

2013

Cutting the Cord to Private Cord Blood Banking: Encouraging Compensation for Public Cord Blood Donations after *Flynn v. Holder*

Seema Mohapatra
Barry University

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CUTTING THE CORD TO PRIVATE CORD BLOOD BANKING: ENCOURAGING COMPENSATION FOR PUBLIC CORD BLOOD DONATIONS AFTER *FLYNN V. HOLDER*

SEEMA MOHAPATRA*

This Article argues that the Ninth Circuit's recent ruling in Flynn v. Holder, which allowed compensation for peripheral blood stem cells ("PBSCs") obtained via apheresis¹ under the National Organ Transplant Act ("NOTA"), also opens up the possibility for compensation for umbilical cord blood ("cord blood"). The holding in Flynn applies to cord blood for several reasons. First, Flynn held that bone marrow was subject to NOTA's prohibition on compensation because bone marrow was explicitly mentioned in the statute. In contrast, no mention of cord blood appears in NOTA or its applicable regulations. Also, the procedure to utilize cord blood was not in practice at the time of NOTA passage and could therefore not have been contemplated by Congress. Additionally, similar to PBSCs, when Congress revisited NOTA and passed later amendments adding fetal organs to the prohibition on payment, it chose not to modify the statute to explicitly include cord blood. Finally, there is a longstanding view that blood should not be covered by NOTA's prohibitions

* Assistant Professor of Law, Barry University School of Law, Orlando, Florida. B.A., Johns Hopkins University, M.P.H., Yale University, J.D., Northwestern University School of Law. I would like to thank participants of the 2012 American Society of Law and Medicine Health Law Professors Conference at the Arizona State University Sandra Day O'Connor College of Law for their helpful insight in developing my research for this Article. I would like to also express my appreciation to Patrick Burton, Madeline Buczynski, Sarah Beres, and Ariel Niles for their helpful research assistance, to Heather Kolinsky, Manas Mohapatra, and Sanjay Reddy for their helpful comments on earlier drafts of this Article, and to Dean Leticia Diaz and Barry University Dwayne O. Andreas School of Law for supporting this research with a Winter Research Grant.

1. Apheresis refers to the process whereby the whole blood is removed from a donor, the blood is separated into individual components, the specific portion of the blood needed is separated and the remaining blood is introduced back into the bloodstream of the donor. Melissa Conrad Stöppler, *Apheresis*, MEDICINENET.COM, <http://www.medicinenet.com/hemapheresis/article.htm>; see also *infra* notes 44–50 and accompanying text.

and this should apply equally to cord blood.

Until recently, bone marrow transplants and PBSC transplants were the only two options for individuals suffering from diseases that damaged bone marrow, such as leukemia and lymphoma. However, advances in technology have allowed cord blood transplants to become a viable alternative to marrow and PBSC transplants for patients who have been unsuccessful in finding a PBSC or bone marrow match. This Article contends that rather than focusing only on increasing the numbers of bone marrow and PBSC donors, it is prudent to focus on increasing cord blood donations as a method of overcoming this problem. The lack of minority or mixed-race bone marrow, PBSC, and cord blood donors in the United States is a significant public health problem that has not been addressed adequately.

Cord blood is taken from the umbilical cord of a newborn after the cord has been detached from the baby. Cord blood can be used to treat more than seventy diseases. Expectant mothers are not well-informed about the option to donate cord blood. Often, a pregnant woman's sole source of information about cord blood is from marketing materials provided by private cord blood banks. These private banks offer to store a baby's cord blood for a hefty yearly fee, selling this service as a sort of life insurance policy that could be cashed in should the child get sick in the future. The American Academy of Pediatrics and the American College of Obstetrics and Gynecology advise against private cord blood banking because stored cord blood is of very little value to the individual from whom it was retrieved. In contrast, cord blood that is donated to a public bank can be very useful to individuals requiring a bone marrow transplant. Additionally, recipients of cord blood transplants are able to withstand an imperfect match compared to recipients of bone marrow or PBSC transplants. This is significant because it is difficult to find exact matches for racial minorities and mixed race individuals. Currently, almost 97 percent of cord blood is discarded as medical waste. In addition to compensation, this Article also suggests other methods of making public cord blood donation a more common practice.

