note 14 (noting that Novartis' Kymriah cancer gene therapy will cost \$475,000); Kolata, *supra* note 12 (noting that Merck's Keytruda cancer drug costs \$156,000 a year).

<sup>184</sup> Art Caplan, *NIH Finally Makes Good with Henrietta Lacks' Family—and It's About Time, Ethicist Says*, NBC NEWS (Aug. 7, 2013), <http://www.nbcnews.com/health/nih-finally-makes-good-henrietta-lacks-family-its-about-time-6C10867941> [https://perma.cc/5WKP-FUH3].

<sup>185</sup> *Id.* In April 2017, Home Box Office released "The Immortal Life of Henrietta Lacks," a movie about the life and legacy of Henrietta Lacks and her cells, capitalizing on the success of a 2010 non-fiction bestseller of the same name. Neil Genzlinger, *Review: 'The Immortal Life of Henrietta Lacks,' Condensed*, N.Y. TIMES (Apr. 20, 2017), [https://www.nytimes.com/2017/04/20/arts/television/review-the-immortal-life-of-henrietta-lacks-condensed.html?\\_r=0](https://www.nytimes.com/2017/04/20/arts/television/review-the-immortal-life-of-henrietta-lacks-condensed.html?_r=0) [https://perma.cc/TL25-G5C9].

<sup>186</sup> Sarah Zielinski, *Henrietta Lacks' 'Immortal' Cells*, SMITHSONIAN MAG. (Jan. 22, 2010), <http://www.smithsonianmag.com/science-nature/henrietta-lacks-immortal-cells-6421299/> [https://perma.cc/VUF9-PQUM]. Lacks, an impoverished black tobacco farmer from Virginia was being treated for cervical cancer at John Hopkins University Hospital. *Id.* The cells were taken from a cervical biopsy performed on her and eventually used to create the HeLa cell line, the first immortal human cell line that was later used to create the polio vaccine and responsible for a variety of other scientific discoveries. *Id.* Lacks never knew her cells were being used for research and never consented to as much. *Id.* The family never received any profits derived from the creation of the cell line. *Id.*

<sup>187</sup> Caplan, *supra* note 184.

<sup>188</sup> *Id.*

tled to for their participation in socially valuable, but also commercially lucrative, medical and scientific research.<sup>189</sup>

*C. Strong Public Policy Justifications Warrant the Proscription of Compensation for Biosamples Donated for Research Purposes*

A societal willingness to allow payment for an individual's biological material for research purposes poses a significant problem in the era of precision medicine and genomic research.<sup>190</sup> Consequently, legislative action needs to be taken that makes it illegal for an individual to contribute his or her biological material for research purposes in exchange for monetary compensation.<sup>191</sup> In a somewhat prophetic opinion, Justice Mosk advanced the position in his dissent in *Moore v. Regents of University of California* that the legislature could create a system that prevents the problems inherent in providing compensation for human biological material for research purposes.<sup>192</sup> The policy justifications for such an action are robust.<sup>193</sup>

If an individual is unwilling to donate his or her biological material absent compensation, potentially valuable information from which all of society could benefit is removed from the public repository of knowledge, thereby hampering societal progress.<sup>194</sup> In economic terms, such a situation presents a classic tragedy of the commons dilemma.<sup>195</sup> The absence of any regulation both fails to cure, and in some respects facilitates, a free-rider problem.<sup>196</sup> Those who

<sup>189</sup> *Id.*

<sup>190</sup> Meyer, *supra* note 153.

<sup>191</sup> *Id.*

<sup>192</sup> 793 P.2d 479, 505–06 (1990) (Mosk, J., dissenting). In his dissent in *Moore*, Justice Mosk stated:

It is certainly arguable that, as a matter of policy or morality, it would be wiser to prohibit any private individual or entity from profiting from the fortuitous value that adheres in a part of a human body, and instead to require all valuable excised body parts to be deposited in a public depository which would make such materials freely available to all scientists for the betterment of society as a whole. The Legislature, if it wished, could create such a system, as it has done with respect to organs that are donated for transplantation.

*Id.*

<sup>193</sup> See *infra* notes 194–219 and accompanying text.

