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The Hidden Economy of HSC Transplantation Is Inconsistent with Prohibiting the Compensation of HSC Donors

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The Hidden Economy of HSC Transplantation Is Inconsistent with Prohibiting the Compensation of HSC Donors

Kristy Williams*

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INTRODUCTION

Hematopoietic stem cell (HSC) transplantation is used clinically to treat and cure a variety of cancers as well as blood and immune disorders.¹ However, every year thousands of individuals in the United States are unable to take advantage of these treatments due to the unavailability of matched donors.² Even with more than twenty-four million HSC donors

1. Jos Domen et al., *Bone Marrow (Hematopoietic) Stem Cells*, in REGENERATIVE MEDICINE 24 (2006), available at http://stemcells.nih.gov/staticresources/info/scireport/PDFs/Regenerative_Medicine_2006.pdf (describing HSCs and their characteristics, sources, and clinical uses).

2. Of the 20,000 patients each year with life-threatening illnesses requiring a bone marrow transplant, approximately 14,000 need unrelated donors to donate healthy bone marrow. See *The Need for More Marrow Donors*, HEALTH RESOURCES & SERVS. ADMIN., http://bloodcell.transplant.hrsa.gov/donor/need_for_donors/index.html (last visited Oct. 14, 2014) [hereinafter *Need for More Donors*]; see also *Detailed Description of Donor Registry Data*, HEALTH RESOURCES & SERVS. ADMIN.,

and cord blood units available worldwide, finding a matched donor is difficult when the recipient is a member of an ethnic or racial minority and especially so where the recipient is of mixed race.³ Given the inability of the current system of HSC donation to meet demand, there is a need to increase the number and diversity of available HSC donors, as well as to motivate existing registered donors to donate when called upon.⁴

The HSC transplantation industry relies on, and mandates, donor altruism.⁵ The National Organ Transplant Act (NOTA) prohibits the exchange of valuable consideration for HSCs collected from bone marrow to be used for transplant.⁶ At present, NOTA does not prohibit compensating donors for HSCs obtained from umbilical cord blood or peripheral (circulating) blood; however, the Health Resources and Services Administration (HRSA) has proposed expanding

http://bloodcell.transplant.hrsa.gov/research/transplant_data/registry_tx_data/longdesc/index.html#Fig1 (last visited Oct. 14, 2014) [hereinafter *Donor Registry Data*] (showing that in 2012, the national registry facilitated 5833 unrelated HSC transplants).

3. *Bone Marrow Donors Worldwide*, BMDW, www.bmdw.org (last visited Nov. 1, 2014) (“The current number of donors and cord blood units in the BMDW database is 24,835,479.”). The patient’s race and ethnicity affect the likelihood of finding an adult bone marrow donor match on the registry. See *Need for More Donors*, *supra* note 2. The likelihood of not finding a match by race is: 24% for African American or Black; 16% for Asian or Pacific Islander; 10% for American Indian or Alaska Native; 17% for Hispanic or Latino; and 3% for white. *Why Race and Ethnicity Matter*, BE THE MATCH, <http://bethematch.org/Transplant-Basics/Matching-patients-with-donors/Why-race-and-ethnicity-matter/> (last visited Oct. 2, 2014).

4. Not only does the number of registered available donors need to increase, the acceptance rate of those registered once they are called upon must increase as well. See R.N. Lown & B.E. Shaw, *Beating the Odds: Factors Implicated in the Speed and Availability of Unrelated Haematopoietic Cell Donor Provision*, 48 *BONE MARROW TRANSPLANTATION* 210, 213 (2013) (“46.9% of U.S. donors were deferred at ‘activation’ for requests in the first half of 2011.”); Kim Carollo, *Woman Dies After Bone Marrow Transplant Donors Back Out*, ABC NEWS, <http://abcnews.go.com/Health/woman-dies-leukemia-bone-marrow-donors-back/story?id=12120620&singlePage=true> (last visited Oct. 2, 2014) (stating that 47% of people on donor registries say no when they are asked to donate).

5. See *infra* Part III.C and accompanying notes (discussing the role of altruism in HSC donation).

6. 42 U.S.C. § 274e (2012); see *infra* Part II.B (reviewing state laws affecting the sale of HSCs).

the NOTA prohibition to cover all HSCs.⁷ In any event, the reliance on altruism is currently so ingrained in HSC transplantation that bureaucratic barriers prevent donors from receiving compensation in situations where it would be legally permissible.⁸

Donors are the only parties in the HSC transplant chain who are not compensated for their involvement.⁹ HSCs are routinely treated as commodities being bought and sold in a hidden economy that crosses international borders.¹⁰ This shadow industry is underpinned by mandated donor altruism, and is also reliant on such altruism for its very existence.¹¹ However, it is advantageous for all parties involved to encourage HSC donation. Not only would the compensation of donors increase the number and retention of donors, but it will also serve as an acknowledgement of the important contribution that donors make.¹² This Article will focus on

7. See Change to the Definition of “Human Organ” Under Section 301 of the National Organ Transplant Act of 1984, 78 Fed. Reg. 60,810, 60,811–12 (proposed Oct. 2, 2013) (to be codified at 42 C.F.R. pt. 121) [hereinafter Change to the Definition of “Human Organ”].

8. Due to stringent tissue compatibility requirements for HSC donations, unrelated donors and recipients rely on national and international HSC registries to be matched. See *infra* notes 35–39 and accompanying text. In the United States, the only registry option is the Be the Match Registry, which refuses to work with compensated donors, regardless of the type of HSCs they donate. See *Coalition Says PBSC Donor Compensation Poses Health Risks to Patients and Donors*, BE THE MATCH, <http://bethematch.org/templates/displaynewsrelease?id=707> (last visited Sept. 30, 2014) (describing the position of Jeffrey W. Chell, M.D., Chief Executive Officer of the National Marrow Donor Program, a coalition member that operates the Be the Match Registry, who said, “[t]hose motivated by self-gain are more likely to withhold health information that would make them unsafe donors. The blood banking experience in the United States shows that this results in donations that are unacceptable from a clinical standpoint”).

9. See *infra* Part III.B.

10. See *infra* Parts III.A–B.

11. See *infra* Parts III.A–B.

12. Individuals who were offered economic rewards to donate blood, and were aware of the rewards prior to donating, were more likely to donate, and the likelihood of donation increased with the higher the value of the rewards; they were also more likely to attract others to donate. See Nicola Lacetera et al., *Rewarding Altruism? A Natural Field Experiment 2* (Nat’l Bureau of Econ. Research, Working Paper No. 17636, 2011), available at <http://www.parisschoolofeconomics.eu/IMG/pdf/may2012-paris-lacetera-macis-slonim.pdf>; see also Theodore C. Bergstrom et al., *One Change in a Million: Altruism and the Bone Marrow Registry*, 99 AM. ECON. REV. 1309, 1327 (2009)

increasing HSC donations by repealing laws prohibiting compensation for HSC donation and permitting limited and regulated compensation for donors.

I. BACKGROUND

A. HSCs AND HSC TRANSPLANTS

1. Hematopoietic (Blood Forming) Stem Cells

Blood cells are essential to a variety of processes in the human body and need to be constantly replenished by HSCs, which give rise to all blood cell types.¹³ When large portions of an individual's HSCs are destroyed, death results from the inability of the body to produce new blood cells.¹⁴ HSC transplantation is used to treat patients with damaged or defective HSCs; the transplanted HSCs replenish the blood cell production in the recipient.¹⁵

HSC transplantation either uses the patient's own cells (autologous transplant) or the cells of a donor (allogeneic transplant).¹⁶ In order for the dysfunctional or destroyed blood production capacity to be fully restored by transplanted HSCs, the HSCs must engraft in the recipient's body and permanently reestablish blood production.¹⁷ After an HSC transplant, the

(arguing that monetary compensation for HSCs would increase both the incentive to join a bone marrow registry and the incentive to donate if asked); David E. Harrington & Edward A. Sayre, *Paying for Bodies, but Not for Organs*, REGULATION, Winter 2006–2007, at 14, 14 (noting that significantly more whole body donations are made to medical schools—which take care of cremation—in states with high funeral costs, indicating that financial considerations are an important component in the decision to donate).

13. HSCs are the sole source of the one hundred billion new blood cells humans require each day. BRUCE ALBERTS ET AL., *MOLECULAR BIOLOGY OF THE CELL* 1283 (4th ed. 2002); Domen et al., *supra* note 1, at 14.

14. ALBERTS ET AL., *supra* note 13, at 1288.

15. Domen et al., *supra* note 1, at 24.

16. *Id.* at 25; Mary M. Horowitz, *Uses and Growth of Hematopoietic Cell Transplantation*, in THOMAS' HEMATOPOIETIC CELL TRANSPLANTATION 15, 17–18 (Frederick R. Appelbaum et al. eds., 4th ed. 2009). Autologous transplantation is common where a patient's own HSCs are healthy, but are expected to be destroyed by high dose chemotherapy or radiation cancer treatment, and can be collected and stored prior to such treatment. See James O. Armitage, *The History of Autologous Hematopoietic Cell Transplantation*, in THOMAS' HEMATOPOIETIC CELL TRANSPLANTATION, *supra*, at 8, 8.

17. ALBERTS ET AL., *supra* note 13, at 1288.

blood produced by the recipient will be genetically identical to the donor and not the recipient.¹⁸

2. The Role of Histocompatibility in HSC Transplants

The success of an allogeneic HSC transplant¹⁹ largely depends on finding an immunologically compatible donor.²⁰ Histocompatibility locus antigen (HLA) genes and proteins are key to compatibility as they are involved in the body's immune response, working with T-cells to respond to and combat foreign materials.²¹

HLA proteins are present in all cells, wherein they bind to foreign proteins; potential sources of which include viruses, microbes, and parasites.²² Once an HLA protein binds to a foreign protein within the cell, the complex is moved to the outside of the cell to signal that the cell is potentially infected.²³ T-cells are selective and only recognize foreign proteins bound to HLA proteins on the outside of a cell.²⁴ When a T-cell recognizes a foreign protein, it marks the cell for destruction.²⁵

18. Paul J. Martin, *Documentation of Engraftment and Characterization of Chimerism Following Hematopoietic Cell Transplantation*, in THOMAS' HEMATOPOIETIC CELL TRANSPLANTATION, *supra* note 16, at 365, 365–69 (explaining that during the first few weeks after a transplant, both donor and recipient cells can be found in the blood, and the portion of recipient cells decreases over time).

19. Hereinafter all references to HSC transplants are to allogeneic HSC transplants.

20. See Cladio Anasetti et al., *Hematopoietic Cell Transplantation from Human Leukocyte Antigen Partially Matched Related Donors*, in THOMAS' HEMATOPOIETIC CELL TRANSPLANTATION, *supra* note 16, at 657, 671 (“Transplant results have demonstrated that an increasing degree of donor HLA incompatibility is associated with a proportionally increased risk of graft failure, GVHD, and transplant-related mortality.”).

21. ALBERTS ET AL., *supra* note 13, at 1409; *see also* Anasetti et al., *supra* note 20 (discussing HSC transplants in partially matched HLA donors).

22. ALBERTS ET AL., *supra* note 13, at 1397.

23. *Id.*

24. *Id.*; Domen et al., *supra* note 1, at 19. The selective nature of T-cells is due to the complex process in which they are generated, wherein T-cells that recognize the “self” are destroyed, and non-self-recognizing T-cells are exported throughout the body where they may replicate. *See* Paul J. Martin, *Overview of Hematopoietic Cell Transplantation Immunology*, in THOMAS' HEMATOPOIETIC CELL TRANSPLANTATION, *supra* note 16, at 131, 134.

25. ALBERTS ET AL., *supra* note 13, at 1392–93.

There are two immunological mechanisms through which an HSC transplant may fail: graft failure and graft versus host disease (GVHD).²⁶ Graft failure occurs where the recipient's immune system recognizes the HLA proteins on the transplanted cells as foreign and targets them for destruction.²⁷ Because T-cells gain their selectivity for foreign material during the development process, T-cells that develop from donor HSCs within a recipient will recognize the recipient as self, but may not recognize other donor HSCs or blood cells originating from donor cells as self.²⁸ Graft failure can be preemptively mitigated by matching the donor and recipient's HLA, by depleting the recipient's immune system prior to transplant, and by continuing to suppress the immune system afterwards using immunosuppressive medication.²⁹

GVHD is unique to HSC transplants and occurs as the result of transplanted donor T-cells (developed in the donor) recognizing the recipient's cells as foreign and marking all the recipients cells for destruction.³⁰ Depleting the recipient's immune system prior to transplant exacerbates any GVHD because the depletion primes the recipient's immune system for a response so that when introduced, the transplanted donor T-cells become activated and divide.³¹ GVHD cannot be successfully treated with immunosuppressant medication, but the risk of GVHD can be reduced by stringently selecting donors with HLA compatibility.³²

26. Martin, *supra* note 24, at 131.

27. Graft failure is similar to the type of organ rejection that occurs after a solid organ transplant. *See id.*

28. ALBERTS ET AL., *supra* note 13, at 1367 (explaining how T-cells develop in the thymus from HSCs that migrate there through the blood). T-cells produced by the recipient may recognize the HLA proteins themselves as foreign, regardless of whether they are bound to foreign proteins. *See id.*

29. Domen et al., *supra* note 1, at 15, 24–27; Martin, *supra* note 24, at 131, 138.

30. Martin, *supra* note 24, at 131 (stating that GVHD does not occur in solid organ transplantation due to the limited number of transplanted T-cells or other cells with immunologic function).

31. James L. M. Ferrara & Joseph H. Antin, *The Pathophysiology of Graft-Versus-Host Disease*, in THOMAS' HEMATOPOIETIC CELL TRANSPLANTATION, *supra* note 16, at 208, 208; Martin, *supra* note 24, at 138.

32. Anasetti et al., *supra* note 20 (stating post-transplant immunosuppression does not control GVHD from highly mismatched donors); Mark F. Anderson, *Encouraging Bone Marrow Transplants from Unrelated*

Five forms of HLA proteins are commonly used to match donors and recipients.³³ Separate genes encode each of the five forms, of which every person has two sets—one from each parent.³⁴ For any one patient there is a twenty-five percent probability that any one of her siblings inherited identical HLA forms (a 10/10 match).³⁵ The probability that a patient will have a match depends on their number of siblings;³⁶ based on the average size of families in the United States, there is a twenty to thirty percent chance that patients will have an HLA-matching sibling.³⁷ The remaining seventy to eighty percent of patients have to rely on a donor registry to be matched to an unrelated donor.³⁸ Much of the difficulty in finding an unrelated donor stems from the fact that each of the

Donors: Some Proposed Solutions to a Pressing Social Problem, 54 U. PITT. L. REV. 477, 483 (1993). Although donor immune cells may cause GVHD, they may also be helpful in destroying the recipient's cancerous cells through the graft versus tumor response. See Domen et al., *supra* note 1, at 25.

33. In the United Kingdom, a 10/10 match of the two sets of HLA-A, HLA-B, HLA-C, HLA-DRB1, and HLA-DQB1 is considered optimal, although a 9/10 may be accepted. See Lown & Shaw, *supra* note 4, at 210, 213–15. While more than five HLA forms exist, only five are commonly used for matching at present. See RICHARD T. MAZIARZ, *BLOOD AND MARROW TRANSPLANT HANDBOOK 4* (Richard T. Maziarz & Susan Slater eds., 2011).

34. Martin, *supra* note 24, at 131.

35. *Id.* at 131–32 (“For a given patient there is a 0.25 probability that any one sibling inherited the same paternal haplotype and the same maternal haplotype, thereby being HLA-genotypically identical.”).

36. James O. Armitage, *Bone Marrow Transplantation*, 330 NEW ENG. J. MED. 827, 827 (1994) (“The formula for calculating the chance that a particular person has an HLA matched sibling is $1 - (0.75)^n$, where n denotes the number of potential sibling donors.”).

37. See Karen K. Ballen et al., *Umbilical Cord Blood Transplantation: The First 25 Years and Beyond*, 122 BLOOD 491, 492 (2013) (“[O]nly 30% of patients who require an allograft will have a human leukocyte antigen (HLA)-matched sibling donor.”); Effie W. Petersdorf, *The World Marrow Donor Association: Twenty Years of International Collaboration for the Support of Unrelated Donor and Cord Blood Hematopoietic Cell Transplantation*, 45 BONE MARROW TRANSPLANTATION 807, 807 (2010) (“[I]t is now estimated that only 20% of patients in the United States in need of a transplant have a genotypically HLA-identical sibling to serve as a donor, largely as a result of the smaller average family size”); M. Oudshoorn et al., *Hematopoietic Stem Cell Donor Selection: The Eurodonor Experience*, 67 HUMAN IMMUNOLOGY 405, 405 (2006) (“[T]he availability of an HLA-matched sibling donor for patients in need of an allogeneic hematopoietic stem cell transplant is only about 30%.”).

