# SHOULD BONE MARROW DONORS BE PAID TO SAVE LIVES? AN ASSESSMENT OF THE LEGAL BAN ON DONOR COMPENSATION AND OTHER OBSTACLES FACING DOMESTIC AND INTERNATIONAL BONE MARROW REGISTRIES

# Brian London\*

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# I. INTRODUCTION

In 1968, the first successful bone marrow took place when an infant with immune deficiency disease received a bone marrow transplant donated by a sibling.<sup>1</sup> Similar successes were soon reported for patients with severe aplastic anemia and acute leukemia.<sup>2</sup> Doctors found that patients with siblings who were born of the same parents each had a twenty-five percent chance of being a suitable donor for each other.<sup>3</sup> However, many patients who could benefit from a transplant could not undergo the procedure because they did not have a sibling with a matching marrow type.<sup>4</sup> As a result, in 1970, a group of doctors in the Netherlands proposed the creation of a European file of unrelated donors to help patients in need of bone marrow.<sup>5</sup>

In 1974, the Nolan Trust became the first registry of unrelated bone marrow donors to routinely provide bone marrow in the United Kingdom and, later, worldwide.<sup>6</sup> In the early 1980s, several local marrow donor registries were created throughout the United States.<sup>7</sup> In 1986, the National Marrow Donor Registry (subsequently named the National Marrow Donor Program, and in 2009 renamed the Be The Match Registry) was created by the U.S. Congress to coordinate recruitment of unrelated bone marrow donors and to facilitate transplants with unrelated donor bone marrow.<sup>8</sup> By 1988, there were eight active registries with 150,000 donors worldwide.<sup>9</sup> An international registry of bone marrow donors, Bone Marrow Donors Worldwide (BMDW), was soon formed.<sup>10</sup>

Today, bone marrow donors and cord blood units,<sup>11</sup> from sixty-four registries and forty-four cord blood banks worldwide, are available to provide life-saving stem cells to patients who need them.<sup>12</sup> Forty-nine percent of the transplants that the Be The Match Registry facilitates involve a U.S. patient receiving cells from an international donor or vice-versa.<sup>13</sup> However, despite a world registry exceeding

<sup>\*</sup> Senior Associate Editor, The Temple International and Comparative Law Journal; J.D. (Expected 2011), The Temple University James E. Beasley School of Law; B.A. in Political Science and Psychology, The University of Pennsylvania.

<sup>1.</sup> SUSAN K. STEWART & JAN SUGAR, BONE MARROW AND BLOOD STEM CELL TRANSPLANTS: A GUIDE FOR PATIENTS 2 (Patrick J. Stiff, M.D. et al. eds., 2002).

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

<sup>3.</sup> Id. at 8.

<sup>4.</sup> Id. at 2.

<sup>5.</sup> J.J. van Rood & M. Oudshoorn, *Eleven Million Donors in Bone Marrow Donors* Worldwide! Time for Reassessment?, 41 BONE MARROW TRANSPLANTATION 1, 1 (2008).

<sup>6.</sup> Id.

<sup>7.</sup> STEWART & SUGAR, supra note 1, at 2.

<sup>8.</sup> STEWART & SUGAR, *supra* note 1, at 2.

<sup>9.</sup> Van Rood & Oudshoorn, *supra* note 5, at 1

<sup>10.</sup> *Id*.

<sup>11.</sup> See infra Part III.

<sup>12.</sup> Welcome to Bone Marrow Donors Worldwide, BONE MARROW DONORS WORLDWIDE, http://www.bmdw.org/ (last visited Oct. 28, 2010) [hereinafter Welcome, BMDW].

<sup>13.</sup> C.K. Hurley et al., Maximizing Optimal Hematopoietic Stem Cell Donor Selection from Registries of Unrelated Adult Volunteers, 61 TISSUE ANTIGENS 415, 416 (2003).

eleven million bone marrow donors, almost two thirds of the patients awaiting a bone marrow transplant do not achieve transplantation.<sup>14</sup> Many of these individuals will die unless they get a transplant from a matching donor.<sup>15</sup> Racial and ethnic minorities have particular difficulty finding a match and ultimately receiving a transplant.<sup>16</sup> As a result, the shortage of acceptable donors is considered to be the primary cause of the failure to transplant patients worldwide.<sup>17</sup> While empirical evidence shows that providing compensation will increase the number of donors who sign up for a registry (and consequently increase a patient's odds of finding a matching donor),<sup>18</sup> compensation for bone marrow donors is illegal under the laws of most countries. On October 28, 2009, the plaintiffs in *Flynn v. Holder*<sup>19</sup> brought suit against the U.S. Attorney General, challenging the legality of the current ban on compensation for bone marrow donors in the U.S.<sup>20</sup>

The purpose of this comment is to examine the obstacles facing domestic and international bone marrow registries and to explore the possibility of offering compensation to potential donors as a means to achieving a higher number of patient-donor matches. This comment will also discuss the legal and ethical issues involved in *Flynn* and how the case may affect the future of donor registries. Part II provides an overview of bone marrow, peripheral blood stem cell, and cord

18. See, e.g., Theodore C. Bergstrom et al., One Chance in a Million: Altruism and the Bone Marrow Registry, 99:4 AM. ECON. REV. 1309, 1325-30 (2009) (describing an economic study that found monetary compensation would increase both the incentive to join a bone marrow registry and the incentive to donate if asked).

<sup>14.</sup> Van Rood & Oudshoorn, *supra* note 5, at 1-2.

<sup>15.</sup> Who We Are - About the National Marrow Donor Program, BE THE MATCH, http://www.marrow.org/ABOUT/Who We Are/index.html (last visited Oct. 25, 2010).

<sup>16.</sup> U.S. GEN. ACCT. OFF., BONE MARROW TRANSPLANTS: DESPITE RECRUITMENT SUCCESS, NAT'L PROGRAM MAY BE UNDERUTILIZED 11 (2002).

<sup>17.</sup> M.B.A. Heemskerk et al., Donor Identification: How to Improve the Search for an Unrelated Haematopoietic Stem Cell Donor. Faster is Better than More!, 35 BONE MARROW TRANSPLANTATION 645, 645 (2005).

<sup>19.</sup> Complaint, Flynn v. Holder, CV 09-07772 (C.D. Cal Oct. 26, 2009).

<sup>20.</sup> Saving Lives: Challenging the Federal Ban on Compensating Bone Marrow Donors, INSTITUTE FOR JUSTICE. http://www.ij.org/index.php?option=com\_content&task=view&id=2899&Itemid=165#\_ednref23 (last visited Feb. 26, 2010). The suit, Flynn v. Holder, was filed in the Los Angeles Division of the U.S. District Court for the Central District of California. Id. This is the first time the ban has ever been the subject of a constitutional challenge. Id. On January 19, 2010, the defendants in Flynn filed a motion to dismiss for lack of subject matter jurisdiction and for failure to state a claim. Notice of Motion and Motion to Dismiss, Flynn v. Holder, CV 09-07772 (C.D. Cal Jan. 19, 2010). The court denied defendant's motion to dismiss for lack of subject matter jurisdiction but granted defendant's motion to dismiss for failure to state a claim, finding that plaintiffs' complaint stated neither an equal protection claim nor a due process claim. Court Order re: Defendant's Motion to Dismiss, Flynn v. Holder, CV 09-07772 (C.D. Cal Mar. 29, 2010). The plaintiffs subsequently appealed the court's ruling and a hearing is scheduled for January 23, 2011. Notice of Appeal, Flynn v. Holder, No. 10-55643 (9th Cir. Apr. 27, 2010); MICHAEL BOO, UPDATE ON DONOR COMPENSATION (June 2010), avaiable at http://www.worldmarrow.org/fileadmin/WorkingGroups Subcommittees/EWG/EWG Donor Re munaration 06-2010.pdf (powerpoint slides presented in Dublin).

blood transplantation. It also examines the history of unrelated donor registries, as well as their operation. Part III discusses the shortage of acceptable donors and other obstacles that domestic and international registries face. Finally, Part IV focuses on financial compensation as a potential solution to the shortage of international donors, while Part V explores the legal, ethical, and moral obstacles that could prevent compensation as a viable solution. Finally, Part VI addresses the issues raised by Flynn v. Holder, how the court will likely rule, and what alternatives may be available if the plaintiffs lose. This comment argues that the ban on bone marrow compensation in the United States and other countries should be repealed in order to assist thousands of patients who will otherwise die while waiting for a matching donor. Unfortunately, as this comment will argue, Flynn is not the solution because the plaintiffs' approach is not likely to prevail. Instead, advocates for marrow donor compensation should look to the legislatures for a solution. However, this change will likely take years to occur. In the meantime, there are legal avenues already available that could make recruitment efforts and the donation process more efficient, so that fewer patients die from severe, but curable, diseases.

# **II. BACKGROUND**

## A. Blood Stem Cell Transplantation

Bone marrow contains blood stem cells that generate most of the body's blood cells.<sup>21</sup> Blood stem cells are necessary to produce white blood cells (leukocytes) that fight infections; red blood cells (erythrocytes) that carry oxygen and remove waste; and platelets, which control excessive bleeding.<sup>22</sup> Because of these vital functions, patients need a stem cell transplant when the blood stem cells in the bone marrow malfunction.<sup>23</sup>

Blood stem cells may malfunction in two instances. First, stem cells may produce "too many defective or immature blood cells."<sup>24</sup> In this case, "the defective or immature blood cells interfere with the production of normal blood cells and may invade other tissues."<sup>25</sup> Alternatively, stem cells may produce too few blood cells.<sup>26</sup>

In either case, a blood stem cell transplant may be necessary.<sup>27</sup> Stem cell transplants have been used to treat patients diagnosed with more than seventy-five life-threatening diseases<sup>28</sup> including leukemia, severe aplastic anemia, Hodgkin's

<sup>21.</sup> STEWART & SUGAR, *supra* note 1, at 6 ("Bone marrow is a spongy tissue found inside bones.").

<sup>22.</sup> Id.

<sup>23.</sup> Id.

<sup>24.</sup> Id.

<sup>25.</sup> Id.

<sup>26.</sup> Id.

<sup>27.</sup> STEWART & SUGAR, supra note 1, at 6.

