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## Lesson Learned: Why Federal Stem Cell Policy Must Be Informed by Minority Disadvantage in Organ Allocation

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# LESSON LEARNED: WHY FEDERAL STEM CELL POLICY MUST BE INFORMED BY MINORITY DISADVANTAGE IN ORGAN ALLOCATION

MARGARET BICHLER\*

WHOSE BODY IS IT ANYWAY? JUSTICE AND THE INTEGRITY OF THE PERSON. By Cécile Fabre. New York: Oxford University Press. 2006. Pp. 268.

**Abstract:** Ever since advancements in medical technology made organ transplantation possible, the demand for organs has been far greater than the supply, thus creating an organ shortage. The medical necessity of genetic matching between donor and donee has disadvantaged minorities in their pursuit of healthy organs because most organ donors are Caucasian and are therefore not a genetic “match” for minorities. Minority disadvantage in organ allocation must inform federal stem cell policy lest the same genetic incompatibility hinder minority access to potentially life-saving stem cell therapies. The federal government must take affirmative and timely steps in order to ensure equitable access to stem cell therapies in the future. This book review outlines those steps, arguing that Congress should: (1) fund stem cell research in order to secure march-in rights under the Bayh-Dole Act; and (2) condition the receipt of funds on the use of diverse stem cell lines in order to promote the creation of therapies genetically accessible to a diverse citizenship.

## INTRODUCTION

*As members of societies that have a history of ethnic discrimination, we have an obligation to reduce ethnic disparities in life expectancy and other indicators of health. Insofar as these disparities are understood as present injustices, at the very least, public policy should not be formulated in ways that make them worse.*

—Ruth R. Faden<sup>1</sup>

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<sup>1</sup> Ruth R. Faden, *Public Stem Cell Banks: Considerations of Justice in Stem Cell Research and Therapy*, 33 HASTINGS CENTER REP. 13, 22 (2003). Faden is professor of Biomedical Ethics and Executive Director of The Berman Institute of Bioethics at the Johns Hopkins Univer-

In recent years, as organ transplantation has progressed and become a safer practice, the demand for organs has increased while the supply has remained the same.<sup>2</sup> Unfortunately, in the resulting organ shortage, minority and impoverished populations have been both disadvantaged in their pursuit of organs and exploited by the organ trade that exists in foreign countries.<sup>3</sup> This situation has left many pondering what social justice requires given such a shortage.<sup>4</sup> Further scientific advancement has made the medical community newly hopeful that stem cells—unspecialized, raw biological materials capable of developing into numerous more specialized cells, such as muscle, heart, nerve, and blood—will one day render the organ shortage a crisis of the past.<sup>5</sup> As research efforts progress, and social debate continues, one thing seems certain: insofar as stem cell research promises to bridge the gap between organ supply and demand, sound federal policy must be implemented now in order to guide the research efforts and to ensure equitable distribution of its fruits in the future.<sup>6</sup>

Cécile Fabre, author of *Whose Body Is It Anyway? Justice and the Integrity of the Person*, explores the organ shortage within a broader discussion of social justice.<sup>7</sup> She defines a just society as one in which: (1) every citizen has the resources necessary to lead a minimally flourishing life, and (2) once everybody has such a life, individuals are allowed to “enjoy the fruits of their labor in pursuit of their conception of the

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sity. Johns Hopkins Berman Institute of Bioethics: People, <http://www.hopkinsmedicine.org/bioethics/people/personnel/faden.html> (last visited Mar. 15, 2007). She is also a Senior Research Scholar at the Kennedy Institute of Ethics at Georgetown University and author of numerous books and articles on biomedical ethics and health policy. *Id.* Her article, *Public Stem Cell Banks: Considerations of Justice in Stem Cell Research and Therapy*, is relied on throughout this book review primarily because Faden is both an expert and a pioneer in the field of stem cell policy.

<sup>2</sup> See Eric F. Galen, *Organ Transplantation at the Millennium: Regulatory Framework, Allocation Prerogatives, and Political Interests*, 9 S. CAL. INTERDISC. L.J. 335, 335 (1999).

<sup>3</sup> See *id.* at 363; *Poor Villagers Fall Prey to Kidney Trade*, CHINA DAILY, Aug. 16, 2006, available at [http://english.peopledaily.com.cn/200608/16/eng20060816\\_293544.html](http://english.peopledaily.com.cn/200608/16/eng20060816_293544.html) [hereinafter *Poor Villagers*]; Trupti Patel, *TED Case Studies: India Kidney Trade*, Jan. 1996, <http://www.american.edu/ted/class/all.htm#Jan1996> (follow “Human Kidney Trade, by Trupti Patel” hyperlink) (outlining the Indian kidney trade and the organ shortage).

<sup>4</sup> See, e.g., CÉCILE FABRE, *WHOSE BODY IS IT ANYWAY? JUSTICE AND THE INTEGRITY OF THE PERSON* 5 (2006); Patel, *supra* note 3; INST. OF MED. OF THE NAT’L ACADS., *REPORT BRIEF: ORGAN DONATION: OPPORTUNITIES FOR ACTION I* (2006), available at <http://www.iom.edu/Object.File/Master/34/281/Organ%20Donation%20for%20web.pdf> [hereinafter *REPORT BRIEF*].

<sup>5</sup> See Faden, *supra* note 1, at 13.

<sup>6</sup> See *id.*

<sup>7</sup> See FABRE, *supra* note 4, at 5.

good.”<sup>8</sup> To achieve the first prong, Fabre proposes that just as individuals in a just society have equal rights to the material resources necessary to lead a minimally flourishing life, they have equal rights to personal resources—namely, body parts and personal services (e.g., acts of good samaritanism, prostitution, surrogacy).<sup>9</sup> Based on this understanding, she seeks to show that, insofar as the government has access to one’s *material* resources via taxation for the purpose of redistributing those resources to the poor, the government should also have access to *personal* resources, namely healthy and able bodies and body parts, for the purpose of redistributing organs to the sick or for imposing a duty to act on a third person who witnesses another’s peril.<sup>10</sup> In order for the second prong to be satisfied, that is, in order for individuals to be freely able to pursue their conception of the good, Fabre suggests that individuals should be legally permitted to sell their organs and to lease their bodies for child-bearing or sexual services.<sup>11</sup> Here Fabre explains that organ sales, surrogacy contracts, and prostitution, should be legal for different reasons: though they are not necessities required by all in order to lead a minimally flourishing life, they are desired by some in their pursuit of an ideal existence, which is equally important in a just

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<sup>8</sup> *Id.* at 4. Fabre defines a minimally flourishing life as one in which an individual is capable of “framing, revising, and implementing a conception of the good” with which she identifies. *Id.* at 32. Obtaining such a life requires that one has a “range of opportunities to choose from, and access—time and resources—to some of those opportunities.” *Id.* Fabre then explains that the principle of sufficiency requires steps to be taken (redistributive steps) to provide individuals with the means necessary to lead a minimally flourishing life, namely that poor people are given basic necessities, that individuals are given access to financial services and to markets, and that social services are provided. *Id.* at 33. Achieving sufficiency requires that the autonomy of some is compromised as distributive policies deprive them of some resources for the betterment of others. *Id.*

<sup>9</sup> *Id.* at 7–8. Fabre asserts that organ confiscation from both dead and live bodies should be legalized. *Id.* at 5. Essentially, the viable organs from every dead body would be harvested and donated. *Id.* at 73–74. Citizens would also be commissioned to donate organs such as kidneys, corneas, and liver lobes while living if and when they were determined to be a match for someone in need. *See id.* at 100.