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INTRODUCTION

Devan Tatlow was twenty months old when he was diagnosed with a rare form of leukemia.² The disease had initially responded to chemotherapy and Devan went into remission.³ Unfortunately in 2010, when he was four years old, the disease returned and Devan needed a bone marrow transplant.⁴ Devan's parents launched a desperate campaign to find a suitable bone marrow match for their son.⁵ A match can occur only if a bone marrow donor has a very high genetic similarity to a recipient.⁶ Because Devan is a multiracial child—his father is Irish and his mother half Polish and half South Asian—it was very difficult to find an appropriate bone marrow match.⁷ Only 3 percent of potential bone marrow donors in the National Marrow Donor Program's⁸ "Be the Match" registry ("NMDP") of eight million donors are multiracial.⁹ After an extensive international search and

2. Jonathon LaPook & Phil Hirschhorn, *Leukemia Patient—at 4—Highlights Marrow Need*, CBS NEWS (May 30, 2010, 7:35 AM), http://www.cbsnews.com/2100-18563_162-6531012.html.

3. *Id.*

4. *Id.*

5. Jonathon LaPook, M.D., *Umbilical Cord Blood: Save It and Save Lives*, CBS NEWS (June 18, 2010, 1:39 PM), http://www.cbsnews.com/2100-503823_162-6591788.html.

6. *Id.*

7. LaPook & Hirschhorn, *supra* note 2; see also Tanya Snyder, *Boy, 4, Desperately Needs Bone Marrow Transplant*, WTOP (May, 17, 2010, 10:01 PM), <http://www.wtop.com/109/1958736/Boy-4-desperately-needs-bone-marrow-transplant>.

8. Although still referred to as the National Marrow Donor Program (NMDP), 42 U.S.C. §2741-1(2) (2006) replaced the National Bone Marrow Donor Registry with the C.W. Bill Young Cell Transplantation Program in an effort to increase transplants. 42 U.S.C. §274k (2006). The largest donor registry in the United States is the NMDP. Noel Barnard, *Throw Me a Bone Marrow Transplant: Peripheral Blood Stem Cells and the National Organ Transplant Act*, 13 N.C. J. L. & TECH. 387, 392 (citing AM. CANCER SOC'Y, STEM CELL TRANSPLANTS (PERIPHERAL BLOOD, BONE MARROW, AND CORD BLOOD TRANSPLANTS) 10 (2011)). NMDP's Be The Match Registry ("Registry") contains 16.5 million donors and adds approximately 54,000 donors every month. NAT'L MARROW DONOR PROGRAM & BE THE MATCH, KEY MESSAGE, FACTS & FIGURES 1 (2012), available at <http://marrow.org/workarea/DownloadAsset.aspx?id=1071>. There is a dearth of minority donors in the Registry. The Registry contains almost seven million potential white donors, but only about 685,000 African-American donors. Barnard, *supra*. A white person has a 93 percent chance of finding a donor through the NMDP, while Blacks have only a 66 percent of finding a donor. NAT'L MARROW DONOR PROGRAM & BE THE MATCH, *supra*.

9. Sandra G. Boodman, *Multiracial Patients Struggle to Find Donors for Bone Marrow Transplants*, WASH. POST (June 1, 2010), <http://www.washingtonpost.com/wp-dyn/content/article/2010/05/31/AR2010053102481.html>.

recruitment campaign to attempt to recruit more multiracial donors, Devan's family was still unable to find a bone marrow match.¹⁰

A decade ago, the lack of such a match would have meant that Devan's prospects at survival were dim and the story would end here. However, in the last several years, cord blood transplants are increasingly being used to treat diseases that were previously only treated with bone marrow transplants.¹¹ Thankfully, Devan's family was able to locate a matching cord blood unit, and Devan is a healthy little boy due to a successful cord blood transplant.¹²