<sup>28.</sup> Shannon Folger, The Neglect of the Imbilical Cord: Ohio's Failure to Adequately Promote Banking of Umbilical Cord Blood Stem Cells and the Need for New Legislation, 22 J. L.

disease, non-Hodgkin's lymphoma, multiple myeloma, several other blood disorders, and some solid tumor cancers.<sup>29</sup> Each year over 40,000 patients worldwide are diagnosed with leukemia or other disorders require a stem cell transplant.<sup>30</sup>

In a blood stem cell transplant, the patient's malfunctioning bone marrow is "destroyed and healthy new blood cells are infused into the patient's bloodstream."<sup>31</sup> The new stem cells take up residence or engraft in the cavities of the patient's bones and begin to produce normal, healthy blood cells<sup>32</sup> and immune functions, "thus providing the patient with a means to permanent recovery."<sup>33</sup> When a patient receives stem cells from a donor, the procedure is called an allogenic transplant.<sup>34</sup> When a patient acts as his or her own blood stem cell donor the process is called an autologous stem cell transplant.<sup>35</sup>

In order to be a candidate for a stem cell transplant, a patient must have a suitable donor and be in good health.<sup>36</sup> Further, the genetic makeup of donors must closely match the patient or serious complications can arise.<sup>37</sup> Stem cells can be collected through bone marrow transplantation, peripheral blood transplantation, or cord blood stem cell transplantation.<sup>38</sup>

#### 1. Bone Marrow Transplantation

Traditionally, most transplants have been bone marrow transplants due to the high concentration of blood stem cells there.<sup>39</sup> During bone marrow transplantation, "the donor is under anesthesia [and] a needle is inserted into the rear hipbone where a large quantity of bone marrow is located."<sup>40</sup> The bone marrow is extracted with a needle and syringe.<sup>41</sup> After the harvested bone marrow is processed to remove impurities, it is either transported directly to the patient or stored for later use.<sup>42</sup>

http://www.worldmarrow.org/fileadmin/About WMDA/WMDA Broschuere RZ final.pdf.

- 34. STEWART & SUGAR, supra note 1, at 7.
- 35. Id.
- 36. Id.
- 37. Id.

38. Learning About Bone Marrow or Cord Blood Transplants, BE THE MATCH, http://www.marrow.org/PATIENT/Undrstnd\_Disease\_Treat/Undrstnd\_Treat\_Opt/Lrn\_BMT\_Cor d/index.html (last visited Oct. 26, 2010).

39. STEWART & SUGAR, supra note 1, at 6.

- 40. Id. at 32.
- 41. *Id*.
- 42. Id.

<sup>&</sup>amp; HEALTH 137, 144 (2009).

<sup>29.</sup> STEWART & SUGAR, supra note 1, at 1.

<sup>30.</sup> WORLD MARROW DONOR ASSOCIATION, SHARE LIFE, available at

<sup>31.</sup> STEWART & SUGAR, supra note 1, at 7.

<sup>32.</sup> Id.

<sup>33.</sup> Folger, supra note 28, at 144-45.

Usually, marrow and blood are harvested in quantities ranging from one to two quarts.<sup>43</sup> This represents about two percent of a person's bone marrow, which the body can usually replace in four to six weeks.<sup>44</sup> In order to extract sufficient bone marrow for transplantation, the process requires several skin and bone punctures.<sup>45</sup> No surgical incisions or stitches are involved in the procedure.<sup>46</sup>

# 2. Peripheral Blood Stem Cell Transplantation

Peripheral blood stem cell transplantation, which was pioneered in the mid-1980s,<sup>47</sup> has continued to increase.<sup>48</sup> The transplantations are usually performed as outpatient procedures<sup>49</sup> where the donor is injected with a drug called filgrastin (G-CSF) for four to five days.<sup>50</sup> These injections help to move stem cells out of the bone marrow and into the bloodstream where they are more easily collected with an apheresis machine.<sup>51</sup> Once the donor's stem cells enter the bloodstream, the transplantation may begin.<sup>52</sup> During the procedure, a needle is inserted into a vein in each of the patients' arms.<sup>53</sup> The needles are connected to the apheresis machine by tubing.<sup>54</sup> The machine, after removing blood from one arm and separating out the stem cells, returns the remaining blood to the donor through the needle in the other arm.<sup>55</sup> During the procedure, which can last up to six hours,<sup>56</sup> it is common for donors to feel lightheaded, cold, or numb around the lips.<sup>57</sup> Donors may also experience cramping in their hands, bone pain, headaches, fatigue, and nausea.<sup>58</sup>

# 3. Cord Blood Stem Cell Transplantation

The medical community has used umbilical cord blood as another source of stem cells.<sup>59</sup> The blood remaining in the umbilical cord vein and placenta after childbirth is rich in blood stem cells.<sup>60</sup> The first successful performance of a cord blood stem cell transplant using a sibling donor occurred in 1988.<sup>61</sup> Since then,

- 50. Id.
- 51. Id.
- 52. Id.
- 53. Id.
- 54. Id.
- 55. STEWART & SUGAR, *supra* note 1, at 8-9.
- 56. Id. at 8.
- 57. Id. at 9.
- 58. Id.
- 59. Id. at 2.
- 60. Id.

<sup>43.</sup> *Id.* (explaining that, although harvests vary from individual to individual, the estimate reflects the typical harvest which can be expected from an average adult).

<sup>44.</sup> STEWART & SUGAR, supra note 1, at 33.

<sup>45.</sup> Id. at 32.

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

<sup>47.</sup> *Id*.

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

<sup>49.</sup> STEWART & SUGAR, supra note 1, at 8.

<sup>61.</sup> Jennifer L. Schenk, Rethinking FDA's Draft Document on Cord Blood Stem Cell

doctors have performed over 200 cord blood transplants worldwide.<sup>62</sup> Donated cord blood is analyzed and frozen before it is stored at a cord blood bank for future use.<sup>63</sup>

This source has some downsides, though. Cord blood is mostly used in children because it has a limited amount of blood-forming cells and smaller patients need fewer cells.<sup>64</sup> The lack of sufficient cells required for an adult or larger patient sometimes necessitates the combining of two cord blood units for such patients.<sup>65</sup> Another disadvantage of cord blood is that it can only be donated once, in contrast to a bone marrow donor, who can reproduce marrow and donate repeatedly.<sup>66</sup>

However, there are also many advantages to donated cord blood. The match with the patient may not have to be as close as is needed for marrow or peripheral blood transplants.<sup>67</sup> Additionally, cord blood units are available quickly because they are already stored and ready to use.<sup>68</sup> In fact, a cord blood unit can be selected and delivered to the transplant center in less than two weeks,<sup>69</sup> while it can take two months or more to find an unrelated marrow or peripheral blood donor.<sup>70</sup> Finally, studies have found that fewer patients get Graft-versus-Host Disease (GVHD) after a cord blood transplant than after marrow or peripheral blood transplants.<sup>71</sup>

## **B.** Unrelated Donor Registries

#### 1. History

In the early years of blood stem cell transplants, siblings served as the primary donors for patients.<sup>72</sup> Doctors found that patients with siblings with common

65. Id.

Products, 8 MD. J. CONTEMP. LEGAL ISSUES 151, 154 (1997).

<sup>62.</sup> Id. at 155.

<sup>63.</sup> Cord Blood Transplants, BE THE MATCH, http://www.marrow.org/PATIENT/Undrstnd\_Disease\_Treat/Undrstnd\_Treat\_Opt/Lrn\_BMT\_Cor d/Cord\_Blood\_Tx/index.html (last visited Oct. 28, 2010).

<sup>64.</sup> Id.

<sup>66.</sup> Folger, *supra* note 28, at 147.

<sup>67.</sup> Id.

<sup>68.</sup> Id. at 146.

<sup>69.</sup> Umbilical Cord Blood, MARCH OF DIMES, http://www.marchofdimes.com/professionals/14332\_1160.asp (last visited Oct. 28, 2010). 70. Id.

<sup>71.</sup> Folger, *supra* note 28, at 146. GVHD occurs if the donor's white blood cells are not a good genetic match. James L.M. Ferrara, et al., *Graft-versus-host Disease*, 373 THE LANCET 1550, 1550 (2009). The white blood cells perceive the patient's organs and tissues as foreign material that should be destroyed. *Graft-versus-Host Disease*, MEDLINE PLUS, http://www.nlm.nih.gov/medlineplus/ency/article/001309.htm (last visited Oct. 28, 2010). This condition can be life-threatening. *Id.* 

<sup>72.</sup> Hurley et al., supra note 13, at 416.

parents had a 25% chance of being a matching donor.<sup>73</sup> However, only approximately 30% of patients had matching sibling donors.<sup>74</sup> As a result, many patients in need of a transplant could not receive the procedure because they lacked a sibling with a compatible marrow type.<sup>75</sup>

In 1970, a group of doctors in the Netherlands proposed the creation of a file of unrelated European donors to help patients in need of bone marrow.<sup>76</sup> Throughout the early 1970s, unrelated donor transplants produced promising results.<sup>77</sup> However, it was still onerous to match unrelated donors to a specific patient because of the elaborate diversity of the blood stem cell system.<sup>78</sup> In response, organized recruitment of unrelated donors began in 1974.<sup>79</sup> The Anthony Nolan Trust in the United Kingdom was founded by a patient's mother, who sought to find a match for a son afflicted with Wiskott-Aldrich<sup>80</sup> syndrome.<sup>81</sup> Beginning in the United Kingdom and quickly expanding worldwide, the Nolan Trust was the first unrelated bone marrow donor registry.<sup>82</sup> By 1993, the registry had 200,000 volunteer donors.<sup>83</sup>

In 1986, the U.S. Congress created the NMDP (recently renamed the Be The Match registry, or Be The Match) to facilitate recruitment of unrelated bone marrow donors and to increase the potential for more transplants with unrelated donor bone marrow.<sup>84</sup> Today, Be The Match is the world's largest registry of potential blood stem cell donors.<sup>85</sup> While a search of unrelated donors most often begins domestically, searches that fail to identify a donor can expand to foreign registries.<sup>86</sup> Approximately one-third of unrelated transplants worldwide now involve an international donor.<sup>87</sup> Twenty-four percent of the transplants that Be The Match facilitates involve a U.S. patient receiving cells from an international donor or an international patient receiving cells from a U.S. donor.<sup>88</sup>

- 75. STEWART & SUGAR, *supra* note 1, at 2.
- 76. Van Rood & Oudshoorn, supra note 5, at 1.
- 77. Hurley et al., supra note 13, at 416.
- 78. Id.
- 79. Id.