38. Petersdorf, *supra* note 37, at 807.

genes coding for HLA have numerous forms and vary widely in the general population, with some genes having more than 700 forms without any one predominating.³⁹

Even though there are over twenty-four million donors and cord blood units available worldwide, many individuals are unable to find a matching donor.⁴⁰ Additionally, the likelihood of finding a match varies widely depending on the recipient's race and ethnicity, with probabilities ranging from sixty-six percent for African American patients to ninety-three percent for white patients.⁴¹ Even though these percentages have improved greatly over the years as the number of HLA-typed donors in worldwide databases has increased, every year thousands of individuals in the United States alone are unable to find matches.⁴²

3. Sources of HSCs for Transplant

There are three sources of HSCs for transplant: bone marrow, peripheral blood, and umbilical cord blood.⁴³ Bone marrow is aspirated from a donor under anesthesia by applying suction to a needle inserted into the marrow of the posterior

39. ALBERTS ET AL., *supra* note 13, at 1398 (explaining that some HLA genes have more than 200 forms without any one predominating); Martin, *supra* note 24, at 131 (noting that as of 2007 there were 729 known forms of HLA-B). There is a selective advantage for different HLA proteins in order to recognize a wide array of threats, and certain forms will be selected for in communities in response to specific threats, parasites, and viruses. See ALBERTS ET AL., *supra* note 13, at 1409.

40. J.J. van Rood & M. Oudshoorn, *Eleven Million Donors in Bone Marrow Donors Worldwide! Time for Reassessment?*, 41 BONE MARROW TRANSPLANTATION 1, 2 (2008) (“[I]n the period 2000–2006, out of about 151,000 patients qualifying for an HLA unrelated donor (UD) transplant, only 64,720 received one.”); *Bone Marrow Donors Worldwide*, *supra* note 3.

41. *Why Race and Ethnicity Matter*, *supra* note 3.

42. *General Frequently Asked Questions*, HEALTH RESOURCES & SERVS. ADMIN., http://bloodcell.transplant.hrsa.gov/about/general_faqs/index.html#1080%20How%20many%20people%20need (last visited Oct. 4, 2014). Over a decade ago when there were only 7.5 million donors on the list, the probability of finding a matched donor was significantly lower than today. See C.K. Hurley et al., *Maximizing Optimal Hematopoietic Stem Cell Donor Selection from Registries of Unrelated Adult Volunteers*, 61 TISSUE ANTIGENS 415, 415, 419 (2003).

43. Phyllis I. Warkentin & Elizabeth J. Shpall, *Hematopoietic Cell Procurement, Processing, and Transplantation: Standards, Accreditation, and Regulation*, in THOMAS' HEMATOPOIETIC CELL TRANSPLANTATION, *supra* note 16, at 535, 535.

iliac crest.⁴⁴ A typical collection involves 50 to 300 aspirations and the removal of 200 to 1500mL of marrow.⁴⁵

HSCs can also be filtered and collected from peripheral blood by apheresis.⁴⁶ Under normal conditions, the concentration of HSCs in peripheral blood is insufficient for use in transplantation.⁴⁷ Donors receive five days of injections of a compound that stimulates HSCs to migrate from the bone marrow into the peripheral blood in order to increase the concentration of HSCs.⁴⁸ On the fifth day of the injections, the donor attends a blood center or apheresis unit of a hospital where HSCs are filtered from their blood.⁴⁹ The collection process is either performed in one apheresis session up to eight hours in length or two apheresis sessions of four to six hours each.⁵⁰

HSCs are also present in umbilical cord blood.⁵¹ Cord blood can be collected after birth and the HSCs concentrated, tested, frozen, and stored (banked) for future use.⁵² Cord blood is either stored in a public bank where it is accessible to any

44. Dennis L. Confer et al., *Bone Marrow and Peripheral Blood Cell Donors and Donor Registries*, in THOMAS' HEMATOPOIETIC CELL TRANSPLANTATION, *supra* note 16, at 544, 548 (explaining how access to the bone is obtained via small incisions or punctures, and a large bore needle is inserted into the bone).

45. *Id.* (explaining that several aspirations may be obtained from a single bone puncture by advancing the needle after each aspiration); Willis H. Navarro et al., *National Marrow Donor Program: Donor Issues*, 19 BIOLOGY BONE MARROW TRANSPLANTATION S15, S15 (2013).

46. See Confer et al., *supra* note 44.

47. Armitage, *supra* note 16, at 9.

48. Confer et al., *supra* note 44; *Donating Peripheral Blood Stem Cells*, BE THE MATCH, <http://bethematch.org/Support-the-Cause/Donate-bone-marrow/Donation-process/Donating-PBSC/> (last visited Oct. 4, 2014).

49. Confer et al., *supra* note 44 (explaining how blood is withdrawn from the donor through one line, circulated through an apheresis machine where the HSCs are separated and collected, and the remainder of the blood is returned to the donor through a return line).

50. Navarro et al., *supra* note 45, at S15; *Donating Peripheral Blood Stem Cells*, *supra* note 48.

51. Hal E. Broxmeyer & Franklin O. Smith, *Cord Blood Hematopoietic Cell Transplantation*, in THOMAS' HEMATOPOIETIC CELL TRANSPLANTATION, *supra* note 16, at 559, 559.

52. *Id.* at 561.

matching recipient or a private bank for familial use.⁵³ Prior to being stored in a public cord blood bank, samples are HLA typed and tested to ensure safety and a sufficient number of cells for transplant.⁵⁴

Each source has its own set of benefits and drawbacks largely pertaining to availability, number of HSC cells collected, likelihood of GVHD and resulting stringency of HLA matching required, and potential risks to donors.⁵⁵ Many patients in need of an HSC transplant benefit from expediency, so timely access to HSCs has a significant effect on their prognosis.⁵⁶ Cord blood units are much more accessible than other sources of HSCs because registry information on cord blood represents HSCs immediately available for transplant, whereas listings for bone marrow and peripheral blood donors merely represent potential donors.⁵⁷ Moreover, forty-seven percent of potential donors in the United States who were listed in the registry were unable, unavailable, or chose not to donate when contacted about a match, causing delays and increasing the time from the recognition of the need for a transplant to the performance of a transplant.⁵⁸

The number of cells that can be collected for transplant depends on the source of the HSCs. Theoretically, the regeneration of a recipient's hematopoietic system could occur from one cell; however, transplant success rates increase with the number of cells and a minimum ratio of HSCs to body weight is required for optimal results.⁵⁹ The low numbers of

53. In the absence of a family history of blood disorders there is a large push for public and not private banking; several autologous and sibling cord blood transplants have been reported, but they are uncommon. See Ballen et al., *supra* note 37, at 492–93; Broxmeyer & Smith, *supra* note 51, at 559–60.

54. Broxmeyer & Smith, *supra* note 51, at 560–61.

55. See *id.* at 569; Domen et al., *supra* note 1, at 22; Lown & Shaw, *supra* note 4; Ann E. Woolfrey, *Donor Selection for Hematopoietic Cell Transplantation*, in THOMAS' HEMATOPOIETIC CELL TRANSPLANTATION, *supra* note 16, at 692, 695.

56. Effie W. Petersdorf, *Stem Cell Transplantation for Hematologic Malignancies*, in HEMATOPOIETIC STEM CELL TRANSPLANTATION 19, 31 (Robert J. Soiffer ed., 2d ed. 2008).

57. See Ballen et al., *supra* note 37; Domen et al., *supra* note 1, at 22.

58. See Lown & Shaw, *supra* note 4; Carollo, *supra* note 4.

59. Ballen et al., *supra* note 37, at 493; Domen et al., *supra* note 1, at 21 (explaining that animal studies have shown regeneration of the blood forming system from one HSC).

HSCs present in cord blood units have largely restricted the use of cord blood to children.⁶⁰ However, transplants using two combined cord blood units may overcome problems associated with low numbers of cells.⁶¹

Considering the devastating impact of GVHD on transplant success, any differences in the rates of GVHD are very important. Transplants with HSCs obtained from cord blood have lower incidence rates of GVHD compared to HSCs collected by other methods.⁶² The lower GVHD rates have been attributed to the absence of immunologically active cells and the relative immaturity of immune cells that are present.⁶³ Due to these lower GVHD rates, the standard of HLA matching is more permissive for cord blood, and transplants have been successful with as little as four or five out of six HLA genes matched.⁶⁴ This less stringent matching requirement has the potential to assist patients having difficulties finding a match for rare HLA types, including patients of races and ethnicities that are underrepresented in worldwide donor databases.⁶⁵

60. Woolfrey, *supra* note 55 (explaining that the total number of HSCs in cord blood are ten times lower than from bone marrow); see Ballen et al., *supra* note 37, at 493; Claudio G. Brunstein et al., *Allogeneic Hematopoietic Cell Transplantation for Hematologic Malignancy: Relative Risk and Benefits of Double Umbilical Cord Blood*, 116 BLOOD 4693, 4696 (2010); Domen et al., *supra* note 1, at 22.

61. See Ballen et al., *supra* note 37, at 494 (explaining that double umbilical cord blood transplants became very popular in the United States due to the relatively high weight of the population, but results have been mixed and some studies question the benefit of double as opposed to single cord transplants); Brunstein et al., *supra* note 60, at 4693.

62. Broxmeyer & Smith, *supra* note 51, at 569. Studies of HSCs from bone marrow and peripheral blood generally show similar rates of GVHD. See Norbert Schmitz, *Peripheral Blood Hematopoietic Cells for Allogeneic Transplantation*, in THOMAS' HEMATOPOIETIC CELL TRANSPLANTATION, *supra* note 16, at 618, 623.

63. See Woolfrey, *supra* note 55.

64. Lown & Shaw, *supra* note 4, at 215; see Brunstein et al., *supra* note 60, at 4693; Woolfrey, *supra* note 55 (noting that closer matching overall leads to better survival rates, but mismatched HSCs obtained from cord blood are not as fatal as mismatches from other HSC sources).

65. See U.S. DEP'T OF HEALTH & HUMAN SERVS., INTERIM REPORT TO CONGRESS ON HOW FEDERAL FUNDS ARE DISTRIBUTED TO CORD BLOOD BANKS PARTICIPATING IN THE NATIONAL CORD BLOOD INVENTORY 3 (2011), available at http://bloodcell.transplant.hrsa.gov/about/legislation_and_contracts/cbcc/072011interimreport.pdf ("Cord Blood units serve as the source of blood stem cells for minority patients much more frequently than adult donor products.");

Additionally, in an effort to further benefit patients from minority populations, expectant mothers from underrepresented ethnic and racial backgrounds can be selectively encouraged to donate.⁶⁶

The potential health risks faced by donors depend on the source of HSCs. The collection of HSCs from cord blood poses the lowest level of risk to the donor, as the only physical intrusion is a blood test of the mother.⁶⁷ The donation of HSCs via aspiration of bone marrow or apheresis of peripheral blood is not without risks; even though the risk of a severe event from bone marrow donation is less than one percent, this risk is slightly higher than the risk of donating peripheral blood.⁶⁸ Risks involved in the donation of bone marrow are primarily associated with the need for anesthesia and the physical intrusion; symptoms include pain, sore throat, nausea, light-headedness and vomiting.⁶⁹ The risks associated with apheresis are primarily related to the mobilizing compound given to the donor to cause her HSCs to migrate from the bone marrow into the peripheral blood, but may also stem from the placement of the blood draw line during collection.⁷⁰ Symptoms from donation by apheresis may include pain, headache, nausea, vomiting, bruising at vein access site, and alteration of the

id. at 3 n.7 (“Minority patients who are unable to find an adequately matched adult marrow donor on the Registry are often able to find an adequately matched cord blood unit for transplantation.”).

66. *Id.* at 2–3 (noting that the U.S. Department of Health and Human Services emphasizes increasing the number of cord blood units collected from minority donors; the dollar amount reimbursed to cord banks differs based on the patient’s ethnicity and race to further this goal); Lown & Shaw, *supra* note 4, at 214.

67. See N.Y. Blood Center, *Consent Form for Clinical Investigation*, NATIONAL CORD BLOOD PROGRAM, <http://www.nationalcordbloodprogram.org/donation/consent.pdf> (last visited Oct. 14, 2014) (citing the risks of a blood draw and noting that it is possible that results of the blood test may have “negative psychological or financial effects or may affect your ability to get health insurance”).

68. Confer et al., *supra* note 44, at 549 (“The frequency of serious adverse events following marrow donation is estimated at 0.1–0.3 percent.”); Lown & Shaw, *supra* note 4 (explaining that donation of HSCs via apheresis of peripheral blood has a lower incidence of adverse events); Navarro et al., *supra* note 45, at S17 (noting that the risk of a serious adverse event associated with apheresis of peripheral blood is lower than one percent).

69. Confer et al., *supra* note 44, at 548–50.

70. *Id.*

donor's blood composition.⁷¹ As apheresis only became widely used for HSC collection in the 1990s, long-term studies are still being conducted.⁷² Nearly ninety percent of all peripheral blood and bone marrow donors experience pain; the primary differences between the two methods are timing of the symptoms and time to full recovery.⁷³ In addition to health risks, all methods of HSC collection pose a potential risk to the privacy of the donor's genetic information.⁷⁴

B. HISTORY OF HSC TRANSPLANTATION

Even though HSC transplantation did not achieve success as a therapy for blood disorders until 1968,⁷⁵ the idea of transplanting body parts and fluids has been around for thousands of years.⁷⁶ Blood transfusions attempted in the mid-seventeenth century were unsuccessful, and it was not until 1825 that human blood was successfully transfused into another human.⁷⁷ The discovery of different types of blood and

71. See, e.g., *id.* at 547 (explaining how the mobilizing agent may precipitate a severe sickle crisis in persons with sickle cell anemia).

72. Navarro et al., *supra* note 45, at S18 (stating that the National Donor Marrow Program is currently conducting a long-term donor follow-up study specifically aimed at tracking the incidence of malignancies, including hematologic cancers, as well as thrombosis and autoimmunity, and final analysis of this data is expected in 2020).

73. *Id.* at S16, S18. Discomfort from the peripheral blood mobilizing agent begins as early as the second day of shots and continues until collection and symptoms decrease twenty-four to forty-eight hours after stopping stimulation. *Id.* Pain from bone marrow donation does not begin until after collection, and slowly declines over the first week, lingering up to several weeks in some instances. *Id.* at S16.

74. See *infra* note 276 and accompanying text.

75. Fulvio Porta et al., *Hematopoietic Stem Cell Transplantation: 40 Years of Continuous Progress and Evolution*, 93 HAEMATOLOGICA 1607, 1607 (2008).

76. See Kristy Lynn Williams et al., *Just Say No to NOTA: Why the Prohibition of Compensation for Human Transplant Organs in NOTA Should Be Repealed and a Regulated Market for Cadaver Organs Instituted*, AM. J. LAW & MED. (forthcoming) (citing NICHOLAS L. TILNEY, TRANSPLANT: FROM MYTH TO REALITY 10 (2003); J. Englebert Dunphy, *The Story of Organ Transplantation*, 21 HASTINGS L.J. 67, 67 (1969); Laurel R. Siegel, *Re-Engineering the Laws of Organ Transplantation*, 49 EMORY L.J. 917, 919 (2000)) (explaining that over 3000 years ago, procedures using autologous skin grafts to repair mutilated noses were devised in India and later depicted in Egyptian papyri).

77. R. M. Boyce, *Organ Transplantation Crisis: Should the Deficit Be Eliminated Though Inter Vivos Sales?*, 17 AKRON L. REV. 283, 284 (1983)

blood incompatibilities in 1901, and the use of anticoagulants, led to the widespread use of human blood transfusions in World War I.⁷⁸

Bone marrow has been known to be involved in the generation of blood cells since the turn of the nineteenth century, and was proposed as a treatment for diseases resulting from defective hemogenesis.⁷⁹ Human bone marrow was first used as a treatment in 1939, although the treatment was not an attempt at transplantation.⁸⁰

In the late 1940s and early 1950s research revealed that bone marrow was critical in the recovery from high doses of radiation, which would otherwise result in lethal hematopoietic injury.⁸¹ Post-radiation injections of bone marrow saved

(explaining that in 1667, sheep's blood was transfused into a fifteen-year-old boy who subsequently died); *History of Blood Transfusion*, 146 NATURE 228, 228 (1940).

78. Boyce, *supra* note 77 (citing W. R. CLARK, THE EXPERIMENTAL FOUNDATIONS OF MODERN IMMUNOLOGY 8 (1980)); *History of Blood Transfusion*, *supra* note 77, at 229.

79. See Armitage, *supra* note 36 (citing Claude E. Forkner, *Leukemia and Allied Disorders*, 196 AM. J. MED. SCI. 377 (1938)). The only treatments in the 1800s with bone marrow involved the ingestion of bovine marrow. William E. Quine, Section Chairman, Am. Med. Ass'n, Chairman's Address: The Remedial Application of Bone Marrow (May 1896), in XXVI JAMA 1012 (1896), available at http://jama.jamanetwork.com/data/Journals/JAMA/11174/jama_XXVI_21_001c.pdf.

80. See Armitage, *supra* note 36, at 827 (citing Edwin E. Osgood et al., *Aplastic Anemia Treated with Daily Transfusions and Intravenous Marrow; Case Report*, 13 ANNALS INTERNAL MED. 357 (1939)) (explaining that a patient received eighteen milliliters of intravenous marrow from his brother as treatment for aplastic anemia); Maurice Morrison & A. A. Samwick, *Intramedullary (Sternal) Transfusion of Human Bone Marrow*, 115 JAMA 1708, 1709 (1940) (explaining that eight cubic centimeters of bone marrow from the patient's brother was injected into the patient's sternal marrow). Experiments were not attempts at transplantation as the physicians merely hoped that an unknown factor present in the donated marrow might stimulate the diseased marrow to function normally. Morrison & Samwick, *supra*; E. Donnall Thomas, *A History of Allogeneic Hematopoietic Cell Transplantation*, in THOMAS' HEMATOPOIETIC CELL TRANSPLANTATION, *supra* note 16, at 3, 3.