Just as in Devan's case, cord blood transplants are increasingly becoming a viable alternative to bone marrow transplants for those individuals who are unable to find a bone marrow match.¹³ Similar to bone marrow, cord blood contains blood-forming cells that can be used in transplants for patients with leukemia and lymphoma as well as many other life-threatening diseases.¹⁴ This is particularly significant for those in minority and mixed-race populations, who are much less likely to find a bone marrow or PBSC match using the NMDP registry than whites.¹⁵ Bone marrow donors need to have an even higher genetic similarity to their recipients than cord blood and organ donors.¹⁶ It is not rare for minorities or mixed-race individuals in the United States to die while waiting for a matching bone marrow donor or stem cell donor.¹⁷ Within the

10. *Id.*

11. *Cord Blood is Changing Lives*, NAT'L MARROW DONOR PROGRAM, http://marrow.org/Get_Involved/Donate_Cord_Blood/Cord_Blood_is_Changing_Lives/Cord_Blood_Is_Changing_Lives_Today.aspx (last visited Nov. 10, 2012).

12. Tanya Snyder, *Doctors Find Match for Boy in Need of Transplant*, WTOP (June 18, 2010, 2:14 PM), <http://www.wtop.com/?nid=25&sid=1959996>.

13. *Cord Blood is Changing Lives*, *supra* note 11.

14. *Id.*

15. Currently, there are only 165,000 umbilical cord blood units on the Be The Match Registry. *Id.* There is still a lack of cord blood units from minority and mixed race patients. *Id.* "Adding more cord blood units from diverse racial and ethnic backgrounds to the registry increases the likelihood that all patients will find a match." *Id.*

16. Christopher Shay, *Bone Marrow Transplants: When Race Is an Issue*, TIME MAG. (June 3, 2010), <http://www.time.com/time/health/article/0,8599,1993074,00.html>.

17. Shawn Doherty, *Racial Disparities Found Throughout Organ Transplant Process*, THE CAP TIMES (July 30, 2010, 10:00 AM), http://host.madison.com/ct/news/local/health_med_fit/article_1175c506-9b4a-11df-828c-001cc4c002e0.html. Unlike for bone marrow or cord blood, "race is not a direct factor" when seeking an organ match. *Id.* It is possible for a person of one race to receive a kidney from a person of another race. *Id.* However, the "odds are that people of the same ethnic

NMDP registry, the vast majority of donors are white.¹⁸ Unfortunately, there is a dearth of donors of other races.¹⁹ Within the NMDP, white recipients find a willing donor 65 percent of the time, while Latinos find a willing donor only 45 percent of the time, Asian patients only 40 percent of the time,

or racial background are more likely to have compatible blood and tissue types.” *Id.* For this reason, race still plays an important role in organ donations as minorities have a more difficult time than whites in finding matching organ donors. See Nicolette Young, Note, *Altruism or Commercialism? Evaluating the Federal Ban on Compensation for Bone Marrow Donors*, 84 S. CAL. L. REV. 1205, 1212 (2011). For example, in 2010, 108,983 people were on the waiting list for various organs, and over 25 percent of these people were African-Americans. April A. Robinson, *Double Standards and Hypocrisy in the Altruistic Organ Procurement Model: Generous Donors But Irrational Negotiators?* 32 HAMLINE J. PUB. L. & POL’Y 37, 42 (2010). With regard to kidneys, “[w]hile only 13 percent of the country’s population, blacks make up 40 percent of those on dialysis.” Doherty, *supra*. Of African-Americans who registered for a kidney transplant seven years ago, 39 percent are either still waiting or have died. *Id.* This number is “nearly twice the proportion of white patients.” *Id.* The median waiting period for organs is long and it has increased drastically across the board. Michele Goodwin, *The Body Market: Race Politics & Private Ordering*, 49 ARIZ. L. REV. 599, 616 (2007). In 2001 and 2002 the median wait for a kidney was 1,284 days for whites and 1,842 days for African-Americans. *Id.* Part of this problem is the disparity between races in organ donations in general, as there is a reluctance of minorities to become organ donors. Doherty, *supra*. For example, “in Wisconsin, 54 percent of drivers have checked the ‘yes’ box for organ donation on their driver’s licenses.” *Id.* However, consent rates for African-Americans in Wisconsin are half that. *Id.* One of the factors that has been an obstacle to recruiting more African-American donors is “overcoming a profound distrust of the medical system.” *Id.* The number of Hispanic organ donors also shows a disinclination towards donating an organ. Jim Forsyth, *Many Hispanics Hesitant About Organ Donation*, REUTERS (Mar. 28, 2011, 11:23 AM), <http://www.reuters.com/article/2011/03/28/us-transplants-organs-idUSTRE72R46R20110328>. This trend has been credited by some to religious beliefs. Carmen Radecki Breitkopf, *Attitudes, Beliefs and Behaviors Surrounding Organ Donation Among Hispanic Women*, 14 *Current Opinion in Organ Transplantation* 191(2009), http://journals.lww.com/co-transplantation/Fulltext/2009/04000/Attitudes,_beliefs_and_behaviors_surrounding_organ.17.aspx. In Texas in 2010, 31 percent of organ donors were Hispanic, while “42 percent of the state’s population is [Hispanic].” Jim Forsyth, *Many Hispanics Hesitant About Organ Donation*, REUTERS (Mar. 28, 2011, 11:23 AM), <http://www.reuters.com/article/2011/03/28/us-transplants-organs-idUSTRE72R46R20110328>.