80. "Wiskott-Aldrich syndrome (WAS) is an inherited disorder of the immune system that affects males but not females. It is characterized by recurrent infections, low numbers of circulating blood platelet cells (thrombocytes) and eczema (skin rash)." *Inherited Immunodeficiencies: Wiskott-Aldrich Syndrome*, ST. JUDE CHILDREN'S RESEARCH HOSPITAL, http://www.stjude.org/stjude/v/index.jsp?vgnextoid=dd8c061585f70110VgnVCM1000001e0215 acRCRD&vgnextchannel=bc4fbfe82e118010VgnVCM100000e2015acRCRD (last visited Dec. 1, 2010).

81. Van Rood & Oudshoorn, supra note 5, at 1.

- 83. Hurley et al., supra note 13, at 416.
- 84. STEWART & SUGAR, supra note 1, at 2.
- 85. Hurley et al., supra note 13, at 416.
- 86. *Id*.
- 87. Id.
- 88. Id. (stating that Be the Match has provided 15,550 transplants since 1986. U.S. patients

<sup>73.</sup> STEWART & SUGAR, supra note 1, at 8.

<sup>74.</sup> Hurley et al., supra note 13, at 416.

<sup>82.</sup> Id.

In 1988, Bone Marrow Donors Worldwide (BMDW) was created to establish an international registry of volunteer donors.<sup>89</sup> Today, BMDW coordinates sixtyfour stem cell donor registries from forty-four countries, and forty-three cord blood banks from twenty-six countries.<sup>90</sup> As a result, bone marrow donors and cord blood units are available around the world to provide life-saving stem cells to patients in need of them.<sup>91</sup> Due to the diverse genetic compatibility required for bone marrow transplants, it is virtually impossible to find an unrelated matching donor without going through a donor registry.<sup>92</sup>

#### 2. Be The Match Registry

Be The Match is the largest and most comprehensive registry of potential stem cell transplant donors in the world.<sup>93</sup> Its enrollment currently includes more than four million donors.<sup>94</sup> Be The Match manages a worldwide network consisting of over 400 domestic and international donor centers, recruitment groups, laboratories where tissue is typed, apheresis centers, cord blood banks, collection centers where marrow is harvested, blood sample repositories, and transplant centers.<sup>95</sup> Foreign donor centers combine their registries with Be The Match, resulting in an additional one million donors.<sup>96</sup> Be The Match has also agreed to cooperatively share national registries with thirteen foreign countries.<sup>97</sup> Be The Match's relationships with international donor and transplant centers allows for both foreign-to-U.S. and U.S.-to-foreign donations.<sup>98</sup>

A patient initiates contact with Be The Match when his or her or transplant center or physician performs a free search of the registry for potential stem cell donors and cord blood units.<sup>99</sup> This initial search takes roughly twenty-four hours and generates a list of potentially compatible donors and cord blood units.<sup>100</sup> If the physician and patient elect for a more intensive search for an unrelated donor or cord blood, then a formal search may begin.<sup>101</sup> However, only a physician

93. U.S. GEN. ACCT. OFF., supra note 16, at 1.

- 95. Id.
- 96. Id. at 8.

- 100. Id. at 9,
- 101. Id.

have received 1,700 transplants from international donors and international patients have received 1,946 transplants from U.S. donors).

<sup>89.</sup> *Mission Statement*, BONE MARROW DONORS WORLDWIDE, http://www.bmdw.org/index.php?id=mission (last visited Oct. 28, 2010) [hereinafter *Mission*, BMDW].

<sup>90.</sup> Welcome, BMDW, supra note 12.

<sup>91.</sup> Id.

<sup>92.</sup> Saving Lives, supra note 20.

<sup>94.</sup> Id.

<sup>97.</sup> Id. (stating that "[t]hese countries are Australia, Austria, Canada, the Czech Republic, England, France, Ireland, Italy, Japan, Singapore, Spain, Switzerland, and Taiwan").

<sup>98.</sup> Id.

<sup>99.</sup> U.S. GEN. ACCT. OFF., supra note 16, at 9.

associated with the transplant center in the Be The Match network may perform a formal search.  $^{102}$ 

If a donor match is found, and if all requirements are met, then the marrow is "harvested from the donor at a collection center" or peripheral blood stem cells "are collected from the donor at an apheresis center."<sup>103</sup> Finally, the donated marrow or peripheral blood stem cells are injected into the patient's bloodstream.<sup>104</sup> The entire process usually lasts several months – but can sometimes take over one year.<sup>105</sup>

# 3. Bone Marrow Donors Worldwide

Bone Marrow Donors Worldwide (BMDW), created in 1988 and headquartered in the Netherlands, is a collaborative effort of international stem cell registries and cord blood banks.<sup>106</sup> The World Marrow Donor Association (WMDA), a branch of the BMDW, develops the guidelines for the collection and transfer of blood stem cells and regulates the ethical, technical, medical, and financial aspects of each exchange.<sup>107</sup> The BMDW covers an expansive network of sixty-four stem cell donor registries within forty-four countries and forty-three cord blood banks in twenty-six countries.<sup>108</sup> The database currently includes over eleven million volunteer stem cell donors from around the world.<sup>109</sup>

BMDW's stated main goal is to collect the stem cells and cord blood units of volunteer donors and systematize their distribution worldwide.<sup>110</sup> BMDW's other goals include: maximizing the chance of finding a donor, providing advanced search programs to identify partially matched stem cell donors or cord blood units, and facilitating improvement in family search strategies. BMDW also provides informational data about various registries and DNA typed donors.<sup>111</sup>

To become a candidate for stem cell transplantation through BMDW, a recipient must be a patient at a hospital (transplant center) that performs transplants of unrelated stem cells.<sup>112</sup> The transplant center may then begin an unrelated donor search by contacting the national "hub" organization.<sup>113</sup> The hub organization then

105. U.S. GEN. ACCT. OFF., supra note 16, at 10.

106. Mission, BMDW, supra note 89.

113. Id.

<sup>102.</sup> Id.

<sup>103.</sup> Id. at 10.

<sup>104.</sup> Id.

<sup>107.</sup> T. Egeland et al., Donor and Liability Insurance of Donor Registries, Donor Centers, and Collection Centers – Recommendations, 33 BONE MARROW TRANSPLANTATION 467, 467 (2004).

<sup>108.</sup> Mission, BMDW, supra note 89.

<sup>109.</sup> Van Rood & Oudshoorn, *supra* note 5, at 1.

<sup>110.</sup> Mission, BMDW, supra note 89.

<sup>111.</sup> *Id*.

<sup>112.</sup> Information for Patients, BONE MARROW DONORS WORLDWIDE, http://www.bmdw.org/index.php?id=for\_patients (last visited Oct. 28, 2010) [hereinafter Information, BMDW].

scans the BMDW database and coordinates any subsequent procedures.<sup>114</sup> If no national hub exists, then the transplant center directly contacts BMDW for a donor search.<sup>115</sup>

If a prospective donor is found, the transplant center is obligated to perform "Confirmatory Testing,"<sup>116</sup> where the stem cell donor's registry initiates donor counseling and collects the donor's blood samples.<sup>117</sup> If the confirmatory tests signal donor-recipient compatibility, then the transplant center may formally request stem cells.<sup>118</sup> If the prospective donor is inclined to donate, he or she will undergo more intensive counseling and a physical examination.<sup>119</sup> The donor can then donate stem cells in his or her own country and his stem cells will be sent to the patient's transplant center for transplantation.<sup>120</sup> The median duration of time between the start of a donor search and transplantation is 4.4 months.<sup>121</sup>

# **III.** THE PROBLEM

Due to an expansion in the international donor pool between 1987 and 2000, the number of patients receiving transplants doubled.<sup>122</sup> However, despite a world registry exceeding eleven million volunteer stem cell donors,<sup>123</sup> today seventy percent of patients awaiting a bone marrow transplant do not find a matching donor.<sup>124</sup> Each year in the United States alone, approximately 10,000 to 15,000 patients needing a bone marrow transplant are unable to find a donor.<sup>125</sup> Worldwide, there are an estimated 120,000 people in need of a stem cell transplant.<sup>126</sup> In many cases, patients who cannot find a donor will die.

This inability to provide bone marrow transplants is a result of the shortage of volunteer donors.<sup>127</sup> Only two to six percent of the U.S. population is on the Be The Match donor registry list.<sup>128</sup> Consequently, twenty percent of Caucasian

122. Id. at 650.

123. Van Rood & Oudshoorn, supra note 5, at 1.

124. Kimberly J. Cogdell, Saving the Leftovers: Models for Banking Cord Blood Stem Cells, 39 U. MEM. L. REV. 229, 242 (2009).

128. Bergstrom et al., *supra* note 18, at 1310 (stating that the registry contains 2-3% of the

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

<sup>115.</sup> *Id*.

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

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

<sup>118.</sup> Information, BMDW, supra note 112.

<sup>119.</sup> Id.

<sup>120.</sup> Id.

<sup>121.</sup> Heemskerk et al., supra note 17, at 648-49.

<sup>125.</sup> Schenk, supra note 61, at 153.

<sup>126.</sup> WORLD MARROW DONOR ASSOCIATION, supra note 30.