81. Thomas, *supra* note 80, at 3, 6 n.5. ("Jacobson and colleagues . . . found that a mouse would survive otherwise lethal irradiation if the spleen were exteriorized and protected from the irradiation . . . Lorenz et al. extended these observations by demonstrating a similar protective effect by an infusion of bone marrow cells.").

irradiated rodents from lethal injury.⁸² It was later shown that the protective effect was due to the ability of the HSCs present in the transplanted bone marrow to regenerate the blood-forming system in the recipient.⁸³

Clinical trials for bone marrow transplants, aimed at regenerating the hematopoietic system in patients, began in the late 1950s; these initial attempts at transplant failed.⁸⁴ The first successful transplant occurred in 1959 between identical twins; it was demonstrated that lethal irradiation followed by intravenous infusion of bone marrow from a healthy identical twin had an antileukemic effect even in advanced leukemia.⁸⁵ The success of the transplant between twins highlighted the importance of marrow coming from a compatible donor.⁸⁶ In the 1950s the role of histocompatibility in immunity and graft rejection was still in its infancy, and by 1958 HLA groups were first described and shown to be inherited.⁸⁷

It was not until 1968 that the first successful allogeneic HSC transplant occurred; however, the recipient patient had a

82. Domen et al., *supra* note 1, at 14–15 (citing Egon Lorenz et al., *Modification of Acute Irradiation Injury in Mice and Guinea Pigs by Bone Marrow Injection*, 58 *RADIOLOGY* 863 (1951)).

83. Domen et al., *supra* note 1, at 15; Thomas, *supra* note 80 (explaining that in 1955 it was shown the protective effect was cellular and not hormonal in nature).

84. Thomas, *supra* note 80, at 5.

85. *Id.* at 3–4 (explaining that an identical twin with terminal leukemia was given total body irradiation and an intravenous infusion of marrow from his healthy twin, and that the level of radiation would have caused death, but the patient recovered and leukemia disappeared for four months). Such a transplantation is not considered to be an allogeneic transplantation due to the similarities between twins; it is considered a syngeneic transplantation. *Id.*

86. *Id.* Histocompatibility was not well understood in the 1950s; the first long term successful kidney transplant occurred in 1954 between twins as well. See Dunphy, *supra* note 76, at 69.

87. See Thomas, *supra* note 80, at 5; see also Boyce, *supra* note 77, at 285 (discussing histocompatibility factors and how medicine has overcome rejection). HLA matching occurred by an assay where the donors' antibodies were introduced to cells from the recipient and cross reactivity of the two were analyzed, and in 1964, the first international meeting was held to discuss HLA and methods for assessing histocompatibility for the matching of donors and recipients. Eric Mickelson & Effie W. Petersdorf, *Histocompatibility*, in THOMAS' HEMATOPOIETIC CELL TRANSPLANTATION, *supra* note 16, at 145, 150.

severe immune deficiency and was not able to reject the graft.⁸⁸ The first HSC transplant involving a recipient that was not immune compromised occurred in 1969 between HLA-matched siblings.⁸⁹ This success sparked an increase in HLA-matched sibling transplants, with studies published in 1975 and 1977 describing the use of HSC transplants for hundreds of patients and reporting a number of survivors, including long-term survivors.⁹⁰

By the early 1970s, the importance of HLA matching for transplants was known.⁹¹ Although up until this time HSC transplants had only been attempted between siblings, the feasibility of using transplants from unrelated HLA matched donors started being discussed.⁹² In 1970, a group of doctors in the Netherlands proposed the creation of a Europe-wide file of potential donors to match recipients and thereby facilitate unrelated HSC transplants.⁹³ In 1974, the mother of a young patient in need of an HSC transplant established the Anthony Nolan Bone Marrow Registry (ANBMR) in England, which was dedicated to recruiting and maintaining a file of volunteers and cataloging the information so that it could easily be determined whether a potential donor's type matched that of a patient in

88. Thomas, *supra* note 80, at 5 (explaining that this transplant used bone marrow from a sibling); van Rood & Oudshoorn, *supra* note 40, at 1. The first successful transplant was soon followed by two others where the recipients were immunocompromised. Horowitz, *supra* note 16, at 15.

89. Thomas, *supra* note 80, at 5 (explaining that the recipient had chronic myelogenous leukemia, was irradiated before the transplantation, only got mild GVHD, and died fifty-six days after transplant).

90. *Id.* at 5–6 (citing E. D. Thomas et al., *Bone-Marrow Transplantation*, 292 NEW ENG. J. MED. 832 (1975); E. D. Thomas et al., *One Hundred Patients with Acute Leukemia Treated by Chemotherapy, Total Body Irradiation, and Allogeneic Marrow Transplantation*, 49 BLOOD 511 (1977)).

91. Thomas, *supra* note 80, at 5.

92. *Id.* By 1970, eleven forms of HLA-A had been described. Mickelson & Petersdorf, *supra* note 87, at 151.

93. Brian London, *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*, 24 TEMP. INT'L & COMP. L.J. 477, 478 (2010); Oudshoorn et al., *supra* note 37, at 405 ("The idea of a European donor registry did not materialize but it developed into the Dutch unrelated hematopoietic stem cell donor registry called Eurodonor . . ."); van Rood & Oudshoorn, *supra* note 40, at 1.

need of a transplant.⁹⁴ Despite these efforts and the success of transplants involving HLA matched siblings, facilitating unrelated transplants proved to be difficult due to the limited number of HLA-typed donors in registries and the diversity of HLA.

Although there are anecdotal reports of successful HSC transplants using unrelated HLA-matched donors as early as 1973,⁹⁵ the first successful HSC transplant to be reported in a clinical journal occurred in 1979.⁹⁶ Further success at matching unrelated donors and recipients occurred, and by 1986 the ANBMR had facilitated fourteen HSC transplants.⁹⁷ In 1987, the United States followed Europe's example, and founded the National Bone Marrow Donor Registry as a cooperative effort of the American Red Cross, Council of Community Blood Centers, and United States Navy to facilitate voluntary, unrelated donor marrow transplants.⁹⁸ One year later, individuals from the United States, London, and the Netherlands organized the Cooperative Marrow Donor Program to establish guidelines and promote transplants between donors and patients in different countries.⁹⁹ This organization created the Bone Marrow Donors Worldwide (BMDW) international registry and served as the impetus for the founding of the World Marrow Donor Association (WMDA) in 1994.¹⁰⁰ Unrelated donor

94. See Confer et al., *supra* note 44, at 545; Oudshoorn et al., *supra* note 37, at 405 (“[T]he Anthony Nolan Trust . . . was the first active bone marrow donor registry.”); Petersdorf, *supra* note 37, at 807 (explaining that Shirley Nolan’s son, Anthony, was diagnosed with Wiskott-Aldrich Syndrome for which transplantation was the only known cure); *Our History*, ANTHONY NOLAN REGISTRY, <http://www.anthonynolan.org/about-us/our-history> (last visited Oct. 4, 2014) [hereinafter ANTHONY NOLAN REGISTRY].

95. Horowitz, *supra* note 16, at 18 nn.1–2; ANTHONY NOLAN REGISTRY, *supra* note 94.

96. Thomas, *supra* note 80, at 6 (citing J. A. Hansen et al., *Transplantation of Marrow from an Unrelated Donor to a Patient with Acute Leukemia*, 303 NEW ENG. J. MED. 565, 565–67 (1980)) (“Quite by chance, it was observed that one of the hematology technicians had an HLA type that matched the patient.”).

97. ANTHONY NOLAN REGISTRY, *supra* note 94.

98. Warkentin & Shpall, *supra* note 43, at 542.

99. See Petersdorf, *supra* note 37, at 807. In 1988, there were eight active registries with about 150,000 donors around the world. van Rood & Oudshoorn, *supra* note 40, at 1–2.

100. See Petersdorf, *supra* note 37, at 807.

registries across the world collaborate through the WMDA to facilitate the international exchange of HSCs for transplant.¹⁰¹

Historically, the primary source of HSCs for transplant was bone marrow, although HSCs were also known to be present in umbilical cord blood as well as in the peripheral blood of adults.¹⁰² Cord blood was first used as a source of HSCs for transplant in 1988, when a sibling's cord blood was successfully transplanted and reestablished hematopoiesis in a child with Fanconi's anemia.¹⁰³ The success of this transplant prompted the opening of the first public cord bank in 1991, which was followed by numerous other cord blood banks opening around the world.¹⁰⁴ Public cord blood banks facilitated the first unrelated donor HSC transplant using cord blood in 1996.¹⁰⁵ The use of cord blood has steadily increased such that

101. Confer et al., *supra* note 44, at 545; Petersdorf, *supra* note 37, at 807; BONE MARROW DONORS WORLDWIDE, ANNUAL REPORT 2012 (2013), available at <http://www.bmdw.org/uploads/media/BMDW2012.pdf> (providing a list of HLA phenotypes and other relevant data of unrelated volunteer HSC donors; participants pay an operation fee to have data files uploaded into BMDW).

102. NAT'L INSTS. OF HEALTH, U.S. DEP'T OF HEALTH & HUMAN SERVS., STEM CELL INFORMATION: HEMATOPOIETIC STEM CELLS (2001), available at <http://stemcells.nih.gov/info/scireport/pages/chapter5.aspx>. The presence of HSCs in the peripheral blood capable of reestablishing hematopoiesis in mice was shown in the early 1960s. See Armitage, *supra* note 16, at 9; Schmitz, *supra* note 62, at 618. The existence of HSCs in the peripheral blood was postulated as early as 1909. Schmitz, *supra* note 62, at 618 (citing A. Maximow, *Der Lymphozyt als gemeinsame Stammzelle der verschiedenen Blutelemente in der embryonalen Entwicklung und im postfetalen Leben der Säugetiere*, 8 FOLIA HAEMAT 125 (1909) (Ger.)). The idea of using HSCs from umbilical cord blood for transplantation was first proposed in 1982. Broxmeyer & Smith, *supra* note 51, at 559.

103. Ballen et al., *supra* note 37, at 492–93 (explaining that the sibling whose cord blood was used underwent prenatal diagnosis of not having Fanconi's anemia and was HLA matched, and twenty-five years later the patient was healthy).

104. Carlo Petrini, *Ethical Issues in Umbilical Cord Blood Banking: A Comparative Analysis of Documents from National and International Institutions*, 53 TRANSFUSION 902, 902 (2013) (“[T]he New York Blood Center was established as the first public [cord blood] bank . . .”).

105. Ballen et al., *supra* note 37, at 493 (citing J. Kurtzberg et al., *Placental Blood as a Source of Hematopoietic Stem Cells for Transplantation into Unrelated Recipients*, 335 NEW ENG. J. MED. 157 (1996)).

in 2012, twenty percent of unrelated HSC transplants occurring through the United States registry use cord blood.¹⁰⁶

Despite initial concerns that HSCs collected from peripheral blood would result in a greater likelihood of GVHD due to higher levels of T-cells in the sample, multiple studies published in 1995 reported acceptable levels of GVHD.¹⁰⁷ The use of HSCs from peripheral blood rapidly increased following these studies and in 2012, sixty percent of unrelated HSC transplants occurring through the United States registry used HSCs collected from peripheral blood.¹⁰⁸

Advances in molecular biology and genetics in the 1980s and 1990s resulted in significant enhancements in HLA matching.¹⁰⁹ In the early 1970s, scientists were only testing for one form of HLA.¹¹⁰ In the 1980s, antigen testing had increased to three HLA forms.¹¹¹ By the 1990s, precise DNA matching was being used to match five HLA forms.¹¹²

Unlike in the past, where HSC transplants were thought of as desperate measures to treat advanced disease, HSC transplants are often used as the first or second line of therapy for many conditions today.¹¹³ Moreover, instead of HSCs primarily being obtained from bone marrow, transplants today use HSCs from a variety of sources.¹¹⁴ Furthermore, the

106. *Donor Registry Data*, *supra* note 2 (showing that in 2012 HRSA recorded transplants using the following HSC sources: 1150 using bone marrow, 3492 using peripheral blood, and 1191 using cord blood).

107. See Horowitz, *supra* note 16, at 18; Schmitz, *supra* note 62, at 622 (citing W. I. Bensinger et al., *Transplantation of Allogeneic Peripheral Blood Stem Cells Mobilized by Recombinant Human Granulocyte Colony-Stimulating Factor*, 85 BLOOD 1655 (1995); M. Körbling et al., *Allogeneic Blood Stem Cell Transplantation for Refractory Leukemia and Lymphoma: Potential Advantage of Blood over Marrow Allografts*, 85 BLOOD 1659 (1995); N. Schmitz et al., *Primary Transplantation of Allogeneic Peripheral Blood Progenitor Cells Mobilized by Filgrastim (Granulocyte Colony-Stimulating Factor)*, 85 BLOOD 1666 (1995)).

108. Horowitz, *supra* note 16, at 18; Schmitz, *supra* note 62, at 618; *Donor Registry Data*, *supra* note 2.

109. See Mickelson & Petersdorf, *supra* note 87, at 151–53.

110. See *id.* at 151, 157.

111. *Id.*

112. *Id.*

113. Horowitz, *supra* note 16, at 17 (explaining that in the 1970s 60% of HSC transplants involved patients with advanced disease, whereas in 2006 only 20% of such patients had advanced disease).

114. See *supra* notes 106, 108 and accompanying text.

sharing of HSC across international borders as facilitated by WMDA has also been a success. In 2008, forty-four percent of HSC transplants in the world involved HSCs crossing international borders.¹¹⁵ Despite this international exchange and the improving likelihood of finding matched HSC donors, many patients are unable to find a matching donor.¹¹⁶

C. THE ADMINISTRATIVE SYSTEM FOR UNRELATED HSC DONATIONS IN THE UNITED STATES

The HRSA, an agency of the U.S. Department of Health and Human Services (HHS), is responsible for the C.W. Bill Young Cell Transplantation Program, which includes a registry of HSC donors as well as a national inventory of cord blood.¹¹⁷ HRSA administers the transplantation program through contracts with nonprofit organizations.¹¹⁸ The National Marrow Donor Program (NMDP) holds three of these contracts with HRSA through which it is responsible for coordinating transplants of HSCs from bone marrow, peripheral blood, and cord blood, as well as administering the electronic database to match donors and recipients.¹¹⁹ NMDP contracts with third party organizations and health practitioners to recruit donors, coordinate the transplants, and perform medical services including testing of donors and retrieving HSCs.¹²⁰ NMDP also operates Be the Match, which provides support for patients and

115. L. M. Foeken et al., *Monitoring the International Use of Unrelated Donors for Transplantation: The WMDA Annual Reports*, 45 BONE MARROW TRANSPLANTATION 811, 818 (2010).

116. *Id.* at 817–18; *Need for More Donors*, *supra* note 2.

117. *About the Program*, HEALTH RESOURCES & SERVS. ADMIN., <http://bloodcell.transplant.hrsa.gov/about/index.html> (last visited Oct. 14, 2014).

118. *Program Contractors*, HEALTH RESOURCES & SERVS. ADMIN., <http://bloodcell.transplant.hrsa.gov/about/contractors/index.html> (last visited Oct. 14, 2014).

119. *Legislation & Contracts*, HEALTH RESOURCES & SERVS. ADMIN., http://bloodcell.transplant.hrsa.gov/about/legislation_and_contracts/index.html (last visited Oct. 14, 2014); *Program Contractors*, *supra* note 118.

120. NAT'L MARROW DONOR PROGRAM & SUBSIDIARY, CONSOLIDATED FINANCIAL STATEMENTS AND ADDITIONAL CONSOLIDATING INFORMATION AS OF AND FOR THE YEARS ENDING SEPTEMBER 30, 2013 AND 2012, AND INDEPENDENT AUDITORS' REPORT 8–10 (2014), *available at* <http://bethematch.org/WorkArea/DownloadAsset.aspx?id=1928>.

recruits people to join the Be the Match Registry.¹²¹ The Be the Match Foundation provides financial support for patients struggling with uninsured transplant costs.¹²²

Prior to 1986, there was no national bone marrow registry in the United States and only around 10,000 individuals had been HLA-typed.¹²³ In 1984, Congress directed the Secretary of HHS to hold a conference on the feasibility of establishing a national registry for bone marrow transplants.¹²⁴ The technology assessment panel recommended against funding a national registry, as did the Secretary of HHS.¹²⁵ Congress then directed the Navy Medical Research Institute to begin a registry on its own.¹²⁶ In 1987, the National Bone Marrow Donor Registry was established, began operating, and conducted its first transplant.¹²⁷ The registry was administered under a government contract by the Red Cross.¹²⁸ In 1988, HHS took over responsibility for the registry and the program name was changed to the NMDP.¹²⁹

121. *Id.*

122. *Id.*

123. Conference Report, Nat'l Insts. of Health Consensus Dev. Program, Donor Registries for Bone Marrow Transplantation (May 13–15, 1985), <http://consensus.nih.gov/1985/1985bonemarrowregistriesta002html.htm>.