18. NAT’L MARROW DONOR PROGRAM & BE THE MATCH, *supra* note 8, at 2. On the national registry, only a small percentage of the 8 million volunteer donors are people of color. *Id.* Seventy-three percent are white, 9 percent are Latino, 8 percent are African-American, 7 percent are Asian/Pacific Islanders, 3 percent are multi-racial, and 1 percent are Native American. Laura Landro, *Building Diversity in Bone-Marrow Registries*, WALL ST. J., May 27, 2009, <http://online.wsj.com/article/SB124338408532856679.html>.

19. Young, *supra* note 17, at 1212 (stating that the proportion of minority bone marrow donors on the National Bone Marrow registry does not equal their population percentage).

and African-Americans only 34 percent of the time.²⁰ Finding a bone marrow donor for a person of mixed race is “more difficult, and often impossible.”²¹ Cord blood is easier to match than bone marrow and requires less genetic similarity.²² Although there is still a racial and ethnic component to cord blood, increasing cord blood donations will help minorities and mixed race individuals who are unable to find a bone marrow or PBSC match.²³

This Article proposes that the recent Ninth Circuit Court of Appeals (“Ninth Circuit”) decision, *Flynn v. Holder*,²⁴ which held that payments for PBSC obtained via apheresis are allowed, would allow payment for cord blood as well. This Article argues that compensating umbilical cord blood donors could be an effective way to close the gap for minorities and mixed-race individuals who are in need of bone marrow transplants, without facing any of the potential ethical landmines that may arise in compensating bone marrow donors.

Part I of this Article discusses the value of cord blood for patients who need bone marrow transplants, particularly minority and mixed race patients. Part I also describes the lack

20. *Id.*

21. *Id.* A recent example of a mixed race individual that died due to the lack of bone marrow donors is Shannon Tavaréz. See Bruce Weber, *Shannon Tavaréz, Nala in ‘Lion King,’ Dies at 11*, N.Y. TIMES, Nov. 3, 2010, <http://www.nytimes.com/2010/11/03/theater/03tavaréz.html>. Tavaréz was diagnosed with acute myelogenous leukemia, an aggressive blood cancer requiring a bone marrow transplant, seven months into her role as Nala on the Broadway show, “The Lion King.” *Id.* Like many mixed race individuals needing bone marrow transplants, Shannon, whose father was Latino and mother was black, was unable to find a suitable bone marrow match. Juliana Barbassa, *Mixed-Race Patients Struggle to Find Marrow Donors*, PHYSORG.COM (May 27, 2009), available at <http://www.physorg.com/news162659550.htm>. She was able to extend her life, however, by finding a match from donated umbilical cord blood and having a cord blood transplant. See Bruce Weber, *Shannon Tavaréz, Nala in ‘Lion King,’ Dies at 11*, N.Y. TIMES, Nov. 3, 2010, <http://www.nytimes.com/2010/11/03/theater/03tavaréz.html>. Unfortunately, the umbilical cord blood transplant was not successful and Shannon died in 2010 when she was only eleven years old. *Id.*