<sup>10</sup> *Id.* at 2–3. Fabre argues for a “highly qualified right to personal integrity” and, in so doing, suggests that personal autonomy and broader access to others’ bodies can and should co-exist. *Id.* at 2. The author proposes that “being committed to coercive taxation for the purpose of distributive justice *does* entail that we cannot be committed to a full right to personal integrity . . . rejecting the view that individuals have such a right does *not* entail sacrificing one of liberalism’s core values . . . to wit, autonomy.” *Id.* at 3. For Fabre, body parts, though not commodities, are resources that are needed by some, for example those who suffer renal failure, to lead a minimally flourishing life. *See id.* at 5. Similarly, other citizens who find themselves in peril have an equal right to the personal services of an able-bodied bystander capable of helping without accepting an unreasonable risk or compromising their own ability to achieve a minimally flourishing life. *Id.* at 4.

<sup>11</sup> *Id.* at 8–9.

society.<sup>12</sup> Anticipating criticism that the legalization of organ sales would ultimately exploit the poor, Fabre situates her argument within “ideal theory”—a theory of distributive justice that assumes every citizen’s need for material resources is met, or, in other words, that there is no poverty.<sup>13</sup>

While Fabre’s arguments are interesting, their utility, at least in the United States, is limited by both the tremendous value consistently placed on personal autonomy by the American legal system and the reality of poverty.<sup>14</sup> The value and preservation of personal autonomy informs so much of the American legal landscape that it is difficult, if not impossible, to imagine a government willing and able to confiscate organs from its citizens.<sup>15</sup> Moreover, poverty plagues the United States and other capitalistic societies, and the legalization of organ sales would inevitably result in the exploitation of poor populations.<sup>16</sup> In fact, in countries where organ sales are currently legal, impoverished citizens sell organs for minimal compensation to their more economically stable counterparts.<sup>17</sup> Despite the limitations that the value of autonomy and poverty place on Fabre’s arguments, the author is simply seeking to outline a solution to a very real problem that has come to haunt both national and international medical fields within recent years: the organ shortage.<sup>18</sup>

Given the value of personal autonomy and the pervasiveness of poverty, this Book Review provides a more realistic examination of the

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<sup>12</sup> FABRE, *supra* note 4, at 8–9.

<sup>13</sup> *Id.* at 8. Fabre realizes that examining organ sales in ideal theory is odd because standard objections to the legalization of organ sales are based on the fact that there is poverty and, as a result, poor people might have no choice but to sell an organ in order to meet their financial and material needs. *Id.* She goes on to explain that, even if there is reason to believe that organ sales would be less prevalent in a just society, the question of their legitimacy would not be completely moot because individuals, she argues, should still have the right regardless of whether or not they exercise it. *Id.*

<sup>14</sup> See, e.g., *Thor v. Superior Court*, 855 P.2d 375, 380 (Cal. 1993); *In re Gardner*, 534 A.2d 947, 950 (Me. 1987) (explaining that “American courts and commentators have long emphasized the importance of personal autonomy”); U.S. Census Bureau, Poverty: 2005 Highlights, <http://www.census.gov/hhes/www/poverty/poverty05/pov05hi.html> (last visited Mar. 22, 2007) [hereinafter Poverty Highlights]. The official poverty rate in 2005 was 12.6%. *Id.* The poverty rate was 24.9% among Blacks and 21.8% among Hispanics. *Id.*

<sup>15</sup> See *Thor*, 855 P.2d at 380; *Gardner*, 534 A.2d at 950.

<sup>16</sup> Poverty Highlights, *supra* note 14.

<sup>17</sup> See *Poor Villagers*, *supra* note 3; Patel, *supra* note 3.

<sup>18</sup> See REPORT BRIEF, *supra* note 4, at 1 (explaining that “as organ transplantation has grown increasingly safe and effective, the demand for transplants has grown far faster than the supply of available organs”). The number of people on the U.S. waiting lists has increased from 16,000 in 1988 to a current total of more than 90,000; approximately 40,000 individuals are added to the transplant waiting list every year. *Id.*

shortage and assesses the need for federal stem cell policy that recognizes the ways in which both minority and poor populations are disadvantaged in their pursuit of healthy organs. It will evaluate the need for federal safeguards against the disadvantage of these populations if and when stem cell research bridges the gap between the supply and demand of organs. The federal government has already created a niche within the scheme of federally funded research via the Bayh-Dole Act of 1980, which creates the right of private research entities to patent federally funded research, but reserves a right for the government to “march-in” if the results of that research are not used for the good of the general public.<sup>19</sup>

Part I will outline the ways in which the organ shortage adversely affects minority and poor populations both domestically and abroad.<sup>20</sup> Part II will discuss stem cell research and the probability that, if left unregulated, its fruits will benefit primarily wealthy Caucasian populations.<sup>21</sup> Because of these risks, it is imperative that the federal government does what it can to direct stem cell research.<sup>22</sup> Part III will introduce the Bayh-Dole Act as a means by which the federal government could provide meaningful guidance to stem cell research efforts to ensure that, if those efforts one day minimize the gap between organ supply and demand, the benefits of such scientific advancements will be enjoyed equitably.<sup>23</sup> Part III will outline the necessary steps to ensure equal access to future stem cell therapies: (1) Congress must pass legislation allocating federal funds to stem cell research, (2) the National Institutes of Health (NIH), or comparable federal entities, must establish stem cell banks comprised of diverse stem cell lines, and (3) Congress must condition the provision of federal funds on the use of diverse stem cell lines in research.<sup>24</sup>

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<sup>19</sup> Bayh-Dole Act of 1980, 35 U.S.C. § 203(a) (2001). The Act stipulates that when the federal government funds research conducted by a nonprofit organization or a small business firm, the contractor has a right to patent the results. *Id.* § 202. With respect to any resulting invention, the funding agency shall have the right to require the patent holder to grant a license to the government or the government’s designee. *Id.* § 203.

<sup>20</sup> See, e.g., Galen, *supra* note 2 at 363; Patel, *supra* note 3; *Poor Villagers*, *supra* note 3.

<sup>21</sup> See Faden, *supra* note 1, at 14.

<sup>22</sup> See *id.*

<sup>23</sup> See 35 U.S.C. § 203(a); Faden, *supra* note 1, at 14.

<sup>24</sup> Steve Mitchell, United Press Int’l, *U.S. Stem Cell Firms Moving Overseas*, Aug. 8, 2006, available at [http://www.spacedaily.com/reports/US\\_Stem\\_Cell\\_Firms\\_Moving\\_Overseas\\_999.html](http://www.spacedaily.com/reports/US_Stem_Cell_Firms_Moving_Overseas_999.html) (explaining that President Bush’s recent veto of federal legislation that would have funded stem cell research on frozen embryos has influenced stem cell research firms to relocate overseas to more favorable research forums); Press Release, Johns Hopkins Medicine, Panel: Clinical Use of Embryonic Stem Cells Jeopardized by Policy on Federal Funding (Nov.