<sup>127.</sup> Heemskerk et al., *supra* note 17, at 645; Jennifer Goodwin, *Shortage of Transplant Organs Spurs Proposals But No Solution*, MEDICINENET.COM, http://www.medicinenet.com/script/main/art.asp?articlekey=116597 (last visited Oct. 28, 2010) (discussing generally the increasing disparity between the supply of organ donors and the demand of organ recipients).

patients in the U.S. who need a transplant are unable to find an unrelated matching donor.<sup>129</sup> The shortage of donors is even more detrimental to patients from racially and ethnically diverse communities.<sup>130</sup> Due to unique human leukocyte antigens (HLA) phenotypes, their genetic diversity makes locating a matching donor similar to "finding the proverbial needle in a haystack."<sup>131</sup> The number of patients of diverse racial or ethnic background unable to find a suitable donor can be as high as seventy-five percent.<sup>132</sup> "Specifically, 'American Indian and Alaska Native, Asian, Black and African American, Hispanic and Latino, Native Hawaiian and Other Pacific Islander, and multiple-race patients face a greater challenge in finding matched donors or cord blood than [Caucasian] patients."<sup>133</sup> Similarly, in Europe, patients of non-Northwest European origin face a much greater challenge in finding a donor than patients of Northwest European origin.<sup>134</sup>

African Americans in particular have more genetic diversity than any other race.<sup>135</sup> As a result, they are significantly disadvantaged in the search for a matching donor.<sup>136</sup> Not only do they have smaller numbers and lower levels of representation on registries, but their rare HLA combinations make the matching itself more difficult.<sup>137</sup> For example, while approximately eighty percent of Caucasian patients in need of a bone marrow transplant are able to find a matching donor through the registry,<sup>138</sup> less than thirty percent of African American patients are successful.<sup>139</sup> Furthermore, African Americans seeking a stem cell donor are unlikely to find one from an African registry.<sup>140</sup> In fact, South Africa is the only country in Africa with a registry.<sup>141</sup> South Africa's registry has approximately 60,000 volunteer donors, the majority of whom are Caucasian.<sup>142</sup> As a result, thousands of African Americans who are diagnosed with life-threatening blood

131. Saving Lives, supra note 20.

132. WORLD MARROW DONOR ASSOCIATION, *supra* note 30.

133. Cogdell, *supra* note 124, at 242 (quoting *The Need for Donors*, NATIONAL MARROW DONOR PROGRAM, http://www.marrow.org/ABOUT/NeedforDonors/index.html (last visited Oct. 28, 2010)).

134. Heemskerk, *supra* note 17, at 650-51.

135. *Why Race Matters*, AFR. AM. MARROW CONNECTION, http://blackbonemarrow.com/facts\_and\_statistics.html (last visited Oct. 28, 2010).

142. Id.

U.S. Caucasian, African-American and Hispanic populations and 6% Asian-American population).

<sup>129.</sup> Cogdell, supra note 124, at 242.

<sup>130.</sup> Dennis L. Confer, *The National Marrow Donor Program: Meeting the Needs of the Medically Underserved*, 7TH BIENNIAL SYMPOSIUM ON MINORITIES, THE MEDICALLY UNDERSERVED & CANCER 274, 274-75 (2000).

<sup>136.</sup> Marianne Engelman Lado, Unfinished Agenda: The Need for Civil Rights Litigation to Address Race Discrimination and Inequalities in Health Care Delivery, 6 TEX. F. ON C.L. & C.R. 1, 8-9 (2001).

<sup>137.</sup> U.S. GEN. ACCT. OFF., *supra* note 16, at 11.

<sup>138.</sup> Cogdell, supra note 124, at 242.

<sup>139.</sup> Id.

<sup>140.</sup> Bergstrom, supra note 18, at 1327.

<sup>141.</sup> Id.

diseases will continue to be deprived of life saving marrow transplants unless stronger incentives are provided to attract a sufficient number of African American registrants.<sup>143</sup>

Besides the shortage of donors, there are other impediments in the donor search process that prevent patients from reaching transplantation. First, the overall search process is too slow.<sup>144</sup> As a result, by the time some patients find a matching donor, their clinical condition has deteriorated to a point that stem cell transplantation is no longer an option.<sup>145</sup> Additionally, procedures used at individual donor centers may detrimentally impact donor availability.<sup>146</sup> For instance, inadequate medical screening, incomplete education, failure to provide a pressure-free environment, and inadequate collection of demographic information may negatively affect donor recruitment.<sup>147</sup> Moreover, the route of contact (for example, timing of phone calls) and the cultural sensitivity used (for example, language spoken) may affect whether matching donors opt to defer when called upon to donate by the registries.<sup>148</sup>

## IV. A PROPOSED SOLUTION: IF YOU PAY THEM, THEY WILL COME

The existing system of bone marrow donations is based on altruism. Neither bone marrow registrants nor donors are paid; in fact, many face significant costs in time and money. For instance, those who join the Be The Match registry must pay \$52 for a tissue-typing kit.<sup>149</sup> Altruism does not provide a strong enough incentive to fill the demand for matching bone marrow donors. In the United States alone, 1,000 people die annually because the supply of matching donors does not meet the demand for those in need of a transplant.<sup>150</sup>

As a result, the idea of compensation for donors has been frequently introduced.<sup>151</sup> This proposal is largely based on common sense: paying people for a service increases the supply of that service. Aside from common sense, empirical evidence in the domain of bone marrow transplantation supports this claim. One economic study found that monetary compensation would increase both the incentive to join a bone marrow registry and the incentive to donate if asked.<sup>152</sup>

<sup>143.</sup> Id.

<sup>144.</sup> Heemskerk, supra note 17, at 651.

<sup>145.</sup> *Id*.

<sup>146.</sup> Confer, *supra* note 129, at 277.

<sup>147.</sup> Id.

<sup>148.</sup> Confer, supra note 129, at 277.

<sup>149.</sup> Bergstrom, *supra* note 18, at 1326 (explaining that when the kit arrives, the registrant takes a swab of his or her cheek cells and mails the swab to the registry for testing).

<sup>150.</sup> Cancer Patients Sue U.S. Attorney General in Bid to Save Lives, INSTITUTE FOR JUSTICE, http://www.ij.org/index.php?option=com\_content&task=view&id=2901&Itemid=165 (last visited Oct. 28, 2010) [hereinafter Cancer Patients].

<sup>151.</sup> See, e.g., *id.* (discussing the Institute for Justice's suit against the U.S. Attorney General to end a ban on offering compensation to bone marrow donors).

<sup>152.</sup> Bergstrom, supra note 18, at 1324-25.

Thus, payments to donors would increase the donor pool, while also decreasing the rate of donor deferral among those registrants.<sup>153</sup> A similar study on organ donation found that monetary incentives would increase the supply of organs available for transplantation and decrease the number of individuals who die while on a waiting list.<sup>154</sup> Since compensation would attract those who have the greatest need for it, a large proportion of new participants in the registries would, in theory, come from poorer groups of society.<sup>155</sup> In the United States, this increased donor pool would particularly help African Americans and Hispanic Americans because these communities are overrepresented among the poor, but underrepresented in bone marrow registries.<sup>156</sup> The development of a legal mechanism for donor compensation is therefore the *only* likely means of effectively eliminating the demand for human organs.<sup>157</sup>

Additionally, countries that permit compensation or rewards for donated biological material have proven more successful in increasing donation than those that do not.<sup>158</sup> For instance, the United States is one of the few countries allowing plasma donors to be paid; as a result, it supplies more than half of the world's plasma.<sup>159</sup> Many countries that prohibit compensation do not collect enough plasma and consequently rely on American plasma or plasma products.<sup>160</sup> Iran is simultaneously the only country in the world where the sale of kidneys is legal and the only country without a shortage of kidney donors;<sup>161</sup> in fact, the supply of available kidneys actually exceeds demand in Iran.<sup>162</sup> By contrast, Canada banned the sale of sperm and eggs in 2004, resulting in both a shortage of those materials and the emergence of a black market.<sup>163</sup> As these examples demonstrate, legal compensation for biological materials is a proven and effective means of increasing supply.

- 162. *Id*.
- 163. *Id*.

<sup>153.</sup> Id.

<sup>154.</sup> Gary S. Becker & Julio Jorge Elias, *Introducing Incentives in the Market for Live and Cadaveric Organ Donations*, 21 J. ECON. PERSP. 3, 3 (2007).

<sup>155.</sup> Mark F. Anderson, *Encouraging Bone Marrow Transplants from Unrelated Donors: Some Proposed Solutions to a Pressing Social Problem*, 54 U. PITT. L. REV. 477, 490 (1993).

<sup>156.</sup> Id.

<sup>157.</sup> Transcript of Debate at 14, *We Should Legalize the Market for Human Organs* (May 13, 2008), http://intelligencesquaredus.org/wp-content/uploads/OrganMarkets-051308.pdf (last visited Oct. 28, 2010) [hereinafter Legalize].

<sup>158.</sup> Video, Liberating Bone Marrow Donors, CATO INSTITUTE (Jan. 19, 2010), http://www.cato.org/event.php?eventid=6833.

<sup>159.</sup> Id.

<sup>160.</sup> *Id*.

<sup>161.</sup> *Id.* 

# V. OBSTACLES TO COMPENSATION

#### A. Legal Problems

The use of monetary incentives to encourage bone marrow donations is, however, illegal in the United States and throughout most of the world. In the United States, organ donation is regulated in part by the Uniform Anatomical Gift Act (UAGA).<sup>164</sup> The UAGA was drafted in 1968 by the National Conference of Commissioners on Uniform State Laws to provide a "legal mechanism whereby persons could designate that their organs could be used for transplant upon death."<sup>165</sup> Although the UAGA did not explicitly ban the sale of human organs, the act repeatedly referred to donated bodies and body parts as "gifts," and the language of the UAGA was widely interpreted to imply that the sale of human organs was illegal.<sup>166</sup>

However, the debate surrounding the legality of selling human organs continued until 1983. At that time, H. Barry Jacobs, a physician, proposed the idea of an international brokerage company to commission kidneys from people living either in the Third World or in poverty in the United States "for whatever price would induce them to sell their organs." <sup>167</sup> Jacobs then suggested negotiating "their acquisition, for a fee, by Americans who could afford to purchase them."<sup>168</sup> The American medical community immediately condemned this proposal, and, in response, Congress passed the National Organ Transplant Act (NOTA or the Act), explicitly prohibiting the sale of human organs.<sup>169</sup>

NOTA provides that it "shall be unlawful for any person to knowingly acquire, receive, or otherwise transfer any human organ for valuable consideration for use in human transplantation if the transfer affects interstate commerce."<sup>170</sup> The statute's definition of "human organ" encompasses the kidney, liver, heart, lung, pancreas, cornea, eye, bone, skin, and bone marrow.<sup>171</sup> Violators of the Act are subject to a fine "of not more than \$50,000" or imprisonment for "not more than five years, or both."<sup>172</sup> While the language of NOTA is limited to transfers that

169. 42 U.S.C. § 274e(a) (2006).

170. *Id.* Section 274e(c)(2) provides that "valuable consideration" does not include "the reasonable payments associated with the removal, transportation, implantation, processing, preservation, quality control, and store of a human organ or the expenses of travel, housing, and lost wages incurred by the donor of a human organ in connection with the donation of the organ." 42 U.S.C. § 274e(c)(2) (2006).

171. 42 U.S.C. § 274e(c) (2006).