22. *HLA Matching: Finding the Best Donor or Cord Blood Unit*, NAT'L MARROW DONOR PROGRAM, http://marrow.org/Patient/Transplant_Process/Search_Process/HLA_Matching_Finding_the_Best_Donor_or_Cord_Blood_Unit.aspx#hla (last visited Nov. 10, 2012).

23. *Id.* “Human leukocyte antigen (HLA) typing is used to match patients and donors for bone marrow transplants or cord blood transplants.” *Id.* Some racial and ethnic groups have HLA types that are less common. *Id.* Therefore, for both bone marrow and cord blood, the best chance of finding a suitable donor is with someone of a similar racial or ethnic background. *Id.*

24. 684 F.3d 852, 865 (9th Cir. 2012).

of public cord blood donations due in part to the proliferation of private cord blood banks. Part II discusses NOTA and the reasons for the ban on compensation for certain organs and bodily materials under NOTA. Part III examines other biological material for which compensation is allowed under NOTA—such as blood, sperm, and eggs—and examines the historical basis for these distinctions. Part IV discusses the *Flynn* decision and the arguments that both parties put forth regarding whether bone marrow and PBSC donors should be compensated under NOTA. Part V addresses the criticisms of the *Flynn* decision regarding allowing payment for certain types of PBSC extractions. Finally, Part VI argues that under *Flynn* and NOTA, cord blood is a biological material for which compensation is or should be allowed. Part VI also proposes ways that the compensation system for cord blood could be structured to create a robust public cord blood donation system in the United States instead of the current system, which is dominated by private cord blood banks and reserves donations for those who can afford to preserve their own cord blood, rather than for those who need it most. This Article concludes that utilizing a combination of policies, including compensation for cord blood, would increase the number of pregnant women who donate their cord blood to a public bank and make a significant public health impact by helping minorities and mixed-race individuals who need bone marrow and stem cell transplants have a greater chance of finding a match.

I. WHY CORD BLOOD TRANSPLANTS ARE IMPORTANT

A. *The Science Behind Cord Blood Transplants*

The advent of cord blood transplantation as a viable alternative to bone marrow transplantation has given hope to patients who have been unsuccessful in finding a PBSC or bone marrow match. Patients whose bone marrow has been destroyed by disease need to replace their damaged bone marrow cells.²⁵ There are three ways to replace bone marrow in a diseased individual: bone marrow, PBSC transplants, or cord blood transplants.²⁶ Each of these methods is explained in turn

25. THE AM. CANCER SOC'Y, STEM CELL TRANSPLANT (PERIPHERAL BLOOD, BONE MARROW, AND CORD BLOOD TRANSPLANTS) 1 (Nov. 1, 2012), <http://www.cancer.org/acs/groups/cid/documents/webcontent/003215-pdf.pdf>.

26. *Id.* Although commonly referred to as bone marrow transplants, the most

below.

1. Bone Marrow and PBSC Transplants

To understand the arguments presented in this Article, it is important to understand the science behind bone marrow transplants and PBSC transplants. Bone marrow refers to the spongy tissue, located inside the hollow part of certain bones,²⁷ which forms red and white blood cells and platelets.²⁸ It contains hematopoietic stem cells that can develop into any type of blood cell.²⁹ When a person suffers from a disease that destroys his or her bone marrow, such as leukemia or lymphoma, he or she often needs a bone marrow transplant.³⁰