## I. MINORITY AND POOR DISADVANTAGE IN THE ORGAN SHORTAGE

The organ shortage is a frustrating and heartbreaking reality for all involved, but it is most costly for members of poor and minority populations.<sup>25</sup> There are at least three ways in which the organ shortage harms minorities and the poor: (1) allocation protocol coupled with biological issues of genetic matching in the United States leaves minorities waiting for organs longer and in greater numbers, (2) the cost of organ transplantation prevents the poor from obtaining organ transplants, and (3) impoverished populations abroad are exploited by wealthy organ donees who buy their organs for minimal compensation.<sup>26</sup> In the United States, African Americans and other minorities are on organ waiting lists in greater percentages and for longer periods of time than their white counterparts.<sup>27</sup> Inasmuch as the following reasons for minority disadvantage center on biological issues and the failure of African Americans to donate organs in high numbers, the federal government is in no position to remedy the disadvantage.<sup>28</sup> However, the federal government currently stands in the ideal position from which to direct stem cell research so that these issues will not result in minority disadvantage in the future allocation of stem cell therapies.

There are numerous reasons for minority disadvantage in organ allocation in the United States.<sup>29</sup> First, minority populations and Cau-

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10, 2003), available at [http://www.hopkinsmedicine.org/Press\\_releases/2003/11\\_10\\_03.html](http://www.hopkinsmedicine.org/Press_releases/2003/11_10_03.html) (explaining that President Bush's decision in 2001 to limit the use of federal funds to research of existing stem cell lines has seriously impinged efforts in the field).

<sup>25</sup> See, e.g., Galen, *supra* note 2, at 363–64 (explaining the ways in which African Americans are disadvantaged in the United States' organ allocation scheme); *Poor Villagers*, *supra* note 3 (discussing the Pakistani impoverished populations that are promised jobs in exchange for their kidneys); Patel, *supra* note 4 (describing the ways in which poor and minority populations in India sell kidneys for minimal funds to wealthy foreigners).

<sup>26</sup> *South Dakota v. Dole*, 483 U.S. 203, 206–07 (1987); *Ivanhoe Irrigation Dist. v. McCracken*, 357 U.S. 275, 295 (1958); see also *United States v. Butler*, 297 U.S. 1, 65 (1936) (interpreting broadly the spending power, and establishing the constitutionality of the conditional grant of federal funds).

<sup>27</sup> See, e.g., Galen, *supra* note 2, at 363; Robert S. Gaston, *Addressing Minority Issues in Renal Transplantation: Is More Equitable Access an Achievable Goal?* 2 AM. J. OF TRANSPLANTATION 1 (2002); Minority Donation Educ. Alliance (MDEA), *Did You Know?*, available at <http://www.mdeda.org/info.asp> (last visited Mar. 22, 2007) (providing statistical data on the current dearth of organ donations made by minorities in America and on-average waiting list times for minority organ donees relative to Caucasian donees).

<sup>28</sup> See Galen *supra* note 2, at 363–64.

<sup>29</sup> See *id.* Much of this “disparate medical phenomenon” has been caused by both biologic factors and allocation priorities. *Id.* at 363. Compared to whites, African Americans suffer approximately four times greater incidence of end stage renal disease. *Id.* Consequently, a disproportionately high number of African Americans are in need of kidney

casians are genetically dissimilar in immune system antigens and blood types, which translates into immune system incompatibilities that prevent minorities from passing the initial screening by which genetic “matches” are paired according to allocation protocol.<sup>30</sup> Second, fewer African Americans than Caucasians elect to become organ donors, which results in Caucasians having a greater likelihood of being successfully matched to a donor sooner.<sup>31</sup> Third, even with governmental guidelines in place to secure equitable distribution of organs, all organ allocations are subject to “medical judgments” concerning the suitability of donees for the transplant.<sup>32</sup> Minority populations are, therefore, left unprotected against discriminatory judgment calls that they are unlikely to lead a life conducive to caring for a healthy organ.<sup>33</sup>

The tremendous cost of an organ transplant disadvantages another marginalized population in their pursuit of healthy organs: the poor.<sup>34</sup> It is estimated that, in the United States, an organ transplant procedure and the necessary post-operation medical care costs as much

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transplants; “African Americans comprise approximately twelve percent of the United States population, and thirty-two percent of the kidney waiting list.” *Id.*

<sup>30</sup> *See id.* at 363–64. Biologic differences, like the dissimilarities in immune system antigens and blood types existing between African Americans and Caucasians, between a donor and a donee, can trigger immune responses from the donee’s body after transplantation causing transplant failure or death. *Id.* Specifically, blood types O and B are more common among African Americans than whites, and since whites are more frequently organ donors, this results in African Americans on the waiting list failing the initial Match System screening when organs from white donors are allocated. *Id.* at 364.

Gaston explains that because immunosuppression technology (used to suppress immune rejection of organs that are of a different genetic type than the donee’s) has become more advanced, the importance of genetic matching to successful transplant outcomes has been greatly reduced. Gaston, *supra* note 27, at 2. The impact of HLA-based allocation, the process by which human leukocyte antigens are matched between donor and donee in order to increase the likelihood of successful transplantation, is to offer rapid transplantation to those with common antigens and reduce access for minorities with uncommon antigens. *See id.* A recent study suggests that reducing reliance on ABO blood-type identity and HLA matching might increase minority access to transplantation by as much as fifteen percent. *Id.*

<sup>31</sup> MDEA, Home/About Us, <http://www.mdeda.org/> (last visited Mar. 22, 2007).

<sup>32</sup> *See Galen, supra* note 2, at 375–77. Galen discusses a scenario in which a doctor might make a judgment call between a healthy, wealthy white male and an alcoholic woman when determining who should get a liver. *Id.* Galen speculates that the doctor might ultimately decide that the healthy, wealthy white male, promising to make a large donation to the hospital, will get the liver because the woman’s alcoholism makes her less medically suitable given that her lifestyle induced the failure of her own liver. *Id.* The same discretionary judgments can be made to disfavor African Americans and other minority populations whom, the doctor may assume, also lead unacceptable lifestyles. *See id.*

<sup>33</sup> *See id.*

<sup>34</sup> *Id.* at 368.

as \$394,000 per patient.<sup>35</sup> While most states have Medicaid programs that cover the majority of transplant procedures, many individuals are not poor enough to qualify for Medicaid, cannot afford private health insurance, and cannot conceivably produce nearly \$400,000 for a life-saving organ transplant—their precarious financial situation will probably leave them on the waiting list indefinitely.<sup>36</sup> Moreover, wealthy Americans can remove themselves from organ transplant waiting lists by flying overseas and securing an organ transplant for a mere \$130,000 to \$160,000.<sup>37</sup> The poor cannot because Medicaid and other insurance providers will not cover an organ transplant in a foreign black market; as a result, the availability of an organ market abroad provides the wealthy with another advantage and leaves the poor waiting longer for organs.<sup>38</sup>

The organ shortage does not just harm people of color in need of transplants; it also leads to the exploitation of minority organ “donors” in foreign markets.<sup>39</sup> This unsettling reality must also inform federal stem cell policy so that the economic incentive to purchase organs abroad will cease once stem cell therapies are developed.<sup>40</sup> In countries where organ sales are legal or where they are illegal but proliferate via the black market, the situation of the poor within the organ shortage is exacerbated as they are exploited by wealthy counterparts seeking healthy organs.<sup>41</sup> The following account of Amjad Ali, a poor villager from eastern Pakistan who was promised a job and money in exchange

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<sup>35</sup> *Id.*

<sup>36</sup> *See id.*

<sup>37</sup> *See A Chinese Horror Story*, ST. LOUIS POST-DISPATCH, Aug. 22, 2006, available at <http://www.clearwisdom.net/emh/articles/2006/8/27/77373.html>.