<sup>194</sup> See Garrett Hardin, *The Tragedy of the Commons*, 162 SCIENCE 1243, 1248 (1968) (describing how society can suffer from an unwavering emphasis on personal liberty at the expense of broader societal benefit). All of society should be able to benefit from the genetic diversity within the human population. *Id.* By creating a system where individuals withhold their unique and scientifically helpful genetic material, all of society is worse off than if such information was shared freely and openly. *Id.*

<sup>195</sup> *Id.* Although Hardin's original paper addressed the issue of overpopulation, the concept has been extended to a variety of fields, including economics. *Id.*

<sup>196</sup> See *The Free Rider Problem*, STAN. ENCYCLOPEDIA PHIL., <https://plato.stanford.edu/entries/free-rider/> [<https://perma.cc/C6NP-GPN2>] (recognizing that society as a whole benefits when individuals participate in research projects that advance scientific understanding, individuals are less incentivized to contribute if they know they will reap the benefits regardless of their participation).

possess valuable genetic information and are unable to receive what they perceive as the appropriate compensation amount may ultimately fail to contribute their biological material.<sup>197</sup> Those individuals will still benefit from those who are willing to contribute their biological material absent compensation.<sup>198</sup>

Because of long-standing and well-founded mistrust of the medical research enterprise, minority communities might be particularly unwilling to contribute their biological material without receiving some form of compensation.<sup>199</sup> Such unwillingness could have the effect of increasing the cost of research and potentially slowing its progress as minority communities can afford great insight into human genetic complexity and could demand high levels of compensation.<sup>200</sup> The fulfillment of the promise of genomic medicine requires significant sample sizes of people with a variety of racial and ethnic profiles and backgrounds.<sup>201</sup> Compensation in the form of nominal amount gift cards, coupons, or simple merchandise, as is currently offered to encourage altruistic blood donation, can serve as sufficient incentives to donate for research purposes.<sup>202</sup> The relative ease of donating a small amount of blood or saliva for a

<sup>197</sup> See *id.* (refusing to accept what is deemed an inferior offer of compensation harms society as valuable information is removed from the public knowledge).

<sup>198</sup> See *id.* (minimizing the downside of refusing to contribute).

<sup>199</sup> Spector-Bagdady, *supra* note 17. The recent public attention surrounding the story of Henrietta Lacks does not strengthen a sense of trust in the research community despite the long-overdue resolution of the matter in the eyes of the research community and the Lacks family. Caplan, *supra* note 184.

<sup>200</sup> See Plunkett et al., *supra* note 109 (recognizing the significant risk that failing to achieve genetic samples from a range of ancestries and ethnicities); see also Steph Yin, *In South Asian Social Castes, a Living Lab for Genetic Disease*, N.Y. TIMES (July 17, 2017), <https://www.nytimes.com/2017/07/17/health/india-south-asia-castes-genetics-diseases.html> [<https://web.archive.org/web/20170728124009/https://www.nytimes.com/2017/07/17/health/india-south-asia-castes-genetics-diseases.html>] (describing how certain genetically isolated South Asian populations, for instance, provide great insight to rare and common disease as well as basic biology). Populations with long histories of restriction of gene flow obtained largely by limiting marriages to within a limited group evidence what scientists refer to as a founder effect. Yin, *supra*. Isolated groups from India and Finland, for instance, as well as Ashkenazi Jews and the Amish, derived from a small group of founders that then bred only with each other. *Id.* Consequently, genetic variants within these groups become amplified and the rate of recessive genetic diseases is higher in offspring. *Id.* Scientists typically utilize animal models in which a disease carrying gene is rendered inoperative or “knocked out” to study the effect of the gene loss. A. Mesut Erzurumluoglu et al., *Importance of Genetic Studies in Consanguineous Populations for the Characterization of Novel Human Gene Functions*, 80 ANNALS HUM. GENETICS 187, 187 (2016). These genetically isolated populations afford scientists the ability to study natural human “knockouts,” with scientists speculating that knockouts of every gene in the genome exists in India. Yin, *supra*.

<sup>201</sup> Spector-Bagdady, *supra* note 17.

<sup>202</sup> *Id.* Many in the genetic research community believe that patients should be compensated for their nominal travel expenses but nothing more. Farr, *supra* note 162. According to medical geneticist Robert Green of Harvard Medical School, academic medical centers should instead improve their outreach programs so that more people will volunteer their data; he argues that offering patients serious compensation would be an act of manipulation. *Id.* From a practical standpoint, offering compensation to those with rare genetic mutations is straightforward. *Id.* But, there are still thousands of people whose genetic data needs to be studied in order to make the comparison necessary to determine if

research study is not as labor intensive a process as an hours-long procedure to donate bone marrow or as demanding on the body as plasma donation.<sup>203</sup>