124. National Organ Transplant Act of 1984, Pub. L. No. 98-507, 98 Stat. 2339, 2347.

125. Anderson, *supra* note 32, at 485 n.25 (citing 132 CONG. REC. S6280 (daily ed. May 21, 1986)); Conference Report, *supra* note 123.

126. Anderson *supra* note 32, at 485 n.25 (citing S. REP. NO. 101-530, at 15 (2d Sess. 1990), *reprinted in* U.S.C.C.A.N. 4625, 4634 WL 201779).

127. *About Us*, BE THE MATCH, <http://bethematch.org/About-Us/Our-story/> (last visited Oct. 14, 2014); Jane E. Brody, *New Registry Is Raising Hope for Those in Need of Bone Marrow*, N.Y. TIMES, Jan. 12, 1988, at C6 (reporting that a six-year-old with rapidly progressing leukemia was the national registry's first beneficiary).

128. COMM. ON ESTABLISHING A NAT'L CORD BLOOD STEM CELL BANK PROGRAM, INST. OF MED., CORD BLOOD: ESTABLISHING A NATIONAL HEMATOPOIETIC STEM CELL BANK PROGRAM 24 (Emily Ann Meyer et al. eds., 2005); *National Bone Marrow Registry Is Seeking Donors*, N.Y. TIMES, Oct. 13, 1987, at C12.

129. COMM. ON ESTABLISHING A NAT'L CORD BLOOD STEM CELL BANK PROGRAM, INST. OF MED., *supra* note 128, at 4–5; Organ Transplant Amendments of 1988, Pub. L. No. 100-607, 102 Stat. 3116 (1988) (explaining that HHS is to administer the registry). The Naval Medical Research Center retained and still operates the portion of the registry pertaining to the military community. H.R. REP. NO. 112-110, at 232 (2012) (“Department of Defense [donor center] volunteers and provides more marrow donors per week

In 1990, the NMDP became a separate nonprofit organization and took over administration from the Red Cross; additionally, Congress established requirements for the operation of the registry and consolidated all registries in the country.¹³⁰ Although the NMDP was originally established to match donors of HSCs from bone marrow, it expanded its scope to cover cord blood banks in 1998 and to offer HSCs from peripheral blood in 1999.¹³¹

The National Cord Blood Inventory program (NCBI), established in 2005, provides federal funding to support the banking of diverse and high quality, publicly available cord blood units.¹³² Cord blood banks funded through the NCBI must list the units collected with government subsidy on the registry operated by the NMDP.¹³³

II. REGULATION OF THE SALE OF HSCS

There are multiple laws, regulations, and rules that affect HSC donor compensation. Federal law currently only prohibits the sale of HSCs from bone marrow for transplant where the transaction affects interstate commerce.¹³⁴ A quarter of the states have prohibited the sale of bone marrow,¹³⁵ while only

than any other donor center in the Nation.”); *Bone Marrow Registry*, NAVAL MED. RES. CENTER, http://www.med.navy.mil/sites/nmrc/Pages/bmr_main.htm (last visited Oct. 4, 2014).

130. Transplant Amendments Act of 1990, Pub. L. No. 101-616, § 101, 104 Stat. 3279; COMM. ON ESTABLISHING A NAT'L CORD BLOOD STEM CELL BANK PROGRAM, INST. OF MED., *supra* note 128.

131. U.S. GEN. ACCOUNTING OFFICE, REPORT TO CONGRESSIONAL COMMITTEES, GAO-03-182, BONE MARROW TRANSPLANTS: DESPITE RECRUITMENT SUCCESSES, NATIONAL PROGRAM MAY BE UNDERUTILIZED 6 (2002), *available at* <http://www.gao.gov/new.items/d03182.pdf>.

132. Stem Cell Therapeutic and Research Act of 2005, Pub. L. No. 109-129, 119 Stat. 2250; U.S. GOV'T ACCOUNTABILITY OFFICE, GAO-12-23, NATIONAL CORD BLOOD INVENTORY: PRACTICES FOR INCREASING AVAILABILITY FOR TRANSPLANTS AND RELATED CHALLENGES 1-2 (2011), *available at* <http://gao.gov/assets/590/585682.pdf>.

133. U.S. GOV'T ACCOUNTABILITY OFFICE, *supra* note 132, at 2-3.

134. National Organ Transplant Act of 1984, Pub. L. No. 98-507, 98 Stat. 2346 (codified as amended at 42 U.S.C. § 274e (2006)).

135. COLO. REV. STAT. §§ 12-34-102(18), 12-34-116 (2013); DEL. CODE ANN. tit. 16, §§ 2710(10), 2713(f) (2003); D.C. CODE § 7-1501.01 (2012 LexisNexis); GA. CODE ANN. § 16-12-160 (2011); 720 ILL. COMP. STAT. ANN. 5/12-20 (West Supp. 2013); IND. CODE ANN. § 35-46-5-1 (LexisNexis 2009); MICH. COMP. LAWS ANN. § 333.10204(1) (West 2012); N.Y. PUB. HEALTH LAW § 4307(1) (McKinney

Delaware prohibits the sale of HSCs from peripheral blood and cord blood.¹³⁶ National and international accreditation organizations also have policies impacting the sale of HSCs.¹³⁷

A. FEDERAL

1. National Organ Transplant Act (NOTA)

The primary focus of NOTA was to create a national system of solid organ procurement, allocation, and distribution in an effort to make organs more widely available and improve donor-recipient matching.¹³⁸ NOTA also contained a prohibition on the sale of organs for transplant providing: "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."¹³⁹

Bone marrow was not included in the initial version of the bill for NOTA when it was first introduced in the Senate, or in a similar bill previously introduced in the House.¹⁴⁰ Multiple hearings on organ transplantation were held; however, the only mention of adding bone marrow to the definition of "human organ" was in two letters read by the House Committee on Ways and Means.¹⁴¹ In both letters the writing physicians cited

2009); TENN. CODE ANN. §§ 68-30-102(17), 68-30-401 (LexisNexis 2013); TEX. PENAL CODE ANN. § 48.02(a) (West 2011); VA. CODE ANN. § 32.1-291.16 (West 2011); W. VA. CODE ANN. §§ 16-19-3(21), 16-19-16 (LexisNexis 2011); WIS. STAT. ANN. § 146.345 (West 2006).

136. DEL. CODE ANN. tit. 16, §§ 2710(10), 2713(f) (2003).

137. See *infra* Part II.C.

138. See National Organ Transplant Act of 1984, Pub. L. No. 98-507, 98 Stat. 2339, 3975, 3977; Harry Hansmann, *The Economics and Ethics of Markets for Human Organs*, 14 J. HEALTH POL. POL'Y & L. 57, 59 (1989); John A. Sten, *Rethinking the National Organ Transplant Program: When Push Comes to Shove*, 11 J. CONTEMP. HEALTH L. & POL'Y 197, 206 (1994). HHS became responsible for the program of organ allocation and distribution in a nationwide system for matching donors and recipients, while regional organizations were created to locate potential donors and coordinate the acquisition and transport of organs. See 42 U.S.C. § 274(a)-(b) (2012).

139. National Organ Transplant Act § 301.

140. Organ Procurement and Transplantation Act, S. 2048, 98th Cong. (1983) (as introduced Nov. 3, 1983); Organ Procurement and Transplantation Act, H.R. 4080, 98th Cong. (1983) (as introduced Oct. 5, 1983).

141. *National Organ Transplant Act: Hearing on H.R. 4080 Before the H. Subcomm. on Health of the House Comm. on Ways and Means*, 98th Cong. 171

the need for a national system for matching bone marrow donors and requesting that bone marrow be added to the definition of human organ.¹⁴² Although one letter did mention the need to prevent patients from offering large sums of money to potential donors, both seemed to advocate the addition of bone marrow to the definition of human organ in order to seek federal funding for a national registry to match bone marrow donors.¹⁴³

The Senate report from the Committee on Labor and Human Resources recommended adding bone marrow to the definition of human organ in S. 2048.¹⁴⁴ Although the report did not discuss the reasons for the addition, it provided some insight into the committee's rationale, stating: "It is the sense of the Committee that individuals or organizations should not profit by the sale of human organs for transplantation. This is not meant to include blood and blood derivatives, which can be replenished and whose donation does not compromise the health of the donor."¹⁴⁵ The final version of NOTA included bone marrow in the definition of human organ as well as funding for studying the feasibility of a national registry for HSC transplants.¹⁴⁶ Since its enactment, two amendments have been made to the definition of "human organ" in NOTA;¹⁴⁷

(1984) [hereinafter Braine Letter] (letter of Hayden G. Braine, Director, John Hopkins Oncology Center); *id.* at 170–71 [hereinafter Owens Letter] (letter of Albert H. Owens, Director, John Hopkins Oncology Center).

142. See *supra* note 141 and accompanying text.

143. Braine Letter, *supra* note 141 ("Fiscal support such as envisioned in H.R. 4080 would greatly accelerate this process and remove marrow donation from commercialism."); Owens Letter, *supra* note 141 ("It will be especially helpful to have a network which will facilitate the prompt distribution of organs to patients in desperate need A national registry of tissue typed donors and a distribution network would aid immeasurably in treating afflicted individuals effectively.")

144. S. REP. NO. 98-382, at 13, 16–17 (1984).

145. *Id.*

146. 42 U.S.C § 274e(c)(1) (2012). This feasibility study recommended against a national marrow registry. See H.R. REP. NO. 98-1127, at 7, 8 (1984) (Conf. Rep.); 130 CONG. REC. H11,087, H11,087–88 (daily ed. Oct. 3, 1984) (statement of Rep. Waxman) (showing that funding for the study of a national registry of volunteer bone marrow donors was added to S. 2048 by an October 1984 conference report); *supra* notes 124–26.

147. Health Omnibus Extension of 1988, Pub. L. No. 100-607, §§ 401–08, 102 Stat. 3048 (amending 42 U.S.C § 274e(c)(1) to include any subpart of any listed organ as well as fetal organs and subparts thereof in the definition of

additionally, HHS has recently proposed another amendment to include all HSCs under the definition.¹⁴⁸

NOTA contains limited exceptions to the definition of valuable consideration. Organ donors may be reimbursed for the “expenses of travel, housing, and lost wages incurred by the donor of a human organ in connection with the donation of the organ.”¹⁴⁹ Additionally, there are exceptions for “reasonable payments associated with the removal, transportation, implantation, processing, preservation, quality control, and storage of a human organ.”¹⁵⁰ Thus, physicians, hospitals, and other organizations involved in the retrieval and transplant process are permitted to be compensated and earn a profit.¹⁵¹

It is generally accepted that the prohibition in NOTA does not apply to blood, semen, or ova.¹⁵² Congress’ intent to exclude blood and blood products is evident in multiple reports including a conference report, which stated that, “[t]he term ‘human organ’ is not intended to include replenishable tissues such as blood or sperm.”¹⁵³ As a result, donors of blood products are not prohibited by federal law from receiving valuable consideration in exchange for their donation.¹⁵⁴

As detailed above, HSCs to be used for transplant may be obtained from bone marrow, cord blood, or peripheral blood.¹⁵⁵ HSCs from bone marrow involve the collection and transfer of

human organ); Organ Procurement and Transplantation Network, 78 Fed. Reg. 40,033 (July 3, 2013) (to be codified at 42 C.F.R. pt. 121) (amending the definition of organs, effective July 3, 2014, to include vascularized composite allografts, such as tissue with blood vessels, like hands).

148. See Change to the Definition of “Human Organ,” *supra* note 7, at 60,810–12; see also *infra* text accompanying notes 161–62.

149. 42 U.S.C. § 274e(c)(2). In 2004, an amendment to NOTA established a grant program for the reimbursement of travel and subsistence expenses incurred by individuals making living donations. Organ Donation and Recovery Improvement Act, Pub. L. No. 108-216, § 3, 118 Stat. 584 (2004) (codified at 42 U.S.C. § 274f).

150. 42 U.S.C. § 274e(c)(2).

151. See *infra* text accompanying notes 252–56 (discussing how Be the Match spends a considerable amount of money paying for medical services).

152. See *supra* text accompanying notes 144–45.

153. H.R. REP. NO. 98-1127, at 16 (1984) (Conf. Rep.); see also *supra* note 144 (identifying blood and blood derivatives as separate from the definition of organs because they can be replenished).

154. Blood donations for transplantation are regulated by the FDA. See *infra* Part II.A.2.

155. See *supra* notes 43–53 and accompanying text.

bone marrow, and will thus fall under the definition of human organ in NOTA and cannot be transferred in exchange for valuable consideration.¹⁵⁶ However, HSCs from peripheral blood and cord blood do not involve the transfer of any body part contained in the current definition of human organ in NOTA as they merely involve the donation of blood.¹⁵⁷ The Ninth Circuit Court in *Flynn v. Holder*¹⁵⁸ held that HSCs collected from peripheral blood did not fall under the definition of bone marrow or human organ in NOTA;¹⁵⁹ as a result, NOTA does not criminalize compensating donors who donate HSCs by peripheral blood apheresis.¹⁶⁰ As HSCs obtained from cord blood also do not involve the donation of bone marrow, one can intimate that a court would also find that they do not fall under the definition of human organ in NOTA.

In response to the Ninth Circuit Court decision in *Flynn*, HHS has proposed to amend the definition of human organ in NOTA to include “bone marrow and other hematopoietic stem/progenitor cells without regard to the method of their collection.”¹⁶¹ If this proposed rule is accepted, all HSCs will fall under the NOTA prohibition regardless of their method of collection.¹⁶² In its proposed rule, HHS purports to justify the change based on the need to: prevent economic exploitation of recipients, uphold the Congressional intent to ban commodification of HSCs, curb coercion and exploitation, encourage altruistic donation, and decrease the likelihood of disease transmission.¹⁶³

2. U.S. Food and Drug Administration (FDA)

The FDA regulates human cells intended for transplant into a human recipient as human cells, tissues, and cellular

156. See National Organ Transplant Act of 1984, Pub. L. No. 98-507, 98 Stat. 2339, 2346–47 (codified as amended at 42 U.S.C. § 274e (2012)).

157. See *id.*

158. *Flynn v. Holder*, 684 F.3d 852 (9th Cir. 2012).

159. *Id.* at 865.

160. *Id.* at 864–65.

161. Change to the Definition of “Human Organ,” *supra* note 7, at 60,811–12.

162. *Id.* at 60,812.

163. *Id.* at 60,811–12.

based products (HCT/Ps).¹⁶⁴ HSCs derived from peripheral and cord blood are regulated as HCT/Ps.¹⁶⁵ However, it is unclear whether HSCs derived from bone marrow fall under the FDA's HCT/Ps regulations. Even though HHS and the Organ Procurement and Transplantation Network (OPTN) have taken the position that body parts meeting the definition of "human organ" in NOTA are automatically excluded from FDA HCT/Ps regulations, this position is not supported by the FDA regulations which broadly define HCT/Ps and only expressly exclude "vascularized human organs"—not the NOTA definition of "human organ."¹⁶⁶ Moreover, as FDA HCT/Ps regulations specifically exclude "minimally manipulated bone marrow for homologous use" from the definition of HCT/Ps, one logical inference from this specific exclusion is that all other bone marrow falls under the regulations.¹⁶⁷

FDA regulations govern the eligibility of donors of HCT/Ps, and set out screening and testing requirements; however, exceptions to some testing requirements may be obtained in cases of urgent need.¹⁶⁸ The FDA does not impose any restrictions on donors receiving compensation in exchange for HCT/P donations, nor does it impose any labeling requirements on the products.¹⁶⁹

164. 21 C.F.R. §§ 1270, 1271 (2014).

165. 21 C.F.R. § 1271.3(d)(2).

166. 21 C.F.R. § 1270.3(j)(4); 21 C.F.R. § 1271.3(d)(2)(i); 78 Fed. Reg. 40,033, 40,034 (July 3, 2013) (to be codified at 42 C.F.R. pt. 121) ("Once a body part is defined as an organ under the OPTN final rule, such body parts are excluded from the coverage of FDA regulations governing HCT/Ps, 21 CFR § 1271.3(d)(1).").

167. 21 C.F.R. § 1271.3(d)(2)(iv).

168. 21 C.F.R. § 1271.60(d)(1). The FDA has a mechanism for collecting human cellular products from ineligible donors where the transplant physician determined there is an "urgent medical need," such as where a suitable donor or graft source is not readily available and the risks of alternative therapies are greater than the risks of proceeding with an ineligible donor. 21 C.F.R. §§ 1271.60(d), 1271.65(b); Confer et al., *supra* note 44, at 546; *see* Lown & Shaw, *supra* note 4, at 213 ("[I]n practice use of [HSCs] from such donors may be permitted, including imports from the United Kingdom.").

169. *See* 21 C.F.R. § 1271.