<sup>38</sup> *See id.*

<sup>39</sup> *See id.*

<sup>40</sup> *See* 35 U.S.C. § 203(a) (2001). Insofar as the government retains the right to “march-in” if the technology is not being used for the public good, if federal funding is provided to stem cell research now, the government can probably ensure the affordability of stem cell therapies in the future, thus removing the incentive for purchasing organs abroad. *See id.*

<sup>41</sup> *Poor Villagers*, *supra* note 3. In January of 1995, the reality of the organ trade and the potential for exploitation was realized; the kidney scandal first came into the public eye when three different underground operations were discovered, all driven by the kidney shortage. Patel, *supra* note 3. Customs officers in Delhi uncovered a “kidney tour” racket in which hundreds of donors had been enticed to go abroad for removal and transplantation of their kidneys. *Id.* Authorities next discovered residents of a leprosy colony selling kidneys for money. *Id.* Finally, police in Bangalore busted a massive racket in which the kidneys of an estimated one thousand individuals had been removed without their knowledge in a leading city hospital where the individuals had been lured with offers of jobs and for the purpose of giving blood. *Id.*

for one of his kidneys, is a striking example of the exploitative black market.<sup>42</sup> Ten months after the procedure, Ali was still jobless, one kidney short, and in constant pain and discomfort.<sup>43</sup> He describes his experience as follows: "They promised me a job and took me to Rawalpindi. They drugged me, made me unconscious for days and cut out my kidney."<sup>44</sup> In order to support Ali's pursuit of compensation or legal remedy, his father has taken loans, sold his goats, crockery, and bricks.<sup>45</sup> All three people arrested for the incident were released after they produced documents showing that Ali had been paid USD \$1250 for his kidney.<sup>46</sup> Ali is one of many who have fallen prey to this scenario, and the social consequences of selling a kidney or other organ can be as permanent as the loss of the organ itself.<sup>47</sup> Men have returned to their communities only to find that they are no longer marriageable because they are not considered "whole," and they are discriminated against by their employers because of beliefs that once one loses a kidney they never regain full strength.<sup>48</sup> These social consequences often place the individual in an even more dire financial situation.<sup>49</sup> A 2002 study on the long-term effects of organ sales in India revealed that, of three-hundred and fifty people who had sold their kidneys for an average price of \$1000, seventy-five percent were still in debt six years after the sale, and the number of individuals living in poverty within the

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<sup>42</sup> *Poor Villagers*, *supra* note 3.

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

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

<sup>45</sup> *Id.*

<sup>46</sup> *Id.*

<sup>47</sup> *Poor Villagers*, *supra* note 3; Julie A. Corwin, *World: The Risks, Benefits of a Free Market in Organs*, RADIO FREE EUROPE RADIO LIBERTY, May 16, 2006, <http://www.rferl.org/features-article/2006/05/837d8204-b7c6-439f-9edc-cfa98f6c756f.html>.

<sup>48</sup> *See id.* Anthropologists Nancy Scheper-Hughes and Lawrence Cohen are members of a task force of social scientists and anthropologists dedicated to investigating and exposing the organ trade and the ways in which it exploits the poor in foreign countries. Kathleen Scalise, *Extreme Research: Nancy Scheper-Hughes and Lawrence Cohen*, BERKELEY MAG., Summer 1999, available at [http://www.berkeley.edu/news/magazine/summer\\_99/feature\\_darkness\\_scheper.html](http://www.berkeley.edu/news/magazine/summer_99/feature_darkness_scheper.html). In India, poor women have sold their kidneys to pay back money borrowed to feed their families. *Id.* In South Africa, cadavers of poor, mostly minority, victims of violence have been "looted" for usable eyes and heart valves. *Id.* In Brazil, the government declares everyone a universal organ donor at birth, and people in poverty are terrified of falling prey to the organ trade. *Id.*

<sup>49</sup> *See* Jeffrey P. Kahn, *Studying Organ Sales: Short Term Profits, Long Term Suffering*, CNN.COM, Oct. 10, 2002, <http://archives.cnn.com/2002/HEALTH/10/01/ethics.matters.selling.organs>.

study group had actually increased from fifty-four to seventy-one percent.<sup>50</sup>

## II. THE PROMISE OF STEM CELL RESEARCH AND THE PERPETUATION OF MINORITY DISADVANTAGE

The organ shortage and, more specifically, its effects on minority populations are daunting realities that should weigh on and inform both the legislature and the executive as stem cell policy is developed.<sup>51</sup> Within recent years the promise of stem cell research has grown as research efforts have shifted from basic science to the development of cures for numerous diseases and disorders.<sup>52</sup> Because all stem cell therapies, from cures for Alzheimer's and diabetes to transplantable organs, will be genetically specific and will thus require "matching," the same genetic issues that define minority disadvantage in the organ shortage will define their access to all stem cell therapies unless preventative measures are taken.<sup>53</sup>

To date, the dominant moral concern in the stem cell debate has had little or nothing to do with securing equitable access to stem cell therapies, but has focused instead on whether it is acceptable practice to extract stem cells from live embryos.<sup>54</sup> In 2001, President Bush took a determined moral stance on the issue when he announced that federally funded stem cell research could proceed but would be re-

<sup>50</sup> *Id.* The study also found that "[m]ore than 85 percent reported that their health declined after the donation, and almost 80 percent said they would not recommend selling a kidney." *Id.*

<sup>51</sup> See Faden, *supra* note 1, at 17.

<sup>52</sup> See, e.g., *id.* at 13. Because of their unique capability to develop into numerous specialized cells, stem cells will potentially cure Alzheimer's, Parkinson's, and diabetes, as well as generate organs. See *id.*

<sup>53</sup> See *id.*

<sup>54</sup> See Geoffrey Winn, *The Stem Cell Debate*, L. SPOT, Sept. 2001, [http://www.law4u.com.au/lil/lis\\_stem.html](http://www.law4u.com.au/lil/lis_stem.html). Pope John Paul II has stated: "Human embryos obtained in vitro are human beings and are subjects with rights; their dignity and right to life must be respected from the first moment of their existence. It is immoral to produce human embryos destined to be exploited as disposable biological material." See *id.* The Catholic Church's opinion, as stated by the late Pope John Paul II, is representative of many groups and centers on the conviction that an embryo is a human life, and thus that the destruction of an embryo is a moral and legal wrong. *Id.* Winn also points to writer Ronald Bailey as a scholar who has convincingly opposed the stance taken by the Catholic Church and many others. *Id.* Bailey urges that while a one-week-old embryo is undeniably alive on a cellular level, molecular biology has recently established that the capacity for life is contained not only within an embryo, but also within adult cells, and thus, the potential for life is no longer a sufficient argument to legally protect human embryos from being "exploited" for the use of their stem cells. *Id.*

stricted to cell lines then in existence.<sup>55</sup> As research continues to reveal more suitable means of harvesting stem cells, the efforts to utilize them for therapeutic purposes will ultimately forge on, and most of the contention regarding right to life issues will most likely dissipate.<sup>56</sup>

Unfortunately, the ethical dilemmas do not stop at the use of live embryos for obtaining stem cells; the debate has overlooked the reality that, unless proactive measures are implemented, minority and impoverished populations stand to be seriously disadvantaged yet again once stem cell research yields cures and therapies for diseases and disorders.<sup>57</sup> This threat is two-fold: (1) the same genetic issues that currently diminish the chances of minorities finding healthy organs that are a “match” will also prevent them from obtaining stem cell therapies that are a “match,” and (2) the race to patent the results of stem cell research will inevitably lead to the commercialization and more expensive therapies, out of the reach of impoverished populations.<sup>58</sup> In order to avoid these threats, Congress must develop proactive legislation regarding stem cell research and related therapies.