172. Id.

<sup>164.</sup> UNIF. ANATOMICAL GIFT ACT (2006), available at http://www.anatomicalgiftact.org/DesktopDefault.aspx?tabindex=1&tabid=63; see also Carson Holloway, Monetary Incentives for Organ Donation, in ORGAN AND TISSUE DONATION: ETHICAL, LEGAL AND POLICY ISSUES 143, 144 (Bethany Spielman, ed.1996).

<sup>165.</sup> Holloway, supra note 164, at 144.

<sup>166.</sup> Id.

<sup>167.</sup> Id.

<sup>168.</sup> Id.

affect interstate commerce, intrastate sales would most likely also be subject to congressional regulation due to the Supreme Court's expansive interpretation of the commerce clause.<sup>173</sup>

The World Health Organization (WHO) has also issued a resolution condemning the sale of organs.<sup>174</sup> By 1989, over twenty nations had instituted legal or political provisions against trafficking in organs.<sup>175</sup> The United Kingdom made the sale of organs illegal in 1989 with the Human Organ Transplant Act, which was superseded by the Human Tissue Act in 2004.<sup>176</sup> Those in the United Kingdom who buy or sell organs, including bone marrow, are subject to up to three years imprisonment and/or a fine.<sup>177</sup> Even those who advertise the sale of organs may be subject to imprisonment for up to fifty-one weeks and/or a fine.<sup>178</sup> India banned the sale of organs in 1994<sup>179</sup> and China passed provisions against commerce in organs last year.<sup>180</sup> Furthermore, a recent study conducted by the United Nations and the Council of Europe calls for an international treaty to ban trafficking of human organs, cells, and tissues worldwide.<sup>181</sup>

#### **B.** Moral and Ethical Problems

One common ethical argument against compensation for organ donation is that payment is "immoral" because it involves the "commodification" of body parts.<sup>182</sup> For example, Dr. Francis Delmonico, a transplant surgeon at Massachusetts General Hospital, argues that "any attempt to assign a monetary value to the human body or its body parts, even in the hope of increasing organ supply, diminishes human dignity and devalues the very human life we seek to save."<sup>183</sup> Others similarly argue that some things, like organs, should never be sold because doing so irreparably harms the way people think about their bodies, their

177. Human Tissue Act, 2004, c. 30 (Eng.), *available at* http://www.opsi.gov.uk/acts/acts/2004/ukpga\_20040030\_en\_4#pt2-pb6-11g33.

178. Id.

180. Video, supra note 158.

181. UN Study Calls for International Ban on Organ Trafficking, EXPRESSINDIA, http://www.expressindia.com/latest-news/UN-study-calls-for-international-ban-on-organtrafficking/528946/ (last visited Oct. 28, 2010).

182. Becker & Elias, supra note 153, at 25.

183. Carey Goldberg, *Fiscal Incentive Weighed to Boost U.S. Organ Supply*, BOSTON GLOBE (Oct. 8, 2003) *available at* http://www.boston.com/news/local/articles/2003/10/08/ fiscal\_incentive\_weighed\_to\_boost\_us\_organ\_supply/.

<sup>173.</sup> See, e.g., U.S. v. Lopez, 514 U.S. 549, 558-59 (1995) (Commerce Clause authority extends to activities that implicate: 1) channels of interstate commerce; or 2) instrumentalities of interstate commerce; or 3) activities having a substantial relationship to interstate commerce).

<sup>174.</sup> Holloway, supra note 164, at 146.

<sup>175.</sup> Id.

<sup>176.</sup> Id.

<sup>179.</sup> Transplantation of Human Organs Act, No. 42 of 1994, INDIA CODE (1994), *available at* http://www.commonlii.org/in/legis/num\_act/tohoa1994339/. Those who violate the act are subject to a sentence of imprisonment for a term of less than two years and a fine less than ten thousand rupees. *Id.* 

lives, and their relationships.<sup>184</sup> The implication is that this would have a general spill-over effect on society as a whole, diminishing perceptions of the value of human life.<sup>185</sup> According to this line of reasoning, the lives saved by an increased donor pool will not justify these effects.<sup>186</sup>

Another argument often raised against paying for bodily materials is that it will reduce the number of people who donate for altruistic reasons.<sup>187</sup> This argument holds that those who donate for altruistic reasons may actually be turned off by financial incentives.<sup>188</sup> Opponents of organ compensation are also concerned with deception; payments could "undermine the integrity of the donor pool" by incentivizing donors to conceal flaws in their medical histories, which might otherwise reduce or eliminate the demand for their stem cells.<sup>189</sup> Such incentives are absent when donations are motivated purely by altruism.

Additionally, opponents argue that a market for organs may exploit the poor. Individuals are particularly vulnerable to exploitation when their bodies or body parts are being sold; desperate persons may take unacceptable risks for compensation.<sup>190</sup> A poor patient with particular medical risks may donate because she needs the money, even though she is knowingly jeopardizing her own health by doing so.<sup>191</sup> Additionally, compensation could create an inequitable system in which only the wealthy possess the requisite finances to buy bodily materials.<sup>192</sup> According to this argument, an organ market must not be introduced into a world with such disparities in wealth and advantage.<sup>193</sup>

Finally, some argue that compensating donors from other countries would endanger would-be donors because of informed consent issues.<sup>194</sup> The fear, according to this argument, is that language and cultural differences may result in citizens of the Third World signing up for bone marrow registries without truly understanding what that obligation entails.<sup>195</sup> If such barriers exist, it is questionable whether these individuals can truly give informed consent.<sup>196</sup>

<sup>184.</sup> Sherry F. Colb, Suit Challenges Federal Ban on Compensation for Bone Marrow Donors, FINDLAW, Nov. 9, 2009, http://writ.news.findlaw.com/colb/20091109.html.

<sup>185.</sup> Id.

<sup>186.</sup> *Id*.

<sup>187.</sup> Becker & Elias, *supra* note 153, at 27.

<sup>188.</sup> P.A. Clark, *Financial Incentives for Cadaveric Organ Donation: An Ethical Analysis*, 4 INTERNET J. LAW, HEALTHCARE & ETHICS (2006), http://www.ispub.com/journal/the\_internet\_journal\_of\_law\_healthcare\_and\_ethics/volume\_4\_nu mber\_1\_25/article/financial\_incentives\_for\_cadaveric\_organ\_donation\_an\_ethical\_analysis.html (last visited Dec. 1, 2010).

<sup>189.</sup> Goldberg, supra note 183.

<sup>190.</sup> Colb, *supra* note 184.

<sup>191.</sup> Id.

<sup>192.</sup> Legalize, supra note 15, at 28.

<sup>193.</sup> Id. at 11.

<sup>194.</sup> Video, supra note 158.

<sup>195.</sup> Id.

<sup>196.</sup> Id.

# VI. *FLYNN V. HOLDER* – A DIRECT CHALLENGE OF NOTA'S BAN ON COMPENSATION FOR BONE MARROW DONORS

# A. Background

On October 28, 2009, MoreMarrowDonors.org (MMD) and its co-plaintiffs joined the Institute for Justice to bring a lawsuit against the U.S. Attorney General, challenging NOTA's ban on compensation for bone marrow donors.<sup>197</sup> MMD is a California nonprofit corporation seeking to use financial incentives to reward the most needed bone marrow donors, particular minorities, with a \$3,000 scholarship, housing allowance, or gift to the charity of the donor's choice.<sup>198</sup> MMD expects financial incentives to increase the number of people with rare marrow-cell types, such as minorities, who sign up for the national registry; to increase the number of people who stay in touch with the registry; and increase the number of completed donations.<sup>199</sup> MMD intends to provide the awards through funds raised from thirdparty philanthropists and to set compensation at a fixed amount.<sup>200</sup> There will be no negotiations regarding the fixed compensation with any donor.<sup>201</sup> Furthermore, the corporation will have no involvement in the transplant process and the matching process will remain anonymous and random.<sup>202</sup> Finally, to receive a reward for donating, potential donors must (1) register with MMD and sign up on the Be The Match registry; (2) indicate that they have informed the presiding transplant doctor of the patient's intention to collect compensation after donating; (3) promise to be honest about their own medical history; and (4) provide signed proof from a medical professional that the donation occurred.<sup>203</sup>

However, MMD's plan is currently illegal under federal law. NOTA prevents MMD from offering incentives for marrow-cell donation, advertising the availability of incentives, and soliciting funds to be used as incentives for donation.<sup>204</sup> Consequently, carrying out any of these activities would risk serious legal consequences for doctors, nurses, donors, patients, staff and financial supporters of MMD; each could face up to five years in federal prison.<sup>205</sup> The U.S. Attorney General has been clear that he will enforce NOTA through investigation, arrest, and prosecution if MMD implements its proposed nationwide pilot program.<sup>206</sup> As a result, MMD and its co-plaintiffs sued the U.S. Attorney General to end the ban on compensation for bone marrow donors.<sup>207</sup>

- 199. Complaint, supra note 19, at 27.
- 200. Id. at 28.
- 201. Id.
- 202. Id.
- 203. Id. at 28-29.
- 204. Id. at 44.
- 205. 42 U.S.C. § 274e(b) (2006).
- 206. Complaint, supra note 19, at 32.
- 207. Id. at 50-51.

<sup>197.</sup> Complaint, supra note 19, at 1.

<sup>198.</sup> Id. at 27.