Whole blood and blood components are regulated by the FDA in a process separate from the regulation of HCT/Ps.¹⁷⁰ FDA regulations require that blood, to be used in transfusion, be labeled indicating whether it was collected from a paid or voluntary donor.¹⁷¹ The labeling requirements do not prohibit the sale of blood.¹⁷² Furthermore, even donors who receive valuable consideration in the form of rewards may still be categorized as a “voluntary donor” as long as the reward is not a monetary payment.¹⁷³

B. STATE LAWS

Although states have jurisdiction to regulate the sale of HSCs within their borders, few have chosen to exercise such jurisdiction.¹⁷⁴ States began enacting laws prohibiting the sale of bodies in the 1960s.¹⁷⁵ However, the laws that were enacted

170. 21 C.F.R. § 1271.3(d)(2) (excluding blood from the definition of HCT/Ps).

171. 21 C.F.R. § 606.121(c)(8)(v) (1994) (applying to whole blood or fresh frozen plasma). The practice of paying for plasma and not whole blood in the United States may in part be explained by the fact that labeling requirements, indicating a donor’s status as paid or unpaid, do not apply to blood products that will not be used for transfusion such as source plasma to be processed into plasma products. See 21 C.F.R. § 606.121(c)(8)(v); *CPG sec. 230.150 Blood Donor Classification Statement, Paid or Volunteer Donor*, U.S. FOOD & DRUG ADMIN., <http://www.fda.gov/ICECI/ComplianceManuals/CompliancePolicyGuidanceManual/ucm122798.htm>, (last updated Sept. 18, 2014).

172. 21 C.F.R. § 1271 (providing no explicit ban or criminal provision for sales inconsistent with requirements).

173. 21 C.F.R. § 606.121(c)(8)(v)(B)–(C) (“(B) A volunteer donor is a person who does not receive monetary payment for a blood donation. (C) Benefits, such as time off from work, membership in blood assurance programs, and cancellation of nonreplacement fees that are not readily convertible to cash, do not constitute monetary payment within the meaning of this paragraph.”); *CPG sec. 230.150 Blood Donor Classification Statement, Paid or Volunteer Donor*, *supra* note 171 (listing incentives that are generally not transferable and would therefore not require a “paid donor” label: product promotional CDs, frequent flyer miles, medical tests performed at the same time as donation such as cholesterol screenings, scholarships where the money goes directly to the school, and gift cards and gift certificates bearing the donor’s name).

174. See Warkentin & Shpall, *supra* note 43, at 536 (describing the few state regulatory schemes for human cellular therapy).

175. From 1961 to 1968, six states (Delaware, Hawaii, Maryland, Massachusetts, Nevada, and New York) enacted legislation prohibiting the receipt of compensation in exchange for the distribution of one’s body after death. See *infra* note 176 and accompanying text.

in 1968 and earlier, prohibiting individuals from receiving compensation for directing the distribution of their body after death, would not have affected the sale of HSCs for transplant as they did not apply to the sale of living body parts.¹⁷⁶ The National Commission on Uniform State Laws subsequently drafted the Uniform Anatomical Gift Act (UAGA) of 1968, which set out procedures to donate one's organs for transplant after death.¹⁷⁷ The 1968 UAGA did not prohibit the purchase and sale of organs,¹⁷⁸ and was enacted by all fifty states and the District of Columbia.¹⁷⁹ All of the states that already had legislation prohibiting individuals from receiving compensation in exchange for organs repealed such legislation when they enacted the 1968 UAGA.¹⁸⁰ Delaware was the only state that reenacted a provision prohibiting compensation in exchange for body parts for transplant within their version of the 1968 UAGA.¹⁸¹

176. Act of Aug. 1, 1968, ch. 429, § 1780(b), 56 Del. Laws 1773 (repealed 1970) ("A person who so directs the manner in which his body shall be disposed of after death shall receive no remuneration or other thing of value for such disposition."); Act of May 20, 1967, Act 94, § 50F-1, 1967 Haw. Sess. Laws 91 (repealed 1969) ("Every person . . . may provide for the disposition of his body after death . . . provided that no person shall receive remuneration or anything of value for such disposition of his body."); Act of Apr. 24, 1961, ch. 315, § 149(b), 1961 Md. Laws 397, 398 (repealed 1968) (voiding an instrument directing the disposition of organs after death "if obtained for a monetary consideration"); Act of June 12, 1967, ch. 353, 1967 Mass. Acts 202 (repealed 1971) (prohibiting payment of compensation for an anatomical gift); Act of Apr. 9, 1963, ch. 293 § 11, 1963 Nev. Stat. 532 (repealed 1969) (prohibiting the anatomical committee from entering into any contract where any sum of money is paid to a living person in exchange for the person's body when they die); Law of Apr. 22, 1964, ch. 702, § 4201(2), 1964 N.Y. Sess. Laws 1117 (McKinney) (repealed 1970) (prohibiting remuneration for distribution after death).

177. UNIF. ANATOMICAL GIFT ACT (1968) § 4, 8A U.L.A. 129 (2014).

178. UNIF. ANATOMICAL GIFT ACT (1968) § 3, 8A U.L.A. 126 cmt. para. 3 ("The statutes in a few states specify that no donor shall ask compensation and no donee shall receive it On the other hand, most of the states seemingly are not concerned over the profit motive and no mention is made of it. The Uniform Act follows the latter course in this regard.")

179. Sten, *supra* note 138, at 205 (stating that all fifty states and the District of Columbia had enacted the 1968 Uniform Act by 1973).

180. See *supra* note 176.

181. Act of May 20, 1970, ch. 445, § 1783(f), 57 Del. Laws 1252 (1970); Susan Hankin Denise, *Regulating the Sale of Human Organs*, 71 VA. L. REV. 1015, 1023 n.82 (1985) ("Delaware was alone in adding a sales prohibition to its version of the Uniform Anatomical Gift Act.")

Unlike the 1968 UAGA, the following two UAGAs, released in 1987 and 2006, prohibited the purchase and sale of organs for transplant.¹⁸² Unlike NOTA, where the federal prohibition applies evenly across the country, many current state prohibitions vary from the UAGA's and differ state to state.¹⁸³ State laws vary in prohibiting compensation for HSCs obtained from different sources, such as bone marrow, peripheral blood, or cord blood.¹⁸⁴ Every state, except Maine, has legislation prohibiting the sale of a type of body part (most commonly solid organs); however, only a few states have prohibitions that prevent the exchange of HSCs for compensation.¹⁸⁵ The only state to prohibit the sale of HSCs from peripheral blood and cord blood is Delaware.¹⁸⁶ Legislation in twelve states (Colorado, Delaware, Georgia, Illinois, Indiana, Michigan, New York, Tennessee, Texas, Virginia, West Virginia, and Wisconsin) and the District of Columbia prohibit the exchange of compensation for HSCs collected from bone marrow.¹⁸⁷

C. ACCREDITING ORGANIZATIONS AND REGISTRY REQUIREMENTS

International collaboration in the area of HSC transplantation has been historically important and continues to be important today.¹⁸⁸ The ability to utilize HSCs from an international pool of donors has increased the probability of a

182. UNIF. ANATOMICAL GIFT ACT (1987) § 10(a), 8A U.L.A. 62 (2014) (“A person may not knowingly, for valuable consideration, purchase or sell a part for transplantation or therapy, if removal of the part is intended to occur after the death of the decedent.”); REVISED UNIF. ANATOMICAL GIFT ACT (2006) § 16, 8A U.L.A. 133 (2014).

183. *See infra* Table 1.

184. *See infra* Table 1.

185. The prohibition against sale of tissue in thirty-four states only applies to tissue from parts that are collected after death. HSC collections only occur from living donors, thus, the prohibitions in those thirty-four states do not apply to HSCs. *See infra* Table 1.

186. DEL. CODE ANN. tit. 16, §§ 2710(10), 2713(f) (2003).

187. *See supra* note 135; *see also infra* Table 1.

188. A series of international meetings fostering international collaboration was imperative in historical advancements in HLA matching. *See* Mickelson & Petersdorf, *supra* note 87, at 145–46, 150–51. Potential pools of unrelated donors have been enlarged through international collaboration. *See* Confer et al., *supra* note 44, at 545; *see supra* notes 93, 99 and accompanying text.

patient finding a matching donor.¹⁸⁹ International matches are facilitated through BMDW, which requires participating registries to be accredited through inspection of the HSC source and to ensure they meet international standards.¹⁹⁰

The WMDA runs an accreditation program for HSC donor registries and accredits registries responsible for seventy-five percent of HSC donors and units accessible through BMDW.¹⁹¹ The WMDA largely does not promulgate specific standards for the operation of collection centers, but focuses on regulating the registry itself and requires that registries demonstrate the safety and effectiveness of activities, usually by requiring further accreditation from another organization.¹⁹² Organizations that accredit collection centers and other aspects of HSC donation are often regionally based; the Foundation for the Accreditation of Cellular Therapy (FACT) is based in the United States, and the Joint Accreditation Committee-International Society for Cellular Therapy and European Group for Blood and Marrow Transplantation (JACIE) is based in Europe.¹⁹³ FACT and JACIE collaborated to create international standards covering the collection, processing, and administration of HSCs and other cellular therapy products.¹⁹⁴

189. *OneMatch Information Package*, CAN. BLOOD SERVS., http://forms.blood.ca/CentreApps/Internet/UW_V502_MainEngine.nsf/printpageview/BD6A6071B47F336F852573670054AE78?OpenDocument (last visited Oct. 4, 2014).

190. *On Participation and Authorization*, BONE MARROW DONORS WORLDWIDE, http://www.bmdw.org/index.php?id=registry_info (last visited Sept. 29, 2014) (requiring adherence to WMDA standards, which include inspection).

191. *Standards and Accreditation*, WORLD MARROW DONOR ASS'N, <http://www.worldmarrow.org/index.php?id=488> (last visited Oct. 4, 2014) (requiring paper-based review and onsite inspection).

192. C. K. Hurley et al., *Standards, Regulations and Accreditation for Registries Involved in the Worldwide Exchange of Hematopoietic Stem Cell Donors and Products*, 45 BONE MARROW TRANSPLANTATION 819, 820 (2010).

193. Warkentin & Shpall, *supra* note 43, at 536–37, 539 (describing creation of FACT and JACIE and accreditation processes in different countries and regions).

194. *Id.* at 537; see FOUND. FOR THE ACCREDITATION OF CELLULAR THERAPY, UNIV. OF NEB. MED. CTR. & JOINT ACCREDITATION COMM. ISCT & EBMT, INTERNATIONAL STANDARDS FOR CELLULAR THERAPY PRODUCT COLLECTION, PROCESSING, AND ADMINISTRATION (5th ed. 2012), available at http://www.factwebsite.org/FACTWeb/Document_Library/Fifth_Edition_Cellular_Therapy_Standards_Version_5_3.aspx.

Additionally, NetCord, an association of umbilical cord banks, and FACT collaborated to provide international standards on cord blood.¹⁹⁵ Accreditation with the above-mentioned organizations is voluntary; in the United States, FACT accreditation is a factor in the U.S. News and World Report ranking of hospitals.¹⁹⁶

Some of the aforementioned organizations have standards involving the compensation of HSC donors. The WMDA lists donor rights, including that “[d]onors must not be paid for their donation but may be reimbursed for expenses incurred during the donation process, for example, time lost from work or travel to the collection centre.”¹⁹⁷ This provision, although arguably not much of a “right,” is similar to the prohibition and exception in NOTA, which only allows valuable consideration for donor expenses of travel, housing, and lost wages incurred in connection with the donation.¹⁹⁸ FACT-JACIE weighed in on the issue of compensation of donors in their guidance on the standards applicable to the collection of HSCs from peripheral blood and bone marrow stating that: “Clinical programs performing allogeneic transplantation should endeavor to receive only voluntary and unpaid donation of cells. Donors may receive compensation, which is strictly limited to making good the expenses and inconveniences related to the donation.”¹⁹⁹

195. See FOUND. FOR THE ACCREDITATION OF CELLULAR THERAPY, UNIV. OF NEB. MED. CTR., NETCORD-FACT INTERNATIONAL STANDARDS FOR CORD BLOOD COLLECTION, BANKING, AND RELEASE FOR ADMINISTRATION (5th ed. 2013) [hereinafter NETCORD & FACT], available at http://www.factweb.org/forms/store/ProductFormPublic/search?action=1&Product_productNumber=627.

196. *What FACT Accreditation Means to Patients and Their Families*, FACT, <http://www.factwebsite.org/Inner.aspx?id=351> (last visited Oct. 4, 2014).

197. WORLD MARROW DONOR ASS'N, INTERNATIONAL STANDARDS FOR UNRELATED HEMATOPOIETIC PROGENITOR CELL DONOR REGISTRIES, pt. B, § 3.03, at 11 (2014), available at <https://www.wmda.info/images/pdf/WMDAStandards.pdf>.

198. See 42 U.S.C. § 274e (2012).

199. INT'L STANDARDS FOR CELLULAR THERAPY PRODUCT COLLECTION, PROCESSING, AND ADMINISTRATION ACCREDITATION MANUAL, pt. B, § B6.1, explanation at 72 (FOUND. ACCRED. CELLULAR THERAPY, UNIV. NEB. MED. CTR. & JOINT ACCRED. COMM. ISCT & EBMT, 5th ed. version 5.3, 2012), available at http://www.factwebsite.org/uploadedFiles/FACT_News/Final%20Draft%205th%20Edition%20Accreditation%20Manual.04.18.11.pdf.

The FACT-JACIE guidance appears to permit donors to receive a greater amount of compensation or reimbursement than NOTA and WMDA by permitting the compensation of donors for inconveniences related to the donation.²⁰⁰ Unlike the FACT-JACIE guidance on the standards for HSCs, the NetCord-FACT International Standards for Cord Blood Collection, Banking, and Release for Administration do not contain any mention of donor compensation.²⁰¹

III. DONORS SHOULD BE PERMITTED TO RECEIVE COMPENSATION IN EXCHANGE FOR HSCS, REGARDLESS OF THE SOURCE OF THE HSCS

Currently, NOTA prohibits donors from receiving valuable consideration in exchange for HSCs obtained from bone marrow.²⁰² Additionally, a current proposed rule from HHS would expand the prohibition to include HSCs from any source, and would thus encompass HSCs obtained from peripheral blood as well as cord blood.²⁰³ Congress and HHS have put forth the following reasons for prohibiting compensation: (1) “human body parts should not be viewed as commodities;”²⁰⁴ (2) “individuals or organizations should not profit by the sale of human organs for transplantation;”²⁰⁵ (3) the altruistic donation of organs should be promoted;²⁰⁶ and (4) compensation would result in increased risks to donors and recipients.²⁰⁷ However, such a prohibition of compensating HSC donors cannot be justified on the basis of the aforementioned reasons.

200. Such payments for inconveniences could be significant. *Cf.* Ethics Comm. of the Am. Soc’y for Reprod. Med., *Financial Compensation of Oocyte Donors*, 88 FERTILITY & STERILITY 304, 308 (2007) (estimating payment of \$3360 to \$4200 to oocyte donors would reflect compensation for the hours spent in the clinic).

201. See NETCORD & FACT, *supra* note 195.

202. See 42 U.S.C. § 274e.

203. See Change to the Definition of “Human Organ,” *supra* note 7.

204. S. REP. NO. 98-382, at 17 (1984); Change to the Definition of “Human Organ,” *supra* note 7, at 60,812; see *supra* text accompanying note 145.

205. S. REP. NO. 98-382, at 16–17; see *supra* text accompanying note 145.

206. Change to the Definition of “Human Organ,” *supra* note 7, at 60,812.

207. S. REP. NO. 98-382, at 16–17.

A. PERMITTING HSC DONORS TO BE COMPENSATED WILL NOT CHANGE THE STATUS OF HSCS AS COMMODITIES

Commodity is a term that is used in a variety of ways. Economists define a commodity as a good that is interchangeable within a market as long as it meets certain minimum standards.²⁰⁸ Commodity is also defined in a more general way, in the Oxford English Dictionary as “[a] kind of thing produced for use or sale, an article of commerce, an object of trade.”²⁰⁹ Regardless of which definition we accept as that intended by Congress, permitting compensation for HSCs will not result in a change in HSCs being viewed and treated either as commodities or not as commodities.

The economic definition of commodity requires the good be fully or partially fungible—that is, that the good is interchangeable for other goods that meet similar quality standards and that the source of the good is largely irrelevant.²¹⁰ Examples of fungible goods include metals and petroleum.²¹¹ For example, as long as a metal meets certain purity standards, it is irrelevant where the metal was mined, processed, or sold.²¹² In terms of body parts, blood and blood products such as plasma are fungible goods.²¹³ Type-A blood that has met all of the requirements of the FDA is the same as any other approved Type-A blood on the market.²¹⁴ There is an active market for blood, and blood is viewed and treated as a commodity by those buying and selling.²¹⁵

208. STEPHEN WILKINSON, *BODIES FOR SALE: ETHICS AND EXPLOITATION IN THE HUMAN BODY TRADE* 46 (2003).

209. *Commodity*, OXFORD ENGLISH DICTIONARY, <http://www.oed.com/view/Entry/37205?redirectedFrom=commodity#eid> (last visited Jan. 17, 2015).