#### A. Immune Rejection and Biological Access

It is well understood that biological factors coupled with the “match” system of organ allocation has disadvantaged minority populations in need of organ transplants.<sup>59</sup> The government must now under-

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<sup>55</sup> See *id.*

<sup>56</sup> See Nicholas Wade, *Stem Cell News Could Intensify Political Debate*, N.Y. TIMES, Aug. 24, 2006, at A1. On August 23, 2006, researchers at Advanced Technology, Inc. announced that they had discovered a new means by which stem cells could be extracted from an embryo while allowing for the embryo to be implanted in the uterus and to develop into a fetus. See *id.* This approach, if proven successful in other laboratories, could potentially provide an answer to the stem cell debate insofar as it would quash ethical concerns regarding the destruction of potential life. *Id.* The new technique would be performed on a two-day-old embryo consisting of only eight cells and would involve one of those cells being removed while the embryo, now consisting of seven cells, could be implanted into the uterus to develop. *Id.* This process has been utilized for over ten years now in order to diagnose Down syndrome in embryos and, throughout that period, has yielded healthy babies. *Id.* Until this breakthrough, stem cells have been harvested from blastocysts, which are 150-cell embryos at a later stage of development; harvesting stem cells from blastocysts kills the embryo and gives rise to the ethical dilemma now fueling the stem cell research debate. *Id.*

<sup>57</sup> See Faden, *supra* note 1, at 17.

<sup>58</sup> See *id.*; Peter Yun-Hyoung Lee, *Inverting the Logic of Scientific Discovery: Applying Common Law Patentable Subject Matter Doctrine to Constrain Patents on Biotechnology Research Tools*, 19 HARV. J.L. & TECH. 79, 103 (2005).

<sup>59</sup> *Organ Donation Allocation Before the Senate Labor and Human Resources Committee and the House Committee on Commerce*, 105th Cong. (1998) (testimony of Hon. Donna E. Shalala, Sec-

stand and guard against the likelihood that the same issues will disadvantage minorities when stem cells are successfully developed into transplantable tissue.<sup>60</sup> For, although stem cells are unspecialized in a very significant sense, they still have biological properties that make them suitable for some populations but not others.<sup>61</sup> Ruth Faden, in her article *Public Stem Cell Banks: Considerations of Justice in Stem Cell Research and Therapy*, calls the discriminatory result of such properties the problem of “biological access”—the situation in which “the biological properties of cells make them less accessible to some potential recipients than to others.”<sup>62</sup> Immune rejection is a large part of the reason that minorities have been disadvantaged in their pursuit of healthy organs to date, and it stands to limit minority access to stem cell therapies in the same way.<sup>63</sup>

A person’s genetic makeup includes a set of genes which code for a type of protein, called human leukocyte antigens (HLA), found on the surface of every cell in the body, including stem cells.<sup>64</sup> HLA proteins play a major role in immune recognition and rejection.<sup>65</sup> Multiple genes code for HLA, and every person has two copies of these genes, one gene inherited from each parent.<sup>66</sup> These HLA-coding genes occur in variant forms, each of which is called an allele, and the array of alleles that each person possesses is called her haplotype.<sup>67</sup> Those with more common haplotypes are more likely to find a donor while those with less common haplotypes are less so.<sup>68</sup> While mismatched transplants can be and are performed between donors and recipients with different haplotypes, a greater number of mismatched alleles between the donor and the recipient results in a greater chance of organ failure or rejection.<sup>69</sup>

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retary, U.S. Dept. of Health and Human Servs.), available at <http://www.hhs.gov/asl/testify/t980618a.html> (addressing the Congress and describing the reasons for minority disadvantage in the organ shortage).

<sup>60</sup> See Faden, *supra* note 1, at 17.

<sup>61</sup> *Id.*

<sup>62</sup> *Id.* at 14.

<sup>63</sup> *Id.* at 17. There are three main strategies currently implemented to remedy the problem of immune rejection: immunosuppressive drugs, clinically induced tolerance, and HLA matching. *Id.* at 16.

<sup>64</sup> *Id.* at 14.

<sup>65</sup> Faden, *supra* note 1, at 14.

<sup>66</sup> *Id.*

<sup>67</sup> *Id.*

<sup>68</sup> *Id.* at 15.

<sup>69</sup> *Id.* Faden explains that rejection is a major research area in the transplantation realm as researchers continue to seek a way to allow patients, regardless of their haplotypes, to receive a transplant that will work for them. *Id.* If this research is successful, the

Interestingly, “HLA has been demonstrated to track with geographical ancestry,” and persons of sub-Saharan African ancestry have the greatest variety of HLA types relative to any other geographical or ethnic group.<sup>70</sup> The issue of HLA-matching thus poses a real problem for ethnic and minority communities in the United States because their HLA types are more varied than the HLA types of other social sectors, and so they are more rarely occurring in the United States population.<sup>71</sup> Minorities will therefore be less likely to find a match, more likely to have a significant number of mismatches, and more likely to suffer failure or rejection.<sup>72</sup> Faden points out that this unfortunate genetic circumstance will extend from organ and bone marrow transplantation to stem cell transplants because stem cells bear the haplotype of the individual from whom the cell line was derived.<sup>73</sup> Thus, “disparities currently present in the field of transplantation are likely to be replicated in the emerging practice of stem cell transplantation, unless specifically guarded against.”<sup>74</sup> The federal government, in developing stem cell research policy, should prevent future disparity in access to stem cell therapies by requiring the use of diverse stem cell lines in federally funded research.<sup>75</sup>

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concept of biological access may cease to exist, but for now, the problem of immune rejection is a very real obstacle to successful transplantation. *Id.* Currently, however, immunosuppressive drugs are the most widely used strategy to deal with immune rejection. *Id.* at 16. In many cases, transplant recipients require continual immunosuppressive therapy in order to avoid either acute rejection or failure. *Id.* But the continuous ingestion of immunosuppressive drugs is not without its own risks which include nephrotoxicity (poisonous effect of the medication on the kidney), diabetic and vascular tendencies, and an increased risk of infection. *Id.* Others have echoed Faden’s concern that issues of HLA-matching will prove prohibitive to many individuals seeking stem cell therapies. See Anver Kuliev et al., *Preimplantation Genetics: Improving Access to Stem Cell Therapy*, 1054 ANNALS N.Y. ACAD. SCI. 223, 223 (2005).

<sup>70</sup> Faden, *supra* note 1, at 15.

<sup>71</sup> *Id.*

<sup>72</sup> See *id.*

<sup>73</sup> *Id.* at 17. The author further explains that HLA-matching will undoubtedly be more crucial to some stem-cell-derived therapies than to others depending on the tissue that is transplanted, but “matching will be critical to clinical success in at least some important therapeutic applications.” *Id.*

<sup>74</sup> *Id.*

<sup>75</sup> See Faden, *supra* note 1, at 17.