MMD has been joined in the lawsuit by Doreen Flynn, a mother of three daughters with Fanconi anemia, a rare and deadly genetic disorder.<sup>208</sup> Each daughter will eventually need a bone marrow transplant to survive, though Flynn's oldest daughter will need one soon because her blood counts are already declining.<sup>209</sup> Flynn is also a member of plaintiff MMD.<sup>210</sup> NOTA prevents her from taking concrete steps to ensure that matched and willing donors are available when her three daughters need transplants.<sup>211</sup> These steps would include raising money for and promoting MMD's financial incentives program.<sup>212</sup>

John Wagner, M.D., an internationally recognized expert in bone marrow transplantation, is also a plaintiff.<sup>213</sup> Dr. Wagner has treated over 2,000 patients who were in need of a bone marrow transplant.<sup>214</sup> Of these patients, at least twenty percent have died because they were unable to find a matching donor.<sup>215</sup> Moreover, Dr. Wagner has been forced hundreds of times to use bone marrow from imperfectly matching donors.<sup>216</sup> These partially mismatched transplants routinely cause severe and even fatal medical complications for his patients.<sup>217</sup> If the current shortage of donors continues, his patients will continue to die or suffer severe medical complications because they cannot find a properly matching donor.<sup>218</sup>

Dr. Wagner believes that providing marrow-cell donors with financial incentives could make a serious impact on the persistent shortage of marrow-cell donors, especially for minorities and other patients with rare marrow-cell types.<sup>219</sup> He seeks to work with plaintiff MMD to offer financial incentives to potential marrow-cell donors under appropriate ethical and medical strictures and/or work with outside groups offering such financial incentives; however, this would violate current federal law as codified in NOTA.<sup>220</sup> Dr. Wagner argues that, but for NOTA's prohibition against providing financial incentives to potential donors, he could have saved the lives of more of his past patients.<sup>221</sup> Additionally, if the ban is repealed, he will be able to save the lives of more of his current and future patients.<sup>222</sup>

Kumud Majumder is also a plaintiff in the suit against the U.S. Attorney General. Kumud and his family are of Indian descent and Kumud's eleven year

- 212. Complaint, supra note 19, at 45.
- 213. Id. at 5-6.
- 214. Id. at 6.
- 215. Id. at 7.
- 216. Id.
- 217. Id.
- 218. Complaint, supra note 19, at 7.
- 219. Id. at 36.
- 220. Id. at 37-38.
- 221. Id. at 38-39.

<sup>208.</sup> Id. at 5.

<sup>209.</sup> Id.

<sup>210.</sup> Id. at 13.

<sup>211.</sup> Id. at 45.

<sup>222.</sup> Id.

old son, Arya, has acute lymphoblastic leukemia (ALL).<sup>223</sup> Arya was treated with chemotherapy, but relapsed in December 2008.<sup>224</sup> Although he needed a bone marrow transplant to survive, none of his family members were a match.<sup>225</sup> His doctors searched the Be The Match registry, but found no match.<sup>226</sup> Arya was forced to undergo a transplant from an unrelated donor that was his next best match.<sup>227</sup> If complications from the first transplant neccessitate a second one, a more suitable donor will need to be found.<sup>228</sup> Similarly, plaintiff Mark Hachey is a father of a multi-racial son with ALL.<sup>229</sup> His son also had a mismatched transplant over a year ago because there was no matching donor; he continues to experience potentially life-threatening complications as a result.<sup>230</sup> Under current federal law, both plaintiffs are prohibited from taking concrete steps to ensure that matched and willing donors will be available when transplants are needed.<sup>231</sup> These steps would include raising money for and promoting MMD's financial incentives program.<sup>232</sup>

Akiim DeShay is on the board of MMD and also runs a website called BlackBoneMarrow.com to advocate for African American bone marrow issues.<sup>233</sup> As an African American leukemia survivor who received a bone marrow transplant from his sister in 2004,<sup>234</sup> DeShay continues to suffer from complications associated with the transplant and nearly died in February 2009.<sup>235</sup> As a result of these serious complications, he cannot work.<sup>236</sup> Under NOTA, he too is prohibited from implementing the objectives of MMD.<sup>237</sup> Additionally, NOTA prohibits him from raising money for MMD through the activist network he created via his website. This money would go to a financial incentive program for marrow-cell donors.<sup>238</sup>

Finally, Mike Harmel is also on the board of MMD and joins this suit as a plaintiff.<sup>239</sup> Harmel is a lymphoma patient who recently underwent a transplant of his own stored marrow cells.<sup>240</sup> He is currently undergoing continuous medical observation to determine if his autologous technique will work or whether he will

- 232. Id.
- 233. Id. at 12; Cancer Patients, supra note 149.
- 234. Complaint, supra note 19, at 10-11.
- 235. Id. at 11.
- 236. Id.
- 237. *Id.* at 45.
- 238. Id.
- 239. Complaint, supra note 19, at 12.
- 240. Id. at 12-13.

<sup>223.</sup> Id. at 8; see also Cancer Patients, supra note 149.

<sup>224.</sup> Complaint, supra note 19, at 8.

<sup>225.</sup> Id.

<sup>226.</sup> Id. at 8-9.

<sup>227.</sup> Id. at 9.

<sup>228.</sup> Complaint, supra note 19, at 9.

<sup>229.</sup> Id.

<sup>230.</sup> Id.

<sup>231.</sup> Id. at 47.

eventually require a bone marrow transplant.<sup>241</sup> NOTA prohibits Hamel from implementing MMD's financial incentives plan and using the network he created through his blog to raise funds as part of a financial incentives program for marrow-cell donors.<sup>242</sup> Additionally, he is harmed because he may need a transplant in the future and desires a financial incentives program that will maximize his chances of finding an available matching and willing donor.<sup>243</sup>

# B. The Claims: NOTA Violates the U.S. Constitution

The plaintiffs in *Flynn* claim that NOTA's criminal prohibition of compensation for marrow donors violates their equal protection rights under the Fifth Amendment in two ways.<sup>244</sup> First, the plaintiffs claim that the statute arbitrarily and irrationally treats dissimilar things similarly by treating renewable bone marrow cells like nonrenewable solid organs such as kidneys, even though marrow cells are neither organs nor tissues, but rather completely renewable loose cells.<sup>245</sup> Second, the plaintiffs claim that the statute arbitrarily and irrationally treats similarly by prohibiting compensation for marrow cells, but not prohibiting compensation for any other renewable or inexhaustible cells, like blood and sperm.<sup>246</sup> In fact, the statute allows compensation for ova despite the fact that ova are not a renewable resource.<sup>247</sup>

Additionally, the plaintiffs argue that the statute violates their substantive due process right to participate in safe, accepted, lifesaving medical treatment under the Due Process Clause of the Fifth Amendment.<sup>248</sup> The plaintiffs seek to exercise that liberty interest by offering strategic financial incentives to marrow cell donors, but cannot because NOTA arbitrarily and irrationally defines marrow cells as "human organs" and, consequently, criminalizes the proposed program as an act of organ selling.<sup>249</sup> The plaintiffs argue that the government's prohibition of the pilot program does not rationally advance any legitimate government interest and, thus, should be struck down because it does not satisfy due process requirements.<sup>250</sup>

<sup>241.</sup> Id. at 13.

<sup>242.</sup> Id. at 46.

<sup>243.</sup> Id.

<sup>244.</sup> Id. at 48-49.

<sup>245.</sup> Complaint, supra note 19, at 48.

<sup>246.</sup> Complaint, *supra* note 19, at 48-49. For instance, in striking down assessments on real property by a West Virginia county, the Supreme Court ruled that the assessments violated the Equal Protection Clause because they arbitrarily subjected the taxpayer to taxes not imposed on others of the same class. Allegheny Pittsburgh Coal Co. v. County Comm'n, 488 U.S. 336, 345-46 (1989); *see also* Romer v. Evans, 517 U.S. 620, 632 (1996) (holding that an amendment that prohibited protection of homosexual persons from discrimination violated the Equal Protection Clause of the Fourteenth Amendment because it imposed a broad and differentiated disability on a single named group and lacked a "rational relationship to legitimate state interest").

<sup>247.</sup> Saving Lives, supra note 20.

<sup>248.</sup> Complaint, supra note 19, at 3.

<sup>249.</sup> Id. at 49-50.

<sup>250.</sup> Id. at 50. For example, in striking down a Texas statute making it a crime for two

They also point out that NOTA's ban on organ selling was motivated by concerns about the invasive nature of organ surgery, the potential loss of an irreplaceable body part, and the possibility of an open market where organs would flow from the poor to the rich.<sup>251</sup> However, none of these governmental interests applies to bone marrow donations, according to the plaintiffs.<sup>252</sup> Donating marrow is not as dangerous or invasive as donating a kidney.<sup>253</sup> In reality, the risks associated with a bone marrow harvest for donors are the same risks associated with undergoing general anesthesia for any surgical procedure.<sup>254</sup> Serious complications such as heart attacks or strokes are rare<sup>255</sup> and more than ninety-five percent of donors experience only temporary minor complaints.<sup>256</sup>

Additionally, a kidney donor may have some problems living the rest of his or her life with only one kidney.<sup>257</sup> Thus, it is reasonable to worry about significant dangers that may occur when poor members of society knowingly jeopardize their health to donate a kidney solely because they are in desperate need of money. However, the plaintiffs contend that the same concerns do not exist in the marrow donation context because marrow cells are renewable. During a bone marrow transplant, the donor usually loses just one or two quarts of marrow and blood, which is only about two percent of a person's bone marrow and is usually replaced in less than four weeks.<sup>258</sup>

Moreover, the plaintiffs claim that the fear of exploitation is not applicable in the case of bone marrow.<sup>259</sup> While a solid organ like a kidney can be sold to the highest bidder in the marketplace, there can be no "market" in marrow cells<sup>260</sup> because the close genetic match required for a marrow cell transplant makes an open market impossible.<sup>261</sup> For instance, the probability that two randomly selected white Americans are of matching type is less than one in ten thousand, while about twenty percent of white Americans are of types that are shared by less than one in a million.<sup>262</sup> The probability that two randomly selected African Americans are of matching type is less than one in ten thousand, national and

251. Complaint, supra note 19, at 32-34.

254. STEWART & SUGAR, supra note 1, at 33.

256. Egeland, supra note 106, at 467.

257. Living Kidney Donor Frequently Asked Questions, UNIV. OF MD. MED. CENTER, http://www.umm.edu/transplant/kidney/qanda.htm#6 (last visited Oct. 29, 2010).

- 261. Id.
- 262. Bergstrom, supra note 18, at 1309.
- 263. Id.

persons of the same sex to engage in certain intimate sexual conduct, the Supreme Court ruled that the statute violated the substantive due process clause because it "furthers no legitimate state interest." Lawrence v. Texas, 539 U.S. 558, 578 (2003).

<sup>252.</sup> Complaint, supra note 19, at 32.

<sup>253.</sup> Id. at 34.

<sup>255.</sup> Id.

<sup>258.</sup> STEWART & SUGAR, supra note 1, at 9.

<sup>259.</sup> Complaint, supra note 19, at 33.

<sup>260.</sup> Id.

international registries match donors and patients anonymously. For these reasons, patients cannot shop around for marrow cells like they could for solid organs.