210. WILKINSON, *supra* note 208.

211. *See id.*

212. *See id.*

213. Anderson, *supra* note 32, at 478–79.

214. Breast milk is also likely treated as a commodity within the market, particularly breast milk that has been treated and is sold through a milk bank. It is arguable that breast milk that is sold directly from the producing mother is not undifferentiated due to the lack of quality controls. *See* Sarah E. Waldeck, *Encouraging a Market in Human Milk*, 11 COLUM. J. GENDER & L. 361, 385 (2002); ONLY THE BREAST, www.onlythebreast.com (last visited Oct. 4, 2014).

215. *See* Kieran Healey, *The Emergence of HIV in the U.S. Blood Supply: Organizations, Obligations, and the Management of Uncertainty*, 28 THEORY &

Solid human organs and tissue likely also meet the economic based definition of commodity. Prior to advances in immunosuppressants, a high level of HLA matching was required between donors and recipients of solid organs and tissues.²¹⁶ However, with the requirement for HLA matching reduced, solid organs are becoming increasingly interchangeable and are at least partially fungible and therefore commodities.²¹⁷ Even though there is no legal market for the sale of human organs from a donor, there is undoubtedly a market, albeit a highly regulated market, for human organs once they have been removed from donors.²¹⁸

Regardless of whether donors are legally allowed to receive compensation for HSC donations, it is unlikely that HSCs would ever be economic commodities due to the stringent need for HLA matching and lack of interchangeability of HSCs. The fact that the probability of finding a match in the general population exceeds 1 in 20,000 demonstrates that HSCs are not interchangeable, and would not meet the definition of commodity regardless of whether they were paid for or not.²¹⁹ Even though less stringency is required for the transplant of HSCs from cord blood than HSCs from other sources, it is still unlikely that such items would ever be considered to be interchangeable.²²⁰

A broader interpretation of the definition of commodity is often used wherein a commodity is defined as an “article of commerce” or something that is purchased and sold.²²¹ When referring to the commodification of human organs, legal academics often use a broad definition of commodity where a

SOC’Y 529, 530–31 (1999) (discussing policy shifts originating in the 1970s and acknowledging the implications of an active market in blood).

216. *Living Kidney Donation, Now . . . About Your Health*, LIVING DONORS ONLINE, <http://www.livingdonorsonline.org/kidney/kidney4.htm> (last visited Oct. 4, 2014).

217. TILNEY, *supra* note 76, at 244–45 (noting the growth and regularization of organ transplantation and clinics following success of chemical immunosuppression); *see infra* note 218 and accompanying text.

218. *Unrelated Donor: Procurement Costs*, BE THE MATCH (Jan. 2014), <https://payor.bethematchclinical.org/WorkArea/DownloadAsset.aspx?id=7502>; Sten, *supra* note 138, at 200–01.

219. Lown & Shaw, *supra* note 4, at 211 (stating that the chance of two randomly selected Caucasian individuals being HLA matches are 1 in 20,000).

220. *See supra* note 62 and accompanying text.

221. *See supra* note 209 and accompanying text.

commodity is something that is purchased and sold.²²² Many body parts and products, including HSCs, meet this broad definition of commodity because they are purchased and sold and generally treated as articles of commerce.²²³ Regardless of whether HSC donors are compensated, HSCs still meet this broad definition of commodity as they are routinely purchased and sold, especially on the international market.²²⁴

There are currently active markets for the purchase and sale of numerous body parts and products that do not fall under the definition of human organ in NOTA, including blood and blood products, sperm, ova, and breast milk.²²⁵ Moreover, parts that fall under the definition of human organ in NOTA are still routinely sold in transactions, such as the sale of parts from organ procurement organizations to tissue banks and the sale of material from for-profit tissue processors to hospitals.²²⁶ It is

222. Anderson, *supra* note 32, at 494 (arguing that tissues and organs will be commodified if donors are paid for them); John A. Robertson, *Paid Organ Donations and the Constitutionality of the National Organ Transplant Act*, 40 HASTINGS CONST. L.Q. 221, 269 (2013) (using the general definition of a commodity as an article that is bought and sold); Nicolette Young, *Altruism or Commercialism? Evaluating the Federal Ban on Compensation for Bone Marrow Donors*, 84 S. CAL. L. REV. 1205, 1223–24 (2011) (conflating commercialization with commodification).

223. See Elizabeth E. Appel Blue, *Redefining Stewardship over Body Parts*, 21 J.L. & HEALTH 75, 77 (2008) (noting the tissue and body parts market had grown to a \$1 billion industry by 2003).

224. See CAN. BLOOD SERVS., A REPORT TO CANADIANS 2012/2013 52 (2013), available at http://video.bloodservices.ca/Annual2013/pdfs/cbs_ar2013_finreport_en.pdf; U.S. DEPT OF HEALTH & HUMAN SERVS., *supra* note 65, at 3–4; U.S. GOV'T ACCOUNTABILITY OFFICE, *supra* note 132, at 12–14; Appel Blue, *supra* note 223.

225. Michele Goodwin, *Altruism's Limits: Law, Capacity, and Organ Commodification*, 56 RUTGERS L. REV. 305, 384–85 (2004); Robertson, *supra* note 222. The majority of the listed items are either capable of being regenerated by the body (blood, milk, sperm); although a woman does not regenerate ova, the donation of ova is not thought to deplete a woman of ova she could have used, but rather stimulates additional ova to develop during a cycle that would have otherwise not been used. See Williams et al., *supra* note 76, at 19.

226. 42 U.S.C. § 274e(c)(2) (2012) (“The term ‘valuable consideration’ does not include the reasonable payments associated with the removal, transportation, implantation, processing, preservation, quality control, and storage of a human organ . . .”); Goodwin, *supra* note 225, at 383 (citing William Heisel & Mark Karches, *Organ Agencies Aid For-Profit Suppliers*, ORANGE COUNTRY REG., June 25, 2000, A01). The tissue industry is able to recover high profits due to the fact that unlike solid organs, tissues do not

hard to characterize sums paid by recipients of solid organs, which are often more than double the hospital's cost in acquiring the organ, as anything other than a sale of the organ.²²⁷

The sale of HSCs is routine in the United States.²²⁸ Within the United States, hospitals purchase HSCs from cord blood banks or through the Be the Match Registry.²²⁹ The charge to hospitals for procuring HSCs through Be the Match currently ranges from \$30,000 to over \$60,000.²³⁰ HSCs can also be purchased from cord blood banks; prices vary by bank as each sets its own fees, and in 2011 the prices ranged from \$22,800 to \$35,000.²³¹ The very nature of cord blood banking, in which cord blood units are collected and stored for the very purpose of being sold, demonstrates that their whole existence is for the purpose of commodification. This commodification is sponsored

need to be transplanted immediately and can be heavily processed (by for-profit processors) and stored for long periods before transplantation. See Laura A. Buck, *Regulating Human Tissue Banks*, 20 ST. THOMAS L. REV. 121, 122, 125 (2007); Robert A. Katz, *The Re-Gift of Life: Who Should Capture the Value of Transplanted Human Tissue?*, 18 HEALTH LAW. 14, 14 (2006); Williams et al., *supra* note 76, at 34–37.

227. See Sten, *supra* note 138, at 200–01 (“[T]ransplant hospitals routinely bill patients more than twice the hospital’s organ acquisition cost . . .”). Estimated average billed procurement charges in the United States in 2011 are: \$80,400 per heart, \$78,500 per intestine, \$67,200 per kidney, \$71,000 per liver, \$73,100 per single lung, \$90,300 per double lung, and \$65,000 per pancreas. MILLMAN, 2011 U.S. ORGAN AND TISSUE TRANSPLANT COST ESTIMATES AND DISCUSSION 4 (2011), available at <http://us.milliman.com/uploadedFiles/insight/research/health-rr/2011-us-organ-tissue.pdf>. In addition to the procurement charge, hospitals and physicians are also billing significant amounts to perform the transplantations. *Id.*

228. See *Unrelated Donor Search and Procurement*, BE THE MATCH (Jan. 2014), <https://payor.bethematchclinical.org/WorkArea/DownloadAsset.aspx?id=7499>.

229. *Id.*

230. *Unrelated Donor: Procurement Costs*, *supra* note 218 (“The cost of procuring unrelated donor cells varies greatly depending on the cell type and transplant protocol. These costs may be as low as \$30,000 or higher than \$60,000 in cases where a patient requires two simultaneous infusions of cells, such as a double cord blood transplant.”). In 2002, it was reported that the cost of hospitals in the United States obtaining HSCs through the NMDP was more than one and a half times as much as obtaining cells directly from overseas registries. See U.S. GEN. ACCOUNTING OFFICE, *supra* note 131, at 20.

231. U.S. GOV’T. ACCOUNTABILITY OFFICE, *supra* note 132, at 14 (“[B]anks received payments ranging from \$22,800 to \$35,000 for cord blood units used for transplantation, with a median payment of \$30,000.”).

by the government through the NCBI program, which pays cord banks a set subsidy for each cord blood unit the bank adds to their publicly available inventory.²³²

HSCs are routinely sold within the United States, but nowhere is the sale of HSCs more apparent than in international transactions. Due to stringent HLA matching requirements, many patients must look beyond their home countries for a match.²³³ Forty-four percent of the world's HSC transplants between unrelated parties involve donors and recipients from different countries.²³⁴ In the United States, more than fifty percent of transplants arranged through the NMDP involve HSCs crossing international borders.²³⁵ International registries each set their own price for HSC products.²³⁶ Furthermore, this price is often more than the cost of rendering the service to procure the HSCs and results in a positive margin for the organization.²³⁷ International exchanges of HSCs are frequently referred to using the same terminology as other international transactions, further evidencing the treatment of HSCs as commodities.²³⁸

Congress may have enacted the prohibition in NOTA with the intent of preventing human body parts from being viewed and treated as commodities,²³⁹ however, NOTA has not stopped virtually any body parts and body products from nonetheless

232. *Id.* at 12–14; U.S. DEPT OF HEALTH & HUMAN SERVS., *supra* note 65, at 3–4.

233. *Unrelated Donor Search and Procurement*, *supra* note 228.

234. Foeken et al., *supra* note 115, at 812 (assessing the 10,481 adult stem cell donations in 2008 between unrelated donors matched through registries in thirty-eight countries).

235. *Unrelated Donor Search and Procurement*, *supra* note 228 (“Since the NMDP Network includes several donor centers, transplant centers and cooperative registries located outside of the United States, more than fifty percent of all transplants facilitated by the NMDP involve either an international donor or recipient.”).

236. *Unrelated Donor: Procurement Costs*, *supra* note 218.

237. The organization responsible for HSC transplants in Canada “bills the international registries based on a set price list established annually by the program, which covers more than the collection fees and donor expenses incurred in rendering the services. The surplus generated by this scenario offsets the deficit incurred in the international donor/Canadian patient scenario.” CAN. BLOOD SERVS., *supra* note 224.

238. *Id.* at 52–53 (using “import,” “export,” and “foreign exchange fluctuations”).

239. S. REP. NO. 98-382, at 17 (1984).

being viewed and treated as commodities.²⁴⁰ Irrespective of the definition used for commodity, providing compensation to HSC donors will not result in a change in how HSCs are viewed and treated either as commodities or not as commodities or significantly change the profits already made today. Regardless of whether compensation is provided for HSCs or not, HSCs are unlikely to meet the narrow definition of commodity used by economists as HSCs are not interchangeable. Moreover, despite NOTA, HSCs already meet a broader definition of commodity, as they are currently articles of commerce that are purchased and sold by all parties other than the donor.²⁴¹ The prohibition in NOTA does not meet Congress' aim to prevent the commodification of HSCs from bone marrow and cannot be justified on this basis. Likewise, the proposed expansion of the prohibition to cover all HSCs can also not be justified, especially as it applies to cord blood, which is collected and stored solely for the purpose of being sold.²⁴²

B. PRECLUDING COMPENSATION FOR HSC DONATION TO PREVENT DONOR PROFITING IS INCONSISTENT WITH THE HIDDEN ECONOMY OF HSC DONATION WHERE ALL PARTIES INVOLVED IN HSC TRANSPLANTATION, EXCEPT THE DONOR, ARE COMPENSATED AND MANY PROFIT

In 1984, when Congress enacted NOTA and noted the importance of preventing individuals and organizations from profiting by the sale of human organs, HSC transplantation was very different than it is today.²⁴³ HSC transplants were rare and considered experimental.²⁴⁴ Most transplants occurred between siblings, with very few unrelated transplants occurring throughout the world.²⁴⁵ Although there was hope for

240. See Williams et al., *supra* note 76, at 34–37.

241. See *supra* notes 230–32 and accompanying text.

242. See *supra* notes 230–32 and accompanying text.

243. S. REP. NO. 98-382, at 16–17 (1984); see 42 U.S.C. § 274e (2012); *supra* text accompanying note 145.

244. Horowitz, *supra* note 16, at 17 (observing that few HSC transplantations “were carried out before the 1970s” and “did not generate much enthusiasm until the middle to late 1980s” but were “diffused rapidly in the late 1980s”).

245. Even after over a decade of being in operation, the Anthony Nolan Bone Marrow Registry in England only matched fourteen donors and patients by 1986. See *supra* notes 94, 97 and accompanying text.

the potential for HSC transplantation to materialize into a routine procedure, that potential had not been achieved. Most significantly, there were not a lot of profits being realized by anyone in the area of HSC transplantation, so the intent to prevent profiting was not an issue in 1984.²⁴⁶ However, the system surrounding HSC transplantation has evolved over the years into an industry where for-profit entities are routine and the compensation to members of nonprofit organizations is so generous that it is difficult to distinguish from profit.²⁴⁷

Payments to individuals involved in HSC transplantation are not prohibited by NOTA as long as they fall under the reasonable payments exception for removal, processing, storage, and transportation.²⁴⁸ As a result, the prohibition in NOTA applies to donors, and has little impact on other parties being compensated and profiting for their contributions.²⁴⁹ The uneven treatment of donors and other individuals involved in the process is inequitable and cannot be justified. Additionally, this treatment is inconsistent with the intent of Congress that organizations should not profit from the sale of organs for transplant.²⁵⁰

Even though the most visible organization involved in HSC transplant in the United States is a nonprofit, the NMDP and the HSC transplantation industry in general have significant involvement with for-profit entities.²⁵¹ In 2013, the NMDP

246. See Horowitz, *supra* note 16, at 17.

247. See National Marrow Donor Program, IRS Form 990, Return of Organization Exempt from Income Tax (OMB No. 1545-0047) 2 (2011), available at <http://www.guidestar.org/FinDocuments/2011/840/865/2011-840865803-087496e4-9.pdf> (reporting annual salaries of NMDP officers as high as \$600,000).

248. 42 U.S.C. § 274e(c)(2) (“The term ‘valuable consideration’ does not include the reasonable payments associated with the removal, transportation, implantation, processing, preservation, quality control, and storage of a human organ . . .”). Although the exceptions permit “reasonable payments,” academics have questioned whether significant profits in the tissue processing area are in fact reasonable. See Buck, *supra* note 226, at 127–28; Katz, *supra* note 226, at 14–17.

249. Although the prohibition currently only applies to HSCs from bone marrow, because the recent proposed rule from HRSA would expand this definition to include all HSCs, this section will address HSCs from all sources.

250. S. REP. NO. 98-382, at 16–17 (1984).

251. Many NMDP transplant centers are owned and operated by for-profit corporations, such as Hospital Corporation of America. *Facilities*, HOSP. CORP. AM., <http://hcahealthcare.com/about/facilities.dot> (last visited Jan. 2, 2015).

spent over \$175 million on medical services.²⁵² There is no obligation that the companies providing these medical services be nonprofit; physicians and other health care organizations involved are likely profiting from these arrangements.²⁵³ Apart from the services billed for by the NMDP, hospitals providing transplant services to a recipient are able to profit from the provision of these services.²⁵⁴ There is no requirement that such hospitals be nonprofit, and moreover, even a nonprofit hospital may use the transplant unit as a profit center to offset other less profitable areas.

The NMDP coordinates the use of cord blood for HSC transplant, an area that utilizes for-profit organizations.²⁵⁵ There is a misconception in the literature, and potentially in the public at large, that cord blood banks with publicly available units are all nonprofit.²⁵⁶ However, there are many for-profit cord blood banks that store cord blood for public

(listing NMDP transplant centers “Presbyterian/St. Lukes Medical Center” and “Sarah Cannon Blood and Marrow Transplant Program at TriStar Centennial Medical Center”); Bob Herman, *HCA’s Profit Up 35% in Q1, Down Slightly in 2013*, BECKER’S HEALTHCARE (Feb. 4, 2014), <http://www.beckershospitalreview.com/finance/hca-s-profit-up-35-in-q1-down-slightly-in-2013.html>; Nat’l Marrow Donor Program, *Transplant Center Directory*, BE THE MATCH, <http://bethematch.org/For-Patients-and-Families/Getting-a-transplant/Choosing-a-transplant-center/U-S-transplant-centers/> (last visited Jan. 2, 2015) (listing facilities owned by Hospital Corporation of America such as “Presbyterian/St. Lukes Medical Center” and “Sarah Cannon Blood and Marrow Transplant Program at TriStar Centennial Medical Center”). For more information on the administration of bone marrow transplants in the United States, see *supra* notes 119–20 and accompanying text.

252. NAT’L MARROW DONOR PROGRAM & SUBSIDIARY, *supra* note 120, at 5, 10 (“The Program procures medical services from third-party health practitioners and clinics and pays for these services based on the Program’s rate schedule or contractual agreements, where applicable.”).