### B. *The Patent Problem*

The issue of biological access is not the only obstacle that stands to inhibit minority access to stem cell therapies.<sup>76</sup> Currently, one patent holder dominates the realm of stem cell research and could quite possibly monopolize the stem cell therapy market in the future.<sup>77</sup> The race to discover, patent, and commercialize new stem cell therapies, if left unregulated, will probably result in those therapies being too expensive for minority and impoverished populations.<sup>78</sup> Here, the Bayh-Dole Act, which states the preservation of public availability of inventions as one of its objectives, speaks to the government's awareness of the ways in which patents can result in the inequitable use of scientific discovery—now they must translate that awareness into federal policy that will prevent that result in the future of stem cell research.<sup>79</sup>

Both common law and statutory law have established that, in order for a patent to create an exclusive right to investigate particular scientific phenomena and theories, it must: (1) claim a specific device and not a general effect, and (2) not limit the use of a technological device that has no substitute and is necessary for the exploration of a certain scientific question.<sup>80</sup> In the race to patent the results of stem cell research, it is unclear whether the patents that have been issued to date are in keeping with these criteria.<sup>81</sup> What is clear, however, is that if pat-

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<sup>76</sup> See Lee, *supra* note 58, at 89–90 (explaining that currently stem cell research patents are held primarily by one entity, thus patent monopoly is a potential problem).

<sup>77</sup> *Id.*

<sup>78</sup> Joseph Mueller, *Claims as Pointers: The Statutory Approach to Claim Construction*, 12 J. INTEL. PROP. L. 501, 509 (2005) (explaining that patent monopolies create higher prices because of greater demand than supply).

<sup>79</sup> 35 U.S.C. § 200 (2001).

<sup>80</sup> Lee, *supra* note 58, at 83–84. The author explains that the prohibition against patenting natural laws and phenomena is largely the result of common law. *Id.* at 93. The Supreme Court, in 1842, stated that “the end to be accomplished is not the subject of a patent,” but the new and useful means for obtaining that end are within the proper scope of patent law. *Carver v. Hyde*, 41 U.S. 513, 519 (1842). The Court has thus generally distinguished between a nonpatentable means and a patentable end. See Lee, *supra* note 58, at 93.

<sup>81</sup> *Id.* at 80–81. Lee argues that the patents currently limiting stem cell research are not in keeping with these criteria. See *id.* Lee distinguishes between upstream and downstream research assets and argues that such a distinction is at the heart of the patent system and is an effective embodiment of common law patent doctrine as well as sound public policy meant to encourage scientific innovation while protecting access to basic scientific knowledge. *Id.* at 81–82. In order for researchers and innovators to be able to freely explore and implement their ideas, basic research tools and tools without substitutes (upstream knowledge) must remain widely available. See *id.* At the same time, in order for researchers and innovators to have incentive to pursue their ideas, they are given exclusive rights (downstream privatization) to their final and unique invention. See *id.*

ent-monopolizing private companies commercialize the results of their stem cell research, access to stem cell therapies will be severely limited by the high price that will inevitably result from monopoly over a specific therapy.<sup>82</sup>

James Thomson was the first researcher to isolate human embryonic stem cells (HESCs).<sup>83</sup> He subsequently secured three incredibly broad patents related to his discovery, which were eventually assigned to Geron Corporation, a private biotechnology firm.<sup>84</sup> Thomson's patents involve numerous claims stipulating what will be in violation of the patents; one of these claims alone encompasses, in effect, virtually all HESCs of significant research value.<sup>85</sup> Arguably, these patents violate the common law patent qualification factors outlined above because isolated HESCs are a research tool with no adequate substitute and their patenting limits many other researchers from exploring the scientific questions surrounding stem cells.<sup>86</sup> The limitations placed on stem cell research by Thomson's patents are substantial; because of the breadth of Thomson's patents, all researchers must negotiate with the patent holder before using HESCs, even if they have isolated new HESCs or use a new method to do so.<sup>87</sup>

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<sup>82</sup> Mueller, *supra* note 78, at 509; see Lee, *supra* note 58, at 102–03. Insofar as HESCs are a research tool lying anterior to knowledge and theory, patents on HESCs have the practical effect of creating monopolies over the knowledge that such a tool will ultimately generate. Lee, *supra* note 58, at 102–03. Lee therefore urges that common law doctrine and public policy require a narrowing of the patentability of HESCs. See *id.* at 104.

<sup>83</sup> See Lee, *supra* note 58, at 89.

<sup>84</sup> *Id.* Lee argues that a patent on HESCs is a patent on an upstream research tool creating an incredibly “wide zone of exclusivity,” since the many discoveries and innovations that may arise from stem cell research are still largely theoretical and will be pursued well into the future. *Id.* at 92. Because HESCs are critical to achieving fundamental new insights into biology and are the means that will be used to explore numerous potential therapies, granting individual property rights over them seems contrary to the policy objective in keeping basic scientific knowledge available to the public at large and to the scientific community intent on pursuing innovation. *Id.*

<sup>85</sup> *Id.* at 90.

<sup>86</sup> *Id.* For Lee, stem cells are prime examples of upstream research tools, with no adequate substitution, that should not be patentable in keeping with the common law. *Id.* at 82.

<sup>87</sup> Christopher Hazuka, *Supporting the Work of Lesser Geniuses: An Argument for Removing Obstructions to Human Embryonic Stem Cell Research*, 57 U. MIAMI L. REV. 157, 178–79 (2002) (explaining that the breadth of Thomson's patents empowers him to control future stem cell research); see Lee, *supra* note 58, at 90. Thomson assigned his patents to the Wisconsin Alumni Research Foundation (WARF) which continues to hold the rights. Lee, *supra* note 58, at 90. Even though Thomson's inventive step merely involved discovering the method by which HESCs could be isolated and cultured (a process that might very well have an adequate substitute), his patents actually cover both the process and the stem cells themselves; the patents' claims cover all HESCs instead of covering only those cell lines isolated

By severely limiting the stem cell research tools available to others, the Thomson patents have laid the foundation for a future monopoly over stem cell therapies.<sup>88</sup> The threat of patent infringement lawsuits has even discouraged foreign biotechnology companies and research institutions from marketing their stem cell advances within the United States.<sup>89</sup> If their stem cells match the claims contained in the Thomson patents, a license must be secured from the patent holder so as to avoid patent litigation.<sup>90</sup> While an agreement between the patent holder and the NIH has eased some concerns over the access to stem cell research tools, the agreement maintains the patent holder's broad legal rights over HESCs, and does nothing to alleviate concerns that a future monopoly over stem cell research therapies derived from HESCs will drastically increase prices, thereby making the therapies available only to the wealthy social sector.<sup>91</sup>

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by Thomson. *Id.* The patent on the method for isolating and culturing stem cells also stands to hinder future research; even if another researcher successfully derived useful stem cells without infringing a patent claim, it would still be likely to infringe the patent on the only known method for maintaining the cells' viability held by WARF. *Id.*

In July 2006, the Foundation for Taxpayer and Consumer Rights, a California consumer group, and the Public Patent Foundation, a New York organization advocating patent reform, petitioned the U.S. Patent and Trademark Office for review of the Thomson patents, and in October 2006 their request was granted. Andrew Pollack, *Agency Agrees to Review Human Stem Cell Patents*, N.Y. TIMES, Oct. 4, 2006, at C3. The review could lead to a rescission or narrowing of the three Thomson patents. *Id.* The groups who filed for the review argue that the patents should not have been granted to Thomson because, at the time of his application, three scientific papers by other researchers and one previous patent had already established the process by which embryonic stem cells could be isolated in mice, pigs, and sheep. *Id.* The patents, which only apply in the United States, have brought many research groups to move abroad, a clear indicator of the drastic ways in which the patents have impeded research efforts within the United States. *Id.* Even if the review relieves this impediment, it could take years for the review to be completed. *Id.*

<sup>88</sup> See Lee, *supra* note 58, at 89–90; Hazuka, *supra* note 87, 175–76.