In addition to the need for a robust and diverse cohort of genetic profiles, the promise of genomic medicine also requires a level of flexibility in investigating different types of clinical conditions and diseases.<sup>204</sup> The interrelatedness of different genetic markers and how they cause or prevent disease means that researchers need to have flexibility to explore potentially promising connections and relations between genes and disease, some of which science has yet to fully understand.<sup>205</sup> It would, therefore, be administratively burdensome and ultimately harmful to the progress of research to have people enter into compensation arrangements that only authorize researchers to use their biological material for the study of a specific disease.<sup>206</sup> Although broad consent to any research use could theoretically be obtained as part of an arrangement, the possibility that people would only provide a biosample for a narrow purpose would increase the costs of research, given the administrative costs of managing such requests, and slow its progress.<sup>207</sup>

From a less practical standpoint, the sale of parts of one's physical body, or in this instance the physical properties of one's body, offends basic notions

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a genetic profile is indeed rare. *Id.* Those thousands of people also need to be compensated in some fashion, as without them the individual with the rare genetic variant would never be able to command serious compensation. *Id.* Additionally, research ventures and commercial applications often fail, which presents a dilemma of having patients then having to partake in any downside risk as part of potential compensation arrangements. *Id.*

<sup>203</sup> Wellington, *supra* note 131.

<sup>204</sup> See M.B. Kapp, *Ethical and Legal Issues in Research Involving Human Subjects: Do You Want a Piece of Me?*, 59 J. CLINICAL PATHOLOGY 335, 336 (2006). A supposition of human genetic research is the complexity of the genetic links of even common diseases. *Id.* For complex diseases, there is an even more tremendous need for large amounts of genetic and clinical data. *Id.* Researchers need to use genetic material to investigate linkages between different diseases in order to work most effectively. *Id.*

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

<sup>206</sup> *Id.*

<sup>207</sup> *Id.* The costs of drug development are already staggering, with the average cost to develop and gain marketing approval for a new drug an estimated \$2.6 billion. *Tufts CSDD Assessment of Cost to Develop and Win Marketing Approval for a New Drug Now Published*, TUFTS CTR. FOR STUDY DRUG DEV. (Mar. 10, 2016), [http://csdd.tufts.edu/news/complete\\_story/tufts\\_csdd\\_rd\\_cost\\_study\\_now\\_published](http://csdd.tufts.edu/news/complete_story/tufts_csdd_rd_cost_study_now_published) [[https://web.archive.org/web/20180323180828/http://csdd.tufts.edu/news/complete\\_story/tufts\\_csdd\\_rd\\_cost\\_study\\_now\\_published](https://web.archive.org/web/20180323180828/http://csdd.tufts.edu/news/complete_story/tufts_csdd_rd_cost_study_now_published)]. *But see* Gina Kolata, *What Does It Cost to Create a Cancer Drug? Less Than You'd Think*, N.Y. TIMES (Sept. 11, 2017), <https://www.nytimes.com/2017/09/11/health/cancer-drug-costs.html> [<https://perma.cc/WL8K-D5M9>] (describing the findings of a recent study that peg the drug development cost at \$757 million). Critics of the study point to its limited sample size of ten cancer medications all developed by relatively small companies with "only one drug approved, with few other drugs of any type of development." *Id.* Such a selection bias, critics argues, fails to account for the fact that 95% percent of cancer drugs that enter clinical trials ultimately fail, and any cost estimates need to include these failed attempts. *Id.*

of human dignity and respect.<sup>208</sup> There is a shared national aversion to the exploitation of one's body for economic gain.<sup>209</sup> The dignity and sanctity with which we regard the human body is offended when we begin to pay people for that which is so fundamental to their very identity.<sup>210</sup> Additionally, failing to proscribe compensation for biosample contributions for research purposes would create a pricing system or market for each individual.<sup>211</sup> The human body should be beyond pricing, and we do not want this pricing to be conducted by the private market.<sup>212</sup> Looking to how the Transplant Act made the sale of organs illegal, the use of consideration in exchange for biological material would offend societal and personal values.<sup>213</sup>

The proscription of offering compensation for the contribution of biological material for research purposes is rooted in numerous public policy justifications.<sup>214</sup> Such a seemingly significant change to the current legal framework

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<sup>208</sup> *Moore*, 793 P.2d at 497–98 (Arabian, J., concurring). The plaintiff in *Moore*, by asking the court to enforce a right to his body tissue for profit, is entreating the court “to regard the human vessel, the single most venerated and protected subject in any civilized society, as equal with the basest commercial commodity. He asks us to commingle the sacred with the profane.” *Id.*