Finally, the plaintiffs argue that there is no evidence as to *why* bone marrow was included in NOTA in the first place.<sup>264</sup> In more than 1,500 pages of legislative history, there is no discussion of bone marrow and no explanation why marrow cells should be treated differently than other renewable or inexhaustible cells like blood, sperm, and eggs.<sup>265</sup> Moreover, the House of Representatives and the Senate issued a Conference Report on the bill explicitly stating that the ban on organ selling was "not intended to include replenishable tissues such as blood or sperm,<sup>266</sup> yet bone marrow was included despite being made up of [blood stem cells] that generate most of the body's blood cells."<sup>267</sup> According to the plaintiffs, this legislative history suggests that the inclusion of bone marrow in NOTA was a mistake; consequently, the ban on compensation for marrow cell donors is irrational and arbitrary.<sup>268</sup> It therefore violates equal protection and substantive due process, and should be repealed.

# C. Analyzing the Claims – Can the Plaintiffs Overcome Rational Basis Review?

The plaintiffs have an appealing argument. If it is legal to compensate donors for other renewable sources like blood and sperm, it seems surprising that it is illegal to compensate donors for bone marrow, especially when so many lives are lost as a direct result of bone marrow shortage. Leukemia alone will strike 44,000 people this year who could be saved by a bone marrow transplant; 3,500 of them will be children.<sup>269</sup> Half of these adults and 700 of the children will eventually die as a result.<sup>270</sup> A victory in this case would "give hope to thousands facing deadly diseases" and ensure that "no one else [will] have to die because of the federal criminal ban on compensation for bone marrow donors."<sup>271</sup>

However, even if the law does not make sense with regard to bone marrow, it is very unlikely to be overturned by the constitutional approach the plaintiffs have chosen. First, equal protection applies to "persons," <sup>272</sup> not cells or body parts like bone marrow, blood, and solid organs, so it is not clear that this claim will even be recognized by the court.

Moreover, while bone marrow appears more similar to blood, eggs, and sperm than to solid organs, there are still significant differences. It has been suggested

- 267. STEWART & SUGAR, supra note 1, at 6.
- 268. Complaint, supra note 19, at 50.
- 269. Saving Lives, supra note 20.
- 270. Id.
- 271. Id.

<sup>264.</sup> Complaint, supra note 19, at 32.

<sup>265.</sup> Id. at 34.

<sup>266.</sup> H.R. REP. NO. 98-1127 (1984) (Conf. Rep.).

<sup>272.</sup> U.S. CONST. amend. XIV, § 1. As an example, pro-life advocates argue that a fetus is a "person" so that fetuses may receive protections under the Equal Protection Clause.

that the risks associated with a bone marrow harvest for donors are the same risks associated with undergoing general anesthesia for any surgical procedure.<sup>273</sup> However, blood donors do not have to undergo general anesthesia and so do not face those risks. Plaintiffs may also point out that more than ninety-five percent of bone marrow donors experience only temporary, minor complaints.<sup>274</sup> While this is true, it is also true that three to five percent of donors suffer more intense side effects and/or suffer effects for a prolonged period of time.<sup>275</sup> Also, while major side effects, complications, or death following donation is extremely low, it does happen.<sup>276</sup> Blood and sperm donors never die from the donation process. Therefore, the risks related to bone marrow donation lie somewhere in between those from solid organs and those from other renewable sources like blood, egg, and sperm. Even if bone marrow is closer to other renewable sources than it is to solid organs, the line distinguishing body parts that can and cannot be paid for must be drawn somewhere.<sup>277</sup> While it may appear arbitrary to some, it is up to the legislature, not the courts, to draw that line.<sup>278</sup>

In addition, while there may be a fundamental right to *refuse* medical treatment,<sup>279</sup> there is no fundamental right to *seek* life-saving medical treatment.<sup>280</sup> As a result, the plaintiffs' due process claim (and equal protection claim, if it is considered) will be subject to a rational basis test, and health and safety regulations are very rarely overturned under this standard of review.<sup>281</sup> For instance, utilizing a rational basis standard, courts consistently uphold FDA regulations that deny life-saving drugs to patients, even though the patients often have no other options for survival.<sup>282</sup>

278. See, e.g., Williamson, 348 U.S. at 487 (finding that, even if the law in question may exact a needless requirement in many cases, it is "for the legislature, not the courts, to balance the advantages and disadvantages of the new requirement").

279. Cruzan v. Dir., Mo. Dept. of Health, 497 U.S. 261, 278-79 (1990) (assuming a patient's liberty interest in refusing life-saving medical treatment under the Due Process Clause of the Fourteenth Amendment); *see also* Washington v. Glucksberg, 521 U.S. 702, 720 (1997) ("We have also assumed, and strongly suggested, that the Due Process Clause protects the traditional right to refuse unwanted lifesaving medical treatment." (citing *Cruzan*, 497 U.S. at 278-89)).

280. See, e.g., Abigail Alliance for Better Access to Developmental Drugs v. Von Eschenbach, 495 F.3d 695, 712 (D.C. Cir. 2007) (holding that access to experimental drugs for terminally ill patients is not a fundamental right).

281. See, e.g., Von Eschenbach, 495 F.3d at 713 ("[P]rior to distribution of a drug outside of controlled studies, the Government has a rational basis for ensuring that there is a scientifically and medically acceptable level of knowledge about the risks and benefits of a drug.")

282. *Id.* ("[T]he FDA's policy of limiting access to investigational drugs is rationally related to the legitimate state interest of protecting patients, including the terminally ill, from potentially unsafe drugs with unknown therapeutic effects.")

<sup>273.</sup> STEWART & SUGAR, supra note 1, at 33.

<sup>274.</sup> Egeland, supra note 106.

<sup>275.</sup> Id.

<sup>276.</sup> Id.

<sup>277.</sup> See, e.g., New Orleans v. Dukes, 427 U.S. 297, 305 (1976) (reasoning that arbitrary line drawing by Congress is inevitable); see also Williamson v. Lee Optical of Okla., Inc., 348 U.S. 483, 489 (1955) ("The legislature may select one phase of one field and apply a remedy there, neglecting the others.").

The reason that courts uphold regulations that deny life-saving medical treatment to patients is because the rational basis test is easily satisfied. Under *FCC v. Beach Communications*, the government will win as long as "there is *any reasonably conceivable state of facts* that could provide a rational basis" for the challenged law.<sup>283</sup> Similarly, the Court in *U.S. Railroad Retirement Board. v. Fritz* reasoned that a law will be upheld under rational basis review if there are "plausible reasons" for Congress' action.<sup>284</sup> In the instant case, the government has several "conceivable" or "plausible" rationales for prohibiting compensation for bone marrow donations, even if the plaintiffs disagree with them.

# 1. Patient and Donor Safety Concerns

The NMDP explained some of the government's justifications in a recent statement:

The rationale for the current law is to ensure patient and donor safety. Offering compensation to potential donors might compel them to withhold important personal health information that would negatively impact the patient. The safety of the donors is equally important. Offering compensation to potential donors might also compel them to withhold personal health information that would normally defer them from donating.<sup>285</sup>

The plaintiffs counter that this hypothetical problem could be resolved by conducting the type of rigorous medical screening used for other donations.<sup>286</sup> For instance, all blood donations are tested for HIV before they enter the available pool, even when the donor claims she has never used intravenous drugs or engaged in any sexual activity.<sup>287</sup> Moreover, the plaintiffs contend that the government's argument is irrational because many of these patients will die anyway if they do not receive a transplant.<sup>288</sup>

However, the plaintiffs' contention is flawed. Medical screening would only solve the safety issues for the recipient, not the donor. At the point the donated marrow was tested, the donor would have of course already donated it, and so *her* health risks would not be alleviated. Moreover, the fact that an alternative exists does not make the government's justification "irrational" under a constitutional analysis. Even if this rationale is questionable or debatable, it is still plausible that a donor's safety would be threatened, and that is all the government needs to establish in order to meet the rational basis standard. The court will not strike

<sup>283.</sup> FCC v. Beach Commc'ns, 508 U.S. 307, 313 (1993) (emphasis added).

<sup>284.</sup> U.S. R.R. Ret. Bd. v. Fritz, 449 U.S. 166, 179 (1980).

<sup>285.</sup> Kevin B. O'Reilly, *Ban on paying bone marrow donors challenged in court*, AM. MED. NEWS (Dec. 21, 2009), http://www.ama-assn.org/amednews/2009/12/21/prsa1221.htm.

<sup>286.</sup> Colb, supra note 184.

<sup>287.</sup> *Id.* (noting that while U.S. blood donors are currently uncompensated, federal law does not criminalize such remuneration).

<sup>288.</sup> Saving Lives, supra note 20.

down a law under rational basis review because it "may be unwise, improvident, or out of harmony with a particular school of thought."<sup>289</sup>

# 2. Commodification of the Human Body and Economic Coercion of the Poor

Additionally, the government may argue that human body parts should never be treated as commodities to be bought or sold because "[c]ommodification of the body would result in a troubling diminution of respect for human dignity."<sup>290</sup> Payment for bone marrow donations may also threaten exploitation of the poor because they will be the ones most eager to sell their body parts and will "be dehumanized by being viewed as commodities."<sup>291</sup>

It will be difficult for the plaintiffs to convince the court that the government's commodification justification is irrational. First, we already forbid certain means of earning money, such as prostitution, because they are perceived as sufficiently degrading.<sup>292</sup> The plaintiffs argue that this rationale does not apply to bone marrow because donors and patients are matched anonymously through registries on the basis of complex genetic factors. Thus, there is no prospect of a highest bidder market.<sup>293</sup> However, this argument either ignores or misunderstands the government's position. Whether or not it is possible to have an open market for bone marrow, the poor will still be the most desperate to donate when compensation is involved and, therefore, the most directly subjected to degradation of their bodies. The government could easily embrace this fear as part of a rational argument against compensation. Even though the plaintiffs want to offer compensation in the form of a scholarship,<sup>294</sup> that does not make their argument more convincing; poor people attend college, too. At the very least, the government's stance is plausible, and again that is all it needs to survive rational basis review.

#### 3. Altruism

Another concern the government has is that those who donate for altruistic reasons may be turned off by financial incentives and, therefore, the donor pool may actually decrease.<sup>295</sup> The plaintiffs counter that even if we believe that payment could potentially reduce the altruistic incentive for some to donate, the current donor pool is already far from adequate,<sup>296</sup> and statistics support the plaintiffs' claim. The U.S. registry currently includes less than 3% of the eligible white population, while an optimal registry would include about 7%.<sup>297</sup> For

<sup>289.</sup> Williamson, 348 U.S. at 488.