<sup>89</sup> Lee, *supra* note 58, at 90–91; Sheryl Gay Stolberg, *Patent on Human Stem Cells Puts U.S. Officials in Bind*, N.Y. TIMES, August 17, 2001, at A1.

<sup>90</sup> Lee, *supra* note 58, at 90.

<sup>91</sup> See *id.* at 90–91. In October of 1999, WARF established WiCell Research Institute, Inc., a non-profit organization designated to hold the licenses to WARF stem cells. *Id.* at 90. WiCell executed a Memorandum of Understanding (MOU) which established that WiCell would offer WARF cells to scientists at NIH laboratories at the cost of preparation. *Id.* WiCell also agreed to allow federally funded non-profit researchers access to the stem cell lines upon negotiating similar arrangements. *Id.* Though this agreement provides more access to the patented stem cells, it includes strict "reach-through" provisions for commercial applications. *Id.* at 90–91. The agreement allows researchers using WARF HESCs to patent any discoveries made in their research but prohibits the commercialization of such discoveries unless a license with WARF is negotiated. *Id.* This stipulation alone should make it abundantly clear that WARF has no intention of loosening its grip on the future market in stem-cell-derived therapies. See *id.* Moreover, the MOU is a voluntary

### III. ENSURING EQUITABLE ACCESS TO STEM CELL THERAPIES VIA SOUND FEDERAL POLICY

Issues of biological access and the potential of future monopolization of stem cell therapies by patent holders are pressing concerns because they will impinge equal access to stem cell therapies unless federal policy regarding stem cell research addresses these foreseeable problems.<sup>92</sup> Faden points out that the public policy responses to the issues faced by minorities in their pursuit of healthy organs have largely focused on appealing to the African American community for donation and to strategies to increase overall donation.<sup>93</sup> In the case of stem cell research, however, the availability and diversity of HLA types represented in the efforts need not be constrained by the vagaries of organ donation.<sup>94</sup> Though technology currently cannot create organs for transplantation, it can create stem cell lines to be used for research and eventually therapies.<sup>95</sup> Thus, “it is within our power to construct a bank of stem cell lines that includes a wide spectrum of HLA types, specifically selected to satisfy considerations of justice.”<sup>96</sup> Because of the Bayh-Dole Act, the government has an opportunity to ensure now that patented stem cell therapies will be both biologically and financially available to all in the future—that they will be used for the public good in general.<sup>97</sup>

President Bush’s 2001 decision that stem cell research could only continue on then-existing stem cell lines (twenty-one total), and his more recent veto of federal legislation that would have provided federal funding to stem cell research efforts, demonstrate not only that his policy is ill-informed, but that it is short-sighted.<sup>98</sup> In issuing his veto, the President said nothing of patent concerns or biological realities, nor did he recognize that research firms were willing and able to move

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agreement that allows WiCell to “exclude any party from using HESCs, charge whatever license fee it desires for their use, or pursue infringement suits against those who use the HESCs without its permission.” *Id.* at 91. Lee points out that the MOU is particularly advantageous to WiCell, which retains all rights to commercialize any discoveries arising from federally funded, basic research. *Id.* Thus, “WiCell’s apparent generosity in allowing at-cost access to its patented cells may ultimately prove quite self-rewarding.” *Id.*

<sup>92</sup> See Lee, *supra* note 58, at 103; Faden, *supra* note 1, at 17.

<sup>93</sup> See Faden, *supra* note 1, at 17.

<sup>94</sup> See *id.*

<sup>95</sup> See *id.*

<sup>96</sup> See *id.*

<sup>97</sup> See 35 U.S.C. § 203(a) (2001).

<sup>98</sup> Dana Bash & Deirdre Walsh, *Bush Vetoes Embryonic Stem-Cell Bill*, CNN.COM, Sept. 25, 2006, <http://www.cnn.com/2006/POLITICS/07/19/stemcells.veto>.

overseas to continue their efforts.<sup>99</sup> Shortly after the veto, the Geron Corporation, sole assignee of the Thomson patents, announced that it was relocating to the U.K. and noted funding support as one of its reasons.<sup>100</sup> In other words, stem cell research will progress with or without federal approval.<sup>101</sup> There is a limited window of opportunity in which domestic research can be guided to achieve future equality in access to stem cell therapies, and that window is open now.<sup>102</sup>

In order for the policy goal of equal access to be achieved, the federal government must (1) fund stem cell research, (2) guide research efforts to involve diverse stem cell lines, and (3) prevent patent monopolies that will drive up the price of future therapies.<sup>103</sup> If effective and remedial federal policy is implemented now, Americans will not only have access to affordable, biologically suitable therapies, but will have no reason to partake in the exploitation of impoverished minority populations abroad.<sup>104</sup>

#### A. Stem Cell Banks

Because the same biological factors that prevent minorities from having sufficient access to transplantable organs currently will limit their access to stem cell therapies in the future, Congress should pass legislation requiring the collection of diverse stem cell lines.<sup>105</sup> Congressional legislation providing federal funds to stem cell research can then condition receipt of federal funds by research institutions on the use of diverse cell lines.<sup>106</sup> Faden and her colleagues describe the stem cell lines currently available to researchers in the United States as “woefully inadequate” because a mere twenty-one stem cell lines have been approved for federally funded research, and these stem cells were derived from embryos created by in vitro fertilization for reproductive use.<sup>107</sup> Because individuals engaged in the process of in vitro fertiliza-

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<sup>99</sup> See *id.*; Mitchell, *supra* note 24.

<sup>100</sup> See Mitchell, *supra* note 24.

<sup>101</sup> See *id.*

<sup>102</sup> See *id.*

<sup>103</sup> See cases cited *supra* note 26; Mueller, *supra* note 78, at 509.

<sup>104</sup> See Faden, *supra* note 1, at 17 (explaining that the establishment of a diverse stem cell bank will render stem cell therapies available to minority populations); *supra* notes 41–48 and accompanying text (describing the exploitation of the poor in foreign organ markets).

<sup>105</sup> Faden, *supra* note 1, at 17.

<sup>106</sup> See cases cited *supra* note 26.

<sup>107</sup> Faden, *supra* note 1, at 17.

tion are generally not minorities,<sup>108</sup> such details lead to the logical conclusion that the diversity of HLA types currently being studied in the United States is incredibly limited.<sup>109</sup> In order to remedy the current dearth of HLA-type diversity in stem cell lines available for research, stem cell banks, like those proposed by Faden, should be created.<sup>110</sup>

### B. Establishing March-in Rights Under the Bayh-Dole Act

Providing federal funds for stem cell research will not only allow the federal government to direct the researchers to use diverse stem cell lines, but will also establish their march-in rights under the Bayh-Dole Act.<sup>111</sup> March-in rights give the federal government (1) a nonexclusive license to whatever patented technology is derived from federally funded research, and (2) the right to, in some cases, grant third parties licenses to the invention against the patent-holder's wishes.<sup>112</sup> These rights will be key to guarding against monopolization and exorbitant prices of stem cell therapies.<sup>113</sup> Congress passed the Bayh-Dole Act in 1980 in order to encourage the commercialization of technologies developed using federal funds by giving researchers the right to patent federally funded inventions.<sup>114</sup> The Act simultaneously created

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<sup>108</sup> B. J. Bankowski et al., *Racial Disparities Amidst In Vitro Fertilization (IVF) Insurance Mandates in the United States*, 84 FERTILITY & STERILITY S242-43 (Supp. 2005). Minorities generally have less access to infertility treatments because of geographic and economic factors. *Id.* at S242. Moreover, state legislation requiring insurance companies to cover the procedures has been ineffective in increasing minority access to infertility care. *Id.* at S243.