253. NMDP contract standards for apheresis centers, collection centers, cord blood banks, donor centers, recruitment groups, and transplant centers stipulate quality and performance standards, but make no requirements on business models. See generally Nat’l Marrow Donor Program, *NMDP Standards*, BE THE MATCH, <http://bethematch.org/about-us/global-transplant-network/standards/> (last visited Oct. 14, 2014).

254. See, e.g., *id.*

255. NAT’L MARROW DONOR PROGRAM & SUBSIDIARY, *supra* note 120, at 8.

256. See, e.g., Petrini, *supra* note 104, at 903 (expressing a common misconception that “[p]ublic [cord blood] banks that store units donated voluntarily also generate considerable capital movements, albeit not for profit”).

use,²⁵⁷ and additionally some of these companies are compensated by HRSA for collecting cord blood for the NCBI.²⁵⁸ Because cord blood banks set their own prices for cord blood units, there is a potential for these banks to make a significant profit.²⁵⁹ Additionally, some nonprofit cord blood banks utilize for-profit companies to collect and transport cord blood to their banks.²⁶⁰ This use of for-profit companies for collection and transportation is analogous to the use of for-profit tissue processing companies in the tissue banking industry,²⁶¹ as they both rely on the exceptions in NOTA for the payment of for-profit entities for items such as collection and processing.²⁶² Although, there have not been reports of a billion dollar industry in HSC collection and processing, as there have been for tissue banking,²⁶³ many for-profit cord blood banks use proprietary methods to collect and separate HSCs from the cord blood, creating the potential for large processing fees

257. See, e.g., CELEBRATION STEM CELL CENTRE, <http://celebrationstemcellcentre.com> (last visited Oct. 4, 2014) (operating both a public and private cord blood bank); LIFEFORCE CRYOBANKS, <https://www.lifeforcecryobanks.com> (last visited Oct. 4, 2014); *Public Banking*, STEMCYTE, <http://www.stemcyte.com/publicbanking> (last visited Oct. 4, 2014) (describing its global mission to collect cord blood for public banking); *Public Cord Blood Bank*, CORD:USE, http://publiccordbloodbank.corduse.com/about_cord_blood_bank_difference.php (last visited Oct. 4, 2014) (operating a private family bank and a nonprofit foundation that provides grants, but is not involved in the banking of cord blood); *Questions & Answers*, NUVACORD NETWORK (Aug. 17, 2012), <https://nuvacord.net/cord-blood/qna> (providing banking as well as collection, transport, and processing services).

258. See *National Cord Blood Inventory Program Contractors*, HEALTH RESOURCES & SERVS. ADMIN., <http://bloodcell.transplant.hrsa.gov/about/contractors/ncbi/index.html> (last visited Oct. 4, 2014) (noting that cord blood banks with NCBI contracts include CORD:USE Public Cord Blood Bank and StemCyte, Inc.).

259. See *supra* note 231 and accompanying text.

260. See *CORD:USE*, PARENT'S GUIDE CORD BLOOD FOUND., <http://parentsguidecordblood.org/bank/corduse> (last visited Oct. 4, 2014) ("Public donations collected by CORD:USE are sent to the Carolinas Cord Blood Bank . . ."); see also *NuvaCord Network*, PARENT'S GUIDE CORD BLOOD FOUND., <http://parentsguidecordblood.org/public/nuvacord-network> (last visited Oct. 4, 2014) ("Cord blood donated through NuvaCord is sent to Community Blood Services, aka New Jersey Cord Blood Bank, a public bank . . .").

261. See Katz, *supra* note 226.

262. See *supra* note 248 and accompanying text.

263. See Katz, *supra* note 226, at 17.

similar to what is currently seen in the tissue bank industry.²⁶⁴ Academics have questioned whether the large profits accrued in the tissue industry truly result from reasonable payments, or if they might be non-compliant with the exception in NOTA.²⁶⁵ If HHS is serious about cracking down on profiting from HSC transplants, they might focus on these for-profit entities while they are still in their infancy and set precedent on a reasonable payment.

Even though the NMDP is a nonprofit, it has numerous employees and board members that are compensated for their work.²⁶⁶ In 2013, the NMDP and its subsidiary Be the Match spent over sixty-one million dollars on compensation.²⁶⁷ Additionally, eleven officers receive yearly compensation that ranges from two hundred thousand dollars to over six hundred thousand dollars.²⁶⁸ While the issue of appropriate executive compensation is beyond the scope of this Article, these individuals are clearly significantly rewarded for their work and it is difficult to see how such significant compensation is distinguishable from a profit.

Through these mechanisms, the HSC transplantation industry involves a hidden economy where for-profit entities

264. See Appel Blue, *supra* note 223, at 77 (noting that the tissue industry expanded to a \$1 billion industry in 2003); Buck, *supra* note 226, at 122–25 (noting that the tissue industry is able to achieve high profits due to the fact that, unlike solid organs, tissues do not need to be transplanted immediately and can be heavily processed—by for-profit processors—and stored for long periods before transplantation); Katz, *supra* note 226; *About Lifeforce*, LIFEFORCE CRYOBANKS, <https://www.lifeforcecryobanks.com/about-lifeforce.html> (last visited Oct. 4, 2014) (describing Lifeforce’s use of the proprietary PremierMaxCB processing system); *Public Cord Blood Bank*, *supra* note 257 (“CORD:USE utilizes the BioArchive cryogenic freezer [for storage and] . . . the SEPAX processing system to help maximize the number of stem cells processed and retained from each banked cord blood unit.”); *Stem Cell Optimization Process*, STEMCYTE, <http://web.archive.org/web/20140710000238/http://www.stemcyte.com/why-choose-stemcyte/stem-cell-optimization-process> (last visited Oct. 4, 2014) (describing StemCyte’s use of a proprietary stem cell optimization process).

265. See *supra* note 248 and accompanying text.

266. See NAT’L MARROW DONOR PROGRAM & SUBSIDIARY, *supra* note 120, at 5; *National Marrow Donor Program and Be the Match Key Messages, Facts and Figures*, BE THE MATCH (Jan. 2013), <http://bethematch.org/News/Facts-and-Figures—PDF/> (“[T]he NMDP employs nearly 860 staff . . .”).

267. NAT’L MARROW DONOR PROGRAM & SUBSIDIARY, *supra* note 120, at 5.

268. National Marrow Donor Program, *supra* note 247.

operate in the shadows of nonprofit organizations, and profit from altruistic donations. The mandated altruism of donors is inequitable with the profits being made by others in the industry. Additionally, although an employee's salary is not a profit per se, it is a benefit that individuals receive within the HSC industry. Even if employee salaries and executive compensation merely reflect reimbursement for the individuals' work, it must be considered whether it is reasonable and ethical to permit employees to be reimbursed for their time while not granting the same level of reimbursement to donors. Furthermore, while donors are permitted to be reimbursed for lost wages and travel as a result of their donation, this is limited and does not permit reimbursement for time spent or pain and suffering incurred.²⁶⁹

C. THE CURRENT RELIANCE ON ALTRUISM AND LIMITED REIMBURSEMENT FAILS TO RESPECT THE INHERENT VALUE OF THE DONORS' TIME AS WELL AS NONTRADITIONAL WORK

As HSC donors are prohibited from receiving compensation, donors are often described as being altruistic.²⁷⁰ Nevertheless, these donors are not without any rewards since many individuals who have donated indicate that they gain great personal satisfaction from knowing that they are able to help others.²⁷¹ However, some individuals will be unable to share the personal satisfaction that comes with HSC donation, and consequently, recipients will be unable to benefit from

269. HSCs collected from peripheral blood involve donors taking drugs for five days, as well as one to two days of aspiration lasting a total of eight to ten hours to collect the HSCs and adverse symptoms for five to six days. *See supra* notes 47–50, 73 and accompanying text. HSCs collected from bone marrow involve daylong surgery under anesthesia and adverse symptoms for the following week or several weeks. *See supra* notes 44–45, 73 and accompanying text; *see also infra* Part III.C (discussing the shortcomings of the current reliance on altruism and limited reimbursement).

270. NOTA only currently prohibits the receipt of compensation for HSCs in bone marrow, but administration of HSC donations results in all HSC donors being unable to receive compensation. *See supra* note 8 and accompanying text.

271. Related donors likely have many motivations for donating besides or in addition to altruism including: love, beneficence, loyalty, guilt, and need. *See* Mark J. Cherry, *Why Should We Compensate Organ Donors When We Can Continue to Take Organs for Free? A Response to Some of My Critics*, 34 J. MED. & PHIL. 649, 656 (2009).

their HSCs where potential donors are financially unable to give the extensive amount of time required for HSC donation.

The exception in NOTA permitting donors to receive reimbursement for lost wages and travel is limited and will likely not sufficiently compensate individuals who are self-employed or who do not earn traditional wages.²⁷² Additionally, the NOTA exception does not recognize the value of traditionally uncompensated services such as individuals who care for family members or who do work around their own homes. The prohibition in NOTA thus prevents individuals who are self-employed or engage in nontraditional work from obtaining the same benefits that others may though HSC donation. By limiting HSC donations only to those who are seen to be donating altruistically, the government fails to recognize the reality that some individuals do not have the luxury of being able to donate without being compensated.

D. STRICTLY REGULATED DONOR COMPENSATION WILL NOT EXPOSE DONORS OR RECIPIENTS TO UNDUE RISK

1. Compensation Will Not Subject Donors to Undue Coercion

HSC donors are subjected to risks associated with their donations, including a risk of physical harm and a risk of intrusion of privacy.²⁷³ Although compensation will not alter the incidence of these risks, concern has been expressed in the context of solid organ donation as to whether compensated donors would be more likely to disregard the risks.²⁷⁴ While preventing the coercion of the poor is a laudable goal, the need for government intrusion to prevent such coercion must be considered relative to the risk faced by the individual.

Society currently permits individuals to engage in activities wherein they face a large risk of physical harm, including clinical trials and high-risk occupations in exchange for compensation. Additionally, individuals are permitted, in many jurisdictions in the United States, to be compensated for the donation of oocytes, which requires anesthesia, and may

272. 42 U.S.C. § 274e(c)(2) (2012).

273. See *supra* notes 67–74 and accompanying text.

274. See Arthur J. Matas et al., *In Defense of a Regulated System of Compensation for Living Donations*, 13 CURRENT OPINION ORGAN TRANSPLANTATION 379, 382 (2008).

also be compensated for gestational surrogacy.²⁷⁵ Furthermore, although the successful transplant of HSCs results in the recipient's blood being comprised of cells with the donor's genetic information and may result in the invasion of the donor's privacy interests, the donor is able to consent to such risks through informed consent.²⁷⁶

The donation of HSCs, therefore, does not subject donors to greater risks than other activities that individuals are permitted to receive compensation for subjecting themselves to. Furthermore, setting a ceiling on the amount of compensation can mitigate the potential for economic coercion of donors. Regardless, the very existence of any risk to the donor supports limited compensation in exchange for this risk.

In any event, Congress did not intend the ban in NOTA to include replenishable items, such as blood, whose donation does not compromise the ongoing health of the donor.²⁷⁷ There have been longstanding arguments made that bone marrow was included in the ban by mistake on the basis that bone marrow is regenerated by the body.²⁷⁸ Nevertheless, the proposal to include all HSCs within the prohibition in NOTA is squarely contrary to Congress' intent that donations of blood and other body parts that do not affect the donors' health would not be included in the ban. First, the proposed rule would cover all HSCs "without regard to the method of their collection,"²⁷⁹

275. See Williams et al., *supra* note 76, at 36.

276. See *supra* notes 17–18 and accompanying text; see, e.g., Peter Aldhous, *Bone Marrow Donors Risk DNA Identity Mix-Up*, 188 NEW SCIENTIST, Oct. 29, 2005, at 11 (discussing the initial misidentification of a suspect for sexual assault, when a semen sample matched the DNA of a bone marrow recipient in jail at the time of the assault, whose DNA had been obtained from a blood sample, and the bone marrow donor was the actual assailant); see also *Forensik: Leiche Trug Mannliche und Weibliche DNA [Forensics: Corpse Containing Male and Female DNA]*, SPIEGEL ONLINE (Oct. 19, 2008) (Ger.), <http://www.spiegel.de/wissenschaft/mensch/forensik-leiche-trug-maennliche-und-weibliche-dna-a-585032.html> (discussing how medical researchers discovered a corpse with both male and female DNA markers, and realized he was the recipient of a bone marrow transplant).

277. See S. REP. NO. 98-382, at 17 (1984); H.R. REP. NO. 98-1127, at 16 (1984); see *supra* notes 145, 153 and accompanying text.

278. See Jeff Rowes, *Saving Lives: IJ Challenges the Federal Ban on Compensating Bone Marrow Donors*, INST. FOR JUSTICE (Dec. 2009), <http://www.ij.org/saving-lives-ij-challenges-the-federal-ban-on-compensating-bone-marrow-donors>.

279. See Change to the Definition of "Human Organ," *supra* note 7.

so the prohibition would apply to donations of blood, which Congress expressly did not intend.²⁸⁰ Second, the donation of cord blood carries minimal risk to the donor's health, and any prohibition could not be justified on the basis of such a negligible risk.²⁸¹

2. Compensation Will Not Subject Recipients to Undue Harm

The regulated compensation of HSC donors will not subject HSC recipients to undue harm as any potential economic exploitation of recipients is preventable, and permitting compensation will not expose recipients to an increased risk of contracting an infectious agent compared to existing blood donations.

i. Any Potential Economic Exploitation of Recipients Is Preventable

In the proposed rule to expand the prohibition in NOTA to cover all HSCs, the HRSA expressed concern that due to stringent matching requirements for HSCs, there was an increased potential for HSC donors to extort high sums of money from recipients.²⁸² However, the allowance of compensation will not necessarily result in a free market for HSCs. Regulations should be put in place to set ceilings for such compensation, to permit compensation only through arm's length transactions, or to specify what type of compensation is permissible. Confidentiality policies currently prevent unrelated donors and recipients from having non-anonymous contact before transplants and during the first year afterwards,²⁸³ so these policies would prevent direct transactions. Further regulations could prohibit all compensation other than that directly paid from a matchmaking organization (such as Be the Match). Regulation of the type of compensation may also serve to protect against donor coercion or extortion. Compensation could be limited to

280. Under normal conditions, HSCs are present at low levels in the peripheral blood supply. *See* Armitage, *supra* note 16, at 9.

281. *See supra* note 67 and accompanying text.

282. *See* Change to the Definition of "Human Organ," *supra* note 7.

283. *See Do Patients and Donors Meet?*, BE THE MATCH, <http://bethematch.org/Transplant-Basics/Do-patients-and-donors-meet/> (last visited Oct. 14, 2014).

nonmonetary forms that cannot readily be exchanged for cash similar to the FDA regulations for “volunteer” blood donations.²⁸⁴

In any event, there is a far greater potential for recipients to be extorted in situations of related donors than with unrelated donors where contact is controlled and regulation is more easily achieved.²⁸⁵ Related transplants account for more than forty percent of all HSC transplants in the United States and the prohibition in NOTA is likely insufficient to prevent compensation in these situations, as they are likely opaque transactions and unlikely to affect interstate commerce.²⁸⁶ Although states have jurisdiction to legislate and regulate such transactions, the fact that very few states prohibit the sale of HSCs suggests a lack of issues in this area.²⁸⁷

284. See *supra* notes 171–73 and accompanying text.

285. See Confer et al., *supra* note 44, at 547 (describing a compatible sister who refused to donate, but changed her mind after media attention); cf. Rakhi Ruparelia, *Giving Away the “Gift of Life”: Surrogacy and the Canadian Assisted Human Reproduction Act*, 23 CAN. J. FAM. L. 11, 11 (2007) (discussing how the potential for exploitation in noncommercial surrogacy—utilizing family members as surrogates—may be greater than in commercial surrogacy due to the inability of individuals to make decisions freely within their family). Other proposals have been made to incentivize organ donation using nonmonetary incentives. See *About Us*, MORE MARROW DONORS, <http://moremarrowdonors.org/about-us/> (last visited Oct. 4, 2014) (proposing incentivizing donors with rare marrow types through small scholarships, housing allowances, or gifts to charity); see also Jake Linford, *The Kidney Donor Scholarship Act: How College Scholarships Can Provide Financial Incentives for Kidney Donation While Preserving Altruistic Meaning*, 2 ST. LOUIS U. J. HEALTH L. & POL'Y 265, 267 (2009) (proposing using methods such as scholarships to incentivize kidney donation from living donors).

286. *General Frequently Asked Questions*, *supra* note 42 (stating that in 2011, HRSA recorded 3114 related HSC transplants and 4421 unrelated transplants). Due to how HLA matching works and the fact that patients have a 25% probability of matching each of their siblings, but a very low probability of matching anyone else in the general population, it is unlikely that related matches impact interstate commerce. See 42 U.S.C. § 274e (2012); *Childhood Hematopoietic Cell Transplantation*, NAT'L CANCER INST., <http://www.cancer.gov/cancertopics/pdq/treatment/childHCT/HealthProfessiona1/page3> (last visited Oct. 4, 2014).