<sup>290.</sup> Holloway, supra note 164, at 152.

<sup>291.</sup> Id. at 153.

<sup>292.</sup> Id. at 154.

<sup>293.</sup> Saving Lives, supra note 20.

<sup>294.</sup> Id.

<sup>295.</sup> Clark, supra note 188.

<sup>296.</sup> Saving Lives, supra note 20.

<sup>297.</sup> Bergstrom et al., supra note 18, at 1327.

minorities, participation is also meager. About 6.5% of eligible Asian Americans and 2.5% of African Americans are currently registered, while an optimal registry would include approximately twenty percent of each group.<sup>298</sup> According to the plaintiffs in *Flynn*, even if the pool were to lose altruistic donors, the increase in donors who would only donate for compensation would significantly make up for the loss, saving an estimated one thousand additional lives per year.<sup>299</sup>

However, the plaintiffs again confuse "rational" as a commonsense term and "rational" as a constitutional level of review. The plaintiffs may disagree with the government's fear, and may even be correct in their analysis, but that does not mean the law will be struck down as irrational. The fear that altruistic donors will be turned off has been expressed by numerous scholars and experts in the field<sup>300</sup> and at the very least is a "conceivable" reason for upholding the ban on bone marrow donor compensation.

## 4. Legislative History

Finally, the absence of any discussion regarding bone marrow in the legislative history will not persuade the court that the ban is irrational because a law does not have to be justified in order to have a rational basis. In *Beach Communications v. FCC*, the Court reasoned that it would "never require a legislature to articulate its reasons for enacting a statute. . . .<sup>301</sup> Therefore, "it is entirely irrelevant . . . whether the conceived reason for the challenged distinction actually motivated the legislature.<sup>302</sup> As a result, if the court in this case determines there is a rational basis for the inclusion of bone marrow in the NOTA ban, it is irrelevant whether there is any discussion of bone marrow in the legislative history.

## **D.** Recommendations for the Future

The ban against compensation for bone marrow results in the death of patients who would otherwise live if they found matching donors, even while we allow compensation for other renewable sources like blood and sperm. Moreover, marrow donation has a relatively low-risk; it is certainly less risky than kidney donation. For these reasons, the societal benefits of allowing compensation for marrow donors seem to outweigh the costs. However, the standard for rational basis review is extremely low, and is one the government will most likely be able to meet when challenged through the judicial process. As a result, compensation for bone marrow donors will not be legalized by the courts. Therefore, rather than ask the Court to strike down the law against compensation, the plaintiffs should

<sup>298.</sup> Id.

<sup>299.</sup> Colb, supra note 184.

<sup>300.</sup> See, e.g., Clark, supra note 188 ("[F]amilies who donate organs for altruistic reasons may be turned off by financial incentives and donations may actually decrease in the long run.").

<sup>301. 508</sup> U.S. at 315.

<sup>302.</sup> Id.

seek change from Congress. As one court has noted, "[o]ur Nation's history and traditions have consistently demonstrated that the democratic branches are better suited to decide the proper balance between the uncertain risks and benefits of medical technology...."<sup>303</sup>

However, change through legislation takes time. In the meantime, there are *legal* ways to make the donation process more efficient and reliable. These avenues should be explored immediately so that fewer patients die from severe, but curable, diseases. First, the overall process for transplantation is much too slow.<sup>304</sup> Often, the process takes so long that by the time a matching donor is located, the patient's health has deteriorated too far to allow for transplantation.<sup>305</sup> This slow search process costs lives and is unacceptable.

Deterioration of a patient's medical condition can be addressed by enhancing the speed and efficiency of the search process. The Be The Match registry has initiated a number of activities to improve it. These activities include encouraging physicians to initiate searches as early as possible, tracking the progress of searching patients, and improving search strategy design through education and assistance.<sup>306</sup> These efforts have decreased the time between initial search and time of transplant.<sup>307</sup> While some obstacles may be beyond control, by employing these strategies registries and donor centers worldwide can improve the efficiency of the donor search process and significantly impact donor availability.

In addition, even when a patient is fortunate enough to find a matching donor and healthy enough to receive a transplant, a relatively high percentage of donors refuse to proceed with donation.<sup>308</sup> Almost twenty percent of all donors are permanently deferred at the time of confirmatory typing.<sup>309</sup> Additionally, twelve percent of donors are temporarily unavailable when contacted for confirmatory typing.<sup>310</sup> One way to address this donor deferral is to assign a backup donor.<sup>311</sup> If a backup donor is available, the average delay for a transplant is only seven days when the first choice is unable to donate, compared to seventy-nine days when no backup donor is assigned.<sup>312</sup> Moreover, several practices of the registries and donor centers contribute to the high rate of donor deferral, including inadequate routes of contact (e.g. timing of phone calls), poor cultural sensitivity (e.g. language

<sup>303.</sup> Von Eschenbach, 495 F.3d at 713.

<sup>304.</sup> Van Rood & Oudshoorn, supra note 5, at 3.

<sup>305.</sup> *Id.*; *see also* Heemskerk, *supra* note 17, at 649 (noting that thirty percent of patients were unable to reach transplantation because of their deteriorated clinical condition by the time they found a matching donor).

<sup>306.</sup> Confer, supra note 129, at 275.

<sup>307.</sup> Id.

<sup>308.</sup> Heemskerk, supra note 17, at 650.

<sup>309.</sup> Confer, *supra* note 129, at 277. At the time of confirmatory typing for donors registered with Be The Match, the donor receives a medical screening interview and additional educational material about stem cell donation processes. *Id.* at 275. The responsible Be The Match center also contacts the donor and arranges for additional blood samples. *Id.* 

<sup>310.</sup> Id. at 277.

<sup>311.</sup> Van Rood, supra note 5, at 5.

<sup>312.</sup> Id.

spoken), and poor efforts expended to reach matching donors.<sup>313</sup> Such practices are unacceptable because they cost lives and can easily be remedied.

Finally, registries need to improve their education and recruitment efforts. Minority group members are least likely to find a potential match, but many are not aware of the need to join a registry; most do not even know the registries exist.<sup>314</sup> Therefore, heightened recruitment efforts are necessary. Opportunities for recruitment may be available through church announcements, college organizations and events, and sporting events.<sup>315</sup> Additionally, various studies have concluded that African Americans have a particularly strong mistrust of the medical system.<sup>316</sup> As a result, they are hesitant to join bone marrow donor registries. However, education efforts may be able to alleviate this problem. If members of the community understand how detrimental the shortage of suitable donors is to thousands of African Americans in need of a transplant, they may be able to look past their mistrust and join a bone marrow registry.<sup>317</sup> This would offer hope to many patients desperately in need of matching donors.

# **VII.** CONCLUSION

Despite a world registry exceeding eleven million volunteer stem cell donors, as many as seventy percent of the patients awaiting a bone marrow transplant do not find a suitable donor.<sup>318</sup> Many of these patients will die as a result.<sup>319</sup> In the United States alone, one thousand patients die every year because they are unable to find a donor.<sup>320</sup> Financial incentives have proven to be an effective way to increase supply of other needed biological materials. However, patients on international bone marrow registries may not legally receive compensation, even though bone marrow donations are not as invasive as solid organ donations and marrow is renewable like other biological sources that are legally sold. For these reasons, the rationale behind laws against the sale of other organs does not apply to bone marrow. Consequently, the prohibition on compensation for bone marrow donation should be repealed so that no more patients die needlessly.<sup>321</sup> Unfortunately, the constitutional challenges brought by the plaintiffs in *Flynn* are unlikely to achieve this goal. Health and safety regulations are very rarely

<sup>313.</sup> Confer, supra note 129, at 277.

<sup>314.</sup> *Why Race Matters*, AFR. AM. MARROW CONNECTION , http://blackbonemarrow.com/facts\_and\_statistics.html (last visited Oct. 29, 2010) (stating that Caucasians have an eighty-five percent chance of finding at least one potential match on the donor registry, while African Americans have only a sixty percent chance) [hereinafter *Why Race Matters*].

<sup>315.</sup> *Id*.

<sup>316.</sup> Why Race Matters, supra note 313.

<sup>317.</sup> Id.

<sup>318.</sup> Cogdell, supra note 124, at 242.

<sup>319.</sup> Id.

<sup>320.</sup> O'Reilly, supra note 286.

<sup>321.</sup> Saving Lives, supra note 20.

overturned under a rational basis test, and the government has plausible reasons for banning compensation for marrow donors.<sup>322</sup>

Nevertheless, the issues in dispute in *Flynn* affect patients in need of bone marrow transplants around the world. Challenging the ban will bring attention to an issue that most people remain unaware of until it affects them or a loved one. While the courts are not likely to legalize compensation for marrow donors, the arguments made by the plaintiffs are "ones that can be aired in the democratic branches, without injecting the courts into unknown questions of science and medicine."<sup>323</sup> Therefore, if the plaintiffs lose, they should lobby Congress to change NOTA based on the fact that it contributes to a preventable shortage of donors on domestic and international bone marrow registries, which ultimately results in the needless deaths of countless patients. If the ban against marrow donor compensation is repealed in the U.S., other countries may consider removing the ban as well.

In the meantime, domestic and international bone marrow registries should pursue *legal* ways to make the donation process more efficient and reliable. Some obstacles may currently be beyond control. However, registries and donor centers can take immediate steps to improve the efficiency of the donor search process, remedy practices that discourage donations, and increase their education and recruitment efforts. By taking these actions, they may significantly impact donor availability so that fewer patients die each year from severe, but curable, diseases.

<sup>322.</sup> In fact, the district court for the Central District of California granted defendant's motion to dismiss on March 29, 2010, finding that plaintiffs' complaint stated neither an equal protection claim nor a due process claim. Court Order re: Defendant's Motion to Dismiss, Flynn v. Holder, CV 09-07772 (C.D. Cal Mar. 29, 2010). The plaintiffs subsequently appealed the court's ruling and a hearing is currently scheduled for January 23, 2011. Notice of Appeal, Flynn v. Holder, No. 10-55643 (9th Cir. Apr. 27, 2010); BOO, *supra* note 20.

<sup>323.</sup> Von Eschenbach, 495 F.3d at 713.