<sup>109</sup> See Faden, *supra* note 1, at 17.

<sup>110</sup> *Id.* at 23. Faden proposes the creation of two stem cell banks. *Id.* The research bank would disburse cell lines for research and should thus be designed to fit research needs; it should consist primarily of homozygous (having identical alleles for a single trait) stem cell lines for the most widely occurring haplotypes in America. See *id.* Still, this bank should include several homozygous stem cell lines common to minorities so that diseases that occur primarily in minority populations are not left without a therapy in the future. See *id.* The therapeutic bank would disburse stem cells to clinicians to create a therapy for a specific individual. See *id.* at 18. Ideally, this bank would be sufficiently diverse so that every potential recipient could receive a match, but the funding required to establish and maintain such a bank renders this option currently unfeasible. See *id.* Given financial constraints, the most common haplotypes from each of the major minority populations in the United States should be included so that an equal percentage of individuals from each group will have access to stem cell therapies. *Id.* at 19, 21-23.

<sup>111</sup> 35 U.S.C. §§ 202(c)(4), 203 (2001) (establishing march-in rights); see *supra* notes 57, 58, and 78 and accompanying text.

<sup>112</sup> *Id.* §§ 202(c)(4), 203.

<sup>113</sup> *Id.* § 202(c); see *supra* notes 57, 58, and 78 and accompanying text.

<sup>114</sup> 35 U.S.C. § 200. Prior to 1980, there was a "free market technology-transfer policy in the United States" based on the notion that, if public funds created the technology, title to the invention should remain with the government and the public. Peter S. Arno & Mi-

an obligation of the patent holder to ensure that her technology would be available to the public on reasonable terms.<sup>115</sup> Thus, Bayh-Dole patent-holders are subject to march-in rights, or the right of the government to require the patent holder to assign a license to a party of their designation, which the government may exercise if the patentee fails to take reasonable steps toward practical application of the invention or if the action is necessary to satisfy health or safety needs.<sup>116</sup>

In order for the government to exercise march-in rights, an aggrieved party (usually one who desires access to the patented technology) must file a petition with the NIH requesting that it initiate march-in proceedings.<sup>117</sup> The NIH then reviews the petition and the evidence and issues a decision appealable in federal court.<sup>118</sup> Because march-in rights have only been petitioned for three times since 1980 and none of the petitions has been successful, there is significant disagreement over what warrants the exercise of march-in rights.<sup>119</sup> In rejecting the three petitions, the NIH stated that it was uncomfortable using march-in rights to control the prices of pharmaceutical drugs.<sup>120</sup> Still, there is reason to believe that the statute's requirements of "practical application" and availability on "reasonable terms" do authorize the government to exercise march-in rights when prices of therapies are exorbitant.<sup>121</sup> Scholars who support this interpretation look to numerous court decisions in which the phrase "reasonable terms" has been inter-

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chael H. Davis, *Why Don't We Enforce Existing Drug Price Controls? The Unrecognized and Unenforced Reasonable Pricing Requirements Imposed upon Patents Deriving in Whole or in Part from Federally Funded Research*, 75 TUL. L. REV. 631, 640 (2001).

<sup>115</sup> 35 U.S.C. § 203(a); Statement of National Institutes of Health Before Senate Appropriations Subcommittee on Labor, Health and Human Services, Education and Related Agencies, 108th Cong. (2001) (testimony of Maria Freire, Director, Office of Technology Transfer, NIH), available at <http://stemcells.nih.gov/policy/statements/080101freire.asp>.

<sup>116</sup> 35 U.S.C. § 203(a). The Act also provides that march-in rights may be exercised if necessary to "meet requirements for public use specified by Federal regulations" or for failure of the patentee to comply with other sections of the Act. *Id.* § 203(a)(3); Aaron Miller, *Repairing the Bayh-Dole Act: A Proposal for Restoring Non-Profit Access to University Science*, 2005 B.C. INTELL. PROP. & TECH. F. 93001 (Sept. 30, 2005), available at [http://www.bc.edu/bc\\_org/avp/law/st\\_org/iptf/articles/index.html](http://www.bc.edu/bc_org/avp/law/st_org/iptf/articles/index.html).

<sup>117</sup> 35 U.S.C. § 203.

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

<sup>119</sup> Compare Arno & Davis, *supra* note 114, at 649 (arguing that the language of Bayh-Dole could be interpreted to allow the exercise of march-in rights for the purpose of price control), with John H. Raubitschek & Norman J. Latker, *Reasonable Pricing—A New Twist for March-In Rights Under the Bayh-Dole Act*, 22 SANTA CLARA COMPUTER & HIGH TECH L.J. 149, 162 (2005) (asserting that the legislative history of Bayh-Dole does not support an interpretation allowing the exercise of march-in rights to control prices).

<sup>120</sup> Raubitschek & Latker, *supra* note 119, at 157–59.

<sup>121</sup> Arno & Davis, *supra* note 114, at 651.

preted to include prices.<sup>122</sup> The government can also exercise march-in rights if required for the public health; a broad interpretation of this provision might also support price control.<sup>123</sup> Finally, there is a difference between stem cell therapies that promise to cure disease and remedy organ failure and prescription medications meant to treat, but not cure, diseases—it seems far more unjust for economics to deny some individuals access to therapies that will cure them.

To date, the NIH has not had to consider whether the effective denial of life-saving therapies to impoverished populations would warrant the exercise of march-in rights, but the federal government should take the steps described herein to ensure that if and when that question arises in the future, it is not a hypothetical one.<sup>124</sup> For if stem cell research efforts continue to be denied federal funding, those efforts will likely render therapies untouchable to the federal government and to many impoverished individuals and minority groups.<sup>125</sup> Therefore, in order to secure government access and the possibility of price control in the future, federal funds must be provided before stem cell research progresses without them.

#### CONCLUSION

While Fabre and other scholars continue to grapple with the question of what social justice requires in addressing the organ shortage, the government is charged with the difficult task of actually achieving that justice. Unfortunately, minority disadvantage in the organ shortage is largely out of the government's control insofar as their disadvantage is primarily due to biological factors and failure to donate organs in higher numbers. The government is also in a precariously helpless situation from which to assist those who are not poor enough to qualify for Medicaid and not financially able to purchase health insurance, and thus unable to secure an organ transplant. But, in developing stem cell policy, the federal government has an unprecedented opportunity to create equal access to life-saving therapies in the future. Sound stem cell policy requires federal funding conditioned on the use of diverse cell lines by researchers. Such funding, under the Bayh-Dole Act, will simultaneously ensure that the government will have the power to di-

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

<sup>123</sup> Raubitschek & Latker, *supra* note 119, at 167.

<sup>124</sup> *Id.* at 157–59 (explaining that the petitions for the exercise of march-in rights have involved medications used to treat cancer and AIDS).

<sup>125</sup> *See id.* at 167 (explaining that the government might control therapy prices via the other provisions of Bayh-Dole or by eminent domain).

rect stem cell research and to potentially engage in price control of the resulting therapies. Denying federal funds to stem cell research will not only impinge research efforts, but, more importantly, it will impinge the achievement of social justice.