<sup>209</sup> *Id.* Justice Arabian, later in his opinion, lauds dissenting Justice Mosk who wrote that, “our society acknowledges a profound ethical imperative to respect the human body as the physical and temporal exposition of the unique human persona.” *Id.* Justice Arabian interpreted such a statement as leading to a contrary conclusion of the issue stressing, “Does it uplift or degrade the unique human persona to treat human tissue as a fungible article of commerce?” *Id.*

<sup>210</sup> *Id.*

<sup>211</sup> GUIDO CALABRESI & PHILIP BOBBITT, TRAGIC CHOICES 92–98 (1978). In a non-tragic context, society often allows allocation decisions to market mechanisms. *Id.* at 31. Society allows individuals to act as the principal actors and choosers and to make decisions to further their goals without any overt coercion or centralized planning. *Id.* Such a system raises concerns when it is applied to situations like being able to buy out of a wartime draft or to auction off cancer chemotherapy to the highest bidder. *Id.* In such situations, there is what the authors refer to as the problem of “costs of costing.” *Id.* at 32. The market is to assign costs to certain goods and bads, which is needed in order for society to make any market-based allocation decisions. *Id.* There are external costs, such as moralism and the affront to certain societal values, to make the value of a life reducible to a monetary figure. *Id.*

<sup>212</sup> *Id.* at 32. Having the market, in this case the medical and healthcare enterprise, dictate the value of one's body offends notions of human dignity and respect. *Id.* Even if such a determination can be made, there are also external costs that all of society must bear by having one's body assigned a monetary value. *Id.* There is little reason to suspect that the private market would not seek to value certain individuals and their genetic uniqueness. See Kolata, *supra* note 12 (describing how only 4% of cancer patients have the genetic variant that is treatable with Merck's Keytruda cancer drug, but that there would still be 60,000 U.S. patients each year who would be candidates for the \$156,000 per year drug therapy); Rob Stein, *FDA Approves First Gene Therapy for Leukemia*, NAT'L PUB. RADIO (Aug. 30, 2017), <https://www.npr.org/sections/health-shots/2017/08/30/547293551/fda-approves-first-gene-therapy-treatment-for-cancer> [<https://perma.cc/PUS6-3D3L>] (estimating that are 3100 patients diagnosed each year with the type of leukemia that is treatable with Novartis's \$475,000 Kymriah gene therapy).

<sup>213</sup> CALABRESI & BOBBITT, *supra* note 211, at 32.

<sup>214</sup> See, e.g., *id.* at 92–98 (describing how pricing what is most fundamental to our identities offends societal notions of dignity and respect for human life).



governing biomedical research is also not unprecedented.<sup>215</sup> Public policy justifications have supported the determination that an individual's ownership rights to his or her tissues are extinguished once the tissue leaves the body.<sup>216</sup> Policy justifications have also supported the determination that consent is not needed for the use of de-identified samples.<sup>217</sup> Furthermore, the Supreme Court's 2013 decision in *Association for Medical Pathologists v. Myriad Genetics* is broadly demonstrative of a desire to encourage research and scientific discovery and not lock up valuable information from which society at large can benefit.<sup>218</sup> Legislative action, or amending the Transplant Act in particular, to prevent individuals from receiving compensation for contributing their biological material for research purposes is supported by numerous public policy justifications.<sup>219</sup>

### CONCLUSION

Swift and targeted legislative action needs to be taken that proscribes the exchange of compensation for contributing one's biological material for research purposes. There is a strong public policy vein throughout the judicial and legislative framework guiding modern human subject research that seeks to encourage access to and use of biosamples. The stakes are too high with the advent of precision medicine and the significant advances being made almost daily in the field to have such progress stifled in any manner, especially by having the research community engage in costly, time consuming, and complicated processes of paying individuals for their biological material. Furthermore, having to engage in this type of pricing of the most fundamental aspects of personhood offends our shared notions of human dignity and respect.

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<sup>215</sup> See, e.g., *Moore*, 793 P.2d at 493–95 (holding that individuals do not retain an ownership interest in their cells after the cells are removed from their bodies).

<sup>216</sup> *Id.*

<sup>217</sup> Kaiser, *supra* note 128.

<sup>218</sup> See *Ass'n for Med. Pathologists v. Myriad Genetics*, 569 U.S. 576, 580 (2013) (holding that naturally occurring human genes are not patentable as they are a product of nature and not patent eligible just because they have been isolated).

<sup>219</sup> See, e.g., Kaiser, *supra* note 128 (warning of the risk to the progress of scientific and medical discoveries posed by impeding researchers' access to the samples they need).