287. Less than 2% of states prohibit receiving compensation for HSCs collected from cord blood and peripheral blood and only 25% of states prohibit compensation for HSCs from bone marrow. See *infra* Table 1.

ii. Permitting Compensation Will Not Expose Recipients to an Increased Risk of Contracting an Infectious Agent Compared to Blood Donations

It was once argued that the practice of paying for blood in the United States resulted in increased hepatitis transmission compared to countries relying solely on altruistic donations; however, the basis for this argument has been questioned by academics and studies.²⁸⁸ In any event, there is no evidence that the risk would be greater for HSC recipients than for blood recipients, which has become a broadly accepted risk with more than thirty million blood transfusions happening every year.²⁸⁹ Additionally, a level of risk is already considered permissible in HSC transplant given the important need for such transplants as evidenced by the exceptions to testing requirements that do not exist for blood donations.²⁹⁰

The receipt of valuable consideration in exchange for blood donations is not prohibited by NOTA, and the only laws on this topic are FDA regulations requiring that blood for transfusion be labeled either as from a paid or voluntary donor.²⁹¹ Furthermore, blood may be labeled as from a voluntary donor when the donor receives valuable consideration, such as gift certificates, in exchange for the donation.²⁹² HSC donors are subject to extensive screening requirements in order to be

288. RICHARD M. TITMUSS, *THE GIFT RELATIONSHIP* 205–07 (Ann Oakley & John Ashton eds., New Press 1997) (arguing that the blood donation system in the United States, which in the 1960s relied heavily on commercial donation, was more likely to have quality issues, including hepatitis contamination, than blood donation systems relying on altruism). Subsequently, many academics argued that Titmuss was wrong to suggest that contamination was a result of payment. See Kenneth Arrow, *Gifts and Exchange*, 1 PHIL. & PUB. AFF. 343, 361–62 (1972); Healey, *supra* note 215, at 532–35 (1999); see also Nicola Lacetera et al., *Economic Rewards to Motivate Blood Donations*, 340 SCIENCE 927, 928 (2013) (explaining that five studies from the United States and Switzerland investigated use of rewards and no effect on blood safety was detected where fifteen different types of rewards were given—where safety data were available).

289. See *Blood Facts and Statistics*, AM. RED CROSS, <http://www.redcrossblood.org/learn-about-blood/blood-facts-and-statistics> (last visited Oct. 4, 2014).

290. See *supra* note 168 and accompanying text.

291. See *supra* notes 171–73 and accompanying text.

292. *CPG sec. 230.150 Blood Donor Classification Statement, Paid or Volunteer Donor*, *supra* note 171.

eligible to donate HSCs.²⁹³ Moreover, the time commitment and process involved in donating HSCs is more intensive than that of donating blood.²⁹⁴ This increase in time may result in the donor feeling more accountable to the recipient. Given the absence of evidence demonstrating an increased safety risk stemming from HSCs as compared to whole blood donations,²⁹⁵ subjecting HSCs to stronger compensation regulations than whole blood is not justified.

E. THE CURRENT PROHIBITION IN NOTA CANNOT BE JUSTIFIED ON THE BASIS OF MAINTAINING INTERNATIONAL NORMS

The international response to a change in the United States' laws on compensation for HSCs will likely depend on the type and amount of compensation that is permitted, and whether the compensation can be categorized as reimbursement. Although there is the potential for a change in American policy to have detrimental effects on the international exchange of HSCs, such effects are unlikely. Three possible reactions to the allowance of compensation include: (1) initiation of changes to international standards to permit compensation; (2) some countries may refuse to accept HSCs from paid donors; and (3) the U.S. registry facilitating paid HSC donations may be removed from BMDW.

Recipients around the world rely on international donors of HSCs.²⁹⁶ The ability to obtain HSCs from outside of the patient's home country have been facilitated by the collaboration of international registries (through BMDW), which has increased the pool of available donors resulting in

293. See U.S. FOOD & DRUG ADMIN., U.S. DEP'T OF HEALTH & HUMAN SERVS., GUIDANCE FOR INDUSTRY: ELIGIBILITY DETERMINATION FOR DONORS OF HUMAN CELLS, TISSUES, AND CELLULAR AND TISSUE-BASED PRODUCTS (HCT/PS) 11 (2007), available at <http://www.fda.gov/downloads/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/CellularandGeneTherapy/ucm078703.pdf>.

294. Compare *Two Paths to Bone Marrow Transplant: Patients and Donors*, BE THE MATCH, <http://bethematch.org/transplant-basics/timeline-of-a-transplant/> (last visited Oct. 14, 2014) (describing the process of bone marrow transplants), with *Donation FAQs*, AM. RED CROSS, <http://www.redcrossblood.org/donating-blood/donation-faqs> (last visited Oct. 14, 2014) (describing the process of blood donation).

295. Joerg Halter et al., *Severe Events in Donors After Allogeneic Hematopoietic Stem Cell Donation*, 94 HEMATOLOGICA 94, 94 (2009).

296. See *supra* notes 115, 234–35 and accompanying text.

increased probabilities of finding a matching donor.²⁹⁷ Donors in international registries agree to make HSCs available to any recipient worldwide, and are unaware at donation of the identity or location of the recipient.²⁹⁸

No one set of standards is applicable to all HSC registries; however, many accreditation programs advocate for the unpaid donation of HSCs, and include standards prohibiting the payment of donors.²⁹⁹ This applies predominantly to the donation of HSCs in bone marrow or peripheral blood.³⁰⁰ Additionally, compensation that does not amount to payment is accepted by many organizations, with the definition of compensation varying from specified expenses (likely similar to that currently permitted in the United States) to broad compensation that reflects the inconveniences of the donation.³⁰¹

The first potential response to the United States permitting compensation for HSCs would be to initiate similar changes in standards and norms across the globe. Such changes would reflect the recognition that HSCs are currently being purchased and sold on an international market. Allowing compensation to reflect inconveniences such as pain and lost time would merely expand upon existing reimbursement for donor expenses for wages and travel. Countries might further choose to allow HSCs from international donors who have been compensated, while still prohibiting their own citizens from being compensated.³⁰²

Another potential response is for countries to refuse to accept HSCs from paid donors. Such a response is unlikely, as many countries at present or in the past prohibited paid donations within their borders, while permitting the purchase of blood products originating from paid donors in the United

297. See *supra* note 189 and accompanying text.

298. See *supra* note 189 and accompanying text.

299. See *supra* notes 197–201 and accompanying text.

300. See *supra* notes 197–201 and accompanying text.

301. See *supra* notes 197–201 and accompanying text.

302. Cf. Kelly Crowe, *Paying for Blood Plasma Raises New Questions*, CBC (Apr. 25, 2013), <http://www.cbc.ca/news/health/paying-for-blood-plasma-raises-new-questions-1.1361316> (demonstrating that although most jurisdictions in Canada prohibit plasma donors from being compensated, Canada relies on intravenous immunoglobulin plasma products purchased from the United States where many of the donors have been paid).

States.³⁰³ It is possible that a donor's compensation status could be considered merely a part of donor screening, either as something to be considered in the original HLA matching algorithm or during the testing process.³⁰⁴ When a search of BMDW reveals a match, potential donors could be asked whether they wish to be compensated for their donation, and countries not permitting paid donors would be free to reject such donors.

Third, the BMDW might respond to paid donors in the United States by prohibiting registries with paid donors from having access to BMDW. This reaction could potentially have the greatest negative impact on bone marrow donations internationally and in the United States. However, this could be mitigated by the creation of two separate registries in the United States—one for volunteer donors and one for paid donors. All international searches could occur through the unpaid registry, and the parallel paid registry would operate separately from the international system. While such a system would continue American patients' access to international HSCs, it would firewall international patients from paid donors in the United States. As the Be the Match Registry contains nearly half of the world's donors, the international impact could be significant.³⁰⁵ If countries outside of the United States were to reject compensated HSC donors on principle, in the end they would be adversely impacting their own citizens by reducing the odds of a match. This might be defensible were it not for the existing market. Thus, the possibility of other countries adopting an ethically dubious restriction of their citizens'

303. *See id.*

304. Be the Match currently permits donors on the registry who would likely be prohibited from donating HSCs within the United States, but who could potentially donate elsewhere. For example, FDA regulations exclude HSC donors who have spent more than three months in the United Kingdom from 1980 to 1996; however, Be the Match does not restrict the registry with respect to travel but indicates that travel will be evaluated if a match is found. *See Medical Guidelines—Who Can Join?*, BE THE MATCH, <http://bethematch.org/Support-the-Cause/Donate-bone-marrow/Join-the-marrow-registry/Medical-guidelines/> (last visited Jan. 17, 2015); *see also* U.S. FOOD & DRUG ADMIN., U.S. DEP'T OF HEALTH & HUMAN SERVS., *supra* note 293, at 18–19 (outlining travel and significant time spent in foreign countries as relevant information for screening potential donors).

305. *See* BONE MARROW DONORS WORLDWIDE, *supra* note 101, at 9.

freedom should not prevent the United States from enacting a policy that is appropriate for its own citizens.

IV. CONCLUSION

HSC transplantation has the potential to save lives, but currently, many patients die waiting for transplants due to a lack of matching donors.³⁰⁶ Compensating HSC donors makes rational, legal, and ethical sense. Such compensation will not only increase the number of registered donors, but also motivate existing registered donors to donate. Compensation will also further recognize the important contribution of donors to the HSC transplantation industry and begin to bring to light the shadow profits currently earned by non-donors.

HRSA should reject the proposed rule to expand the prohibition in NOTA to include all HSCs regardless of source, and moreover, Congress should repeal the application of the prohibition to bone marrow. Congress should legislate and fund a program that permits donor compensation and studies the resulting improvement in HSC availability. In order to fully remedy current bureaucratic obstacles to donor compensation, Congress will also have to instruct the NMDP to work with compensated donors. To prevent potential misuse, the legislation should set a ceiling on the amounts donors may receive, and if politically necessary, potentially only permit compensation to offset actual expenses and inconveniences, but not allow for profits. There is no need for a compensation floor, as altruistic donors will still be welcomed. Such a framework would go a long way towards providing a match for the thousands of Americans who are unable to find matches each year.³⁰⁷

306. See Carollo, *supra* note 4; see also *supra* note 2 and accompanying text (explaining the high rate of cases in which individuals need unrelated donors to donate healthy bone marrow).

307. See *supra* note 2 and accompanying text.

Table 1: Compilation of State Laws

| State | State Statutes That Only Prohibit Sale of Cadaver Body Parts | Relevant Body Parts to Which Prohibition Applies (In Living Donors) | Is Compensation Prohibited for HSCs from: | | |
|----------------------|--|--|---|-------------------|-------------|
| | | | Bone Marrow? | Peripheral Blood? | Cord Blood? |
| Alabama | ALA. CODE § 22-19-175 (LexisNexis Supp. 2013) | — | No | No | No |
| Alaska | ALASKA STAT. § 13.52.233 (2012) | — | No | No | No |
| Arizona | ARIZ. REV. STAT. ANN. § 36-854 (2009) | — | No | No | No |
| Arkansas | ARK. CODE ANN. § 20-17-1216 (2014) | — | No | No | No |
| California | | Nonrenewable or nonregenerative tissue CAL. PENAL CODE § 367f (West 2010) | No | No | No |
| Colorado | | Tissue, not blood COLO. REV. STAT. §§ 12-34-102(18), 12-34-116 (2013) | Yes | No | No |
| Connecticut | CONN. GEN. STAT. ANN. § 19a-289o (West 2011) | — | No | No | No |
| Delaware | | Tissues, blood, other fluids DEL. CODE ANN. tit. 16, §§ 2710(10), 2713(f) (2003) | Yes | Yes | Yes |
| District of Columbia | | Tissue, not blood D.C. CODE § 7-1501.01 (LexisNexis 2012) | Yes | No | No |
| Florida | | Eye, cornea, kidney, liver, heart, lung, pancreas, bone, and skin FLA. STAT. ANN. § 873.01(3) (West 2013) | No | No | No |
| Georgia | | Any part except: whole blood, blood plasma, blood products, blood derivatives, or other self-replicating bodily fluids GA. CODE ANN. § 16-12-160 (2011) | Yes | No | No |
| Hawaii | HAW. REV. STAT. § 327-16 (West Supp. 2013) | — | No | No | No |
| Idaho | IDAHO CODE ANN. § 39-3417 (2007) | — | No | No | No |

| | | | | | |
|---------------|--|--|-----|----|----|
| Illinois | | Any part except: blood, blood products or derivatives, or other body fluids 720 ILL. COMP. STAT. ANN. 5/12-20 (West Supp. 2013) | Yes | No | No |
| Indiana | | Bone marrow IND. CODE ANN. § 35-46-5-1 (LexisNexis 2009) | Yes | No | No |
| Iowa | IOWA CODE ANN. § 142C.10 (West 2014) | — | No | No | No |
| Kansas | KAN. STAT. ANN. § 65-3235 (Supp. 2013) | — | No | No | No |
| Kentucky | KY. REV. STAT. ANN. § 311.1939 (LexisNexis 2011) | — | No | No | No |
| Louisiana | LA. REV. STAT. ANN. § 17:2354.4 (2013) | — | No | No | No |
| Maine | | — | No | No | No |
| Maryland | MD. CODE ANN., EST. & TRUSTS § 4-513 (LexisNexis Supp. 2013) | — | No | No | No |
| Massachusetts | MASS. ANN. LAWS ch. 113A, § 16 (LexisNexis 2014) | — | No | No | No |
| Michigan | | Bone marrow; not: whole blood, blood products, blood derivatives, or other self-replicating bodily fluids MICH. COMP. LAWS ANN. § 333.10204(1), (5) (West 2012) | Yes | No | No |
| Minnesota | MINN. STAT. ANN. § 525A.16 (West 2012) | — | No | No | No |
| Mississippi | MISS. CODE ANN. § 41-39-131 (2013) | — | No | No | No |
| Missouri | MO. ANN. STAT. § 194.275 (West 2011) | — | No | No | No |
| Montana | MONT. CODE ANN. § 72-17-302 (2013) | — | No | No | No |
| Nebraska | NEB. REV. STAT. § 71-4839 (Supp. 2012) | — | No | No | No |

| | | | | | |
|----------------|--|---|-----|----|----|
| Nevada | NEV. REV. STAT. ANN. § 451.590 (LexisNexis 2009) | — | No | No | No |
| New Hampshire | N.H. REV. STAT. ANN. § 291-A:16 (LexisNexis 2014) | — | No | No | No |
| New Jersey | N.J. STAT. ANN. § 2C:22-2 (West Supp. 2014) | — | No | No | No |
| New Mexico | N.M. STAT. ANN. § 24-6B-16 (West 2011) | — | No | No | No |
| New York | Bone marrow, not blood N.Y. PUB. HEALTH LAW § 4307(1) (McKinney 2009) | — | Yes | No | No |
| North Carolina | N.C. GEN. STAT. § 130A-412.18 (2013) | — | No | No | No |
| North Dakota | N.D. CENT. CODE § 23-06.6-15 (2012) | — | No | No | No |
| Ohio | OHIO REV. CODE ANN. § 2108.18 (LexisNexis 2011) | — | No | No | No |
| Oklahoma | OKLA. STAT. ANN. tit. 63, § 2200.16A (West Supp. 2013) | — | No | No | No |
| Oregon | OR. REV. STAT. ANN. § 97.981 (West 2010) | — | No | No | No |
| Pennsylvania | Nonregenerative tissue; excludes human blood and blood products, in vitro preparation of cells, and other tissues readily renewable by the body 35 PA. CONS. STAT. ANN. § 10025 (West 2012) | — | No | No | No |
| Rhode Island | R.I. GEN. LAWS § 23-18.6.1-16 (Supp. 2013) | — | No | No | No |
| South Carolina | S.C. CODE ANN. § 44-43-375 (2013) | — | No | No | No |
| South Dakota | S.D. CODIFIED LAWS § 34-26-63 (2011) | — | No | No | No |
| Tennessee | Tissue, not blood TENN. CODE ANN. §§ 68- 30-102(17), 68-30-401 (2013) | — | Yes | No | No |

| | | | | | | |
|---------------|--|--|-----|----|----|--|
| Texas | | Tissue; not: blood, blood components, blood derivatives, or blood reagents TEX. PENAL CODE ANN. § 48.02(a) (West 2011) | | | | |
| Utah | UTAH CODE ANN. § 26-28-116 (LexisNexis 2013) | — | No | No | No | |
| Vermont | VT. STAT. ANN. tit 18, § 5250p (2010) | — | No | No | No | |
| Virginia | | Any parts except: blood, and other self-replicating bodily fluids VA. CODE ANN. § 32.1-291.16 (West 2011) | Yes | No | No | |
| Washington | WASH. REV. CODE ANN. § 68.64.150 (West Supp. 2013) | — | No | No | No | |
| West Virginia | | Tissue, not blood W. VA. CODE ANN. §§ 16-19-3(21), 16-19-16 (LexisNexis 2011) | Yes | No | No | |
| Wisconsin | | Bone marrow; not: whole blood, blood plasma, blood products, or blood derivatives WIS. STAT. ANN. § 146.345 (West 2006) | | | | |
| Wyoming | WYO. STAT. ANN. § 35-5-215 (2013) | — | No | No | No | |