Marrow cells and PBSCs carry a marker called the human leukocyte antigen (“HLA”).³¹ HLA proteins, located in a person’s cells, determine that person’s tissue “type.”³² HLA markers allow one’s body to recognize foreign cells.³³ This immune response can be deadly when a person receives a necessary bone marrow or cord blood transplant.³⁴ In order to reduce this adverse immune response, transplant patients are matched with donors having a tissue type that is as similar as possible to that of the recipient.³⁵ HLA tissue types are

common transplants to replace bone marrow are peripheral stem cell transplants. *Id.* at 6. In these transplants, peripheral stem cells are extracted from a donor via apheresis. *Id.* at 11. In rare circumstances, actual bone marrow is transplanted. *Id.* at 8. Bone marrow is retrieved via the aspiration technique. *Fact Sheet, Bone Marrow Transplantation and Peripheral Blood Stem Cell Transplantation*, NAT’L CANCER INST. (Sept. 24, 2010), <http://www.cancer.gov/cancertopics/factsheet/Therapy/bone-marrow-transplant>.

27. THE LEUKEMIA & LYMPHOMA SOC’Y, BLOOD AND MARROW STEM CELL TRANSPLANTATION 38 (2010), <http://www.lls.org/content/nationalcontent/resourcecenter/freeducationmaterials/treatments/pdf/bloodmarrowstemcelltransplantation.pdf>.

28. BE THE MATCH, YOUR INTRODUCTION TO MARROW AND CORD BLOOD TRANSPLANT 7 (2011), [http://marrow.org/Patient/Support_and_Resources/Resource_Library/Learn_resources/An_Introduction_to_Marrow_and_Cord_Blood_Transplant_\(PDF\).aspx](http://marrow.org/Patient/Support_and_Resources/Resource_Library/Learn_resources/An_Introduction_to_Marrow_and_Cord_Blood_Transplant_(PDF).aspx).

29. *Fact Sheet, Bone Marrow Transplantation and Peripheral Blood Stem Cell Transplantation*, *supra* note 26.

30. *Id.*

31. THE LEUKEMIA & LYMPHOMA SOC’Y, *supra* note 27, at 43.

32. *Id.*

33. BE THE MATCH, *supra* note 28, at 8.

34. *HLA Matching: Finding the Best Donor or Cord Blood Unit*, *supra* note 22.

35. *Id.* at 8. Cord blood is now being used as an alternative to peripheral stem cell or bone marrow transplants. AM. ACAD. OF PEDIATRICS, *Cord Blood Banking for Potential Future Transplantation*, 119 PEDIATRICS 165, 165 (2007), available at <http://pediatrics.aappublications.org/content/119/1/165.full.pdf+html>. In comp-

genetically inherited, which is why the most successful matches are usually from one's own family members³⁶—siblings have a 25 percent chance of having the same HLA tissue type.³⁷ Therefore, the instances of HLA identity between unrelated patients and donors are relatively few in number. Patients who are from ethnic minority groups or are of mixed-race backgrounds have an even poorer chance of finding a full HLA match with an unrelated adult donor due to genetic heterogeneity and the fact that most marrow donors are white.³⁸

Once a matching donor is identified, bone marrow can be transplanted in one of two ways: aspiration or stem cell apheresis.³⁹ Bone marrow transplants used to be performed only through aspiration.⁴⁰ Aspiration is a surgical procedure where a special hollow needle is inserted into the pelvic bone to extract the marrow.⁴¹ The donor's body typically replenishes the lost bone marrow within four to six weeks.⁴²

PBSC apheresis was developed three decades ago and is now the most common method of bone marrow transplantation.⁴³ The bloodstream contains hematopoietic stem cells that migrate from the bone marrow.⁴⁴ These cells are collected in a manner similar to that used for collecting blood donations, but after collection the donor's blood is run through

arison to bone marrow, the risk of graft-versus-host disease is diminished compared with similarly mismatched stem cells from the peripheral blood or bone marrow of a related or unrelated donor. *Id.* Cord blood is also a useful option when a patient's cells do not match an adult donor closely enough. *Id.* at 166. "Biologically, a greater degree of human leukocyte antigen mismatch is tolerated by the recipient and the incidence of acute graft-versus-host reaction is decreased when umbilical cord blood is used." THE AM. COLL. OF OBSTETRICIANS & GYNECOLOGISTS, ACOG COMMITTEE OPINION NO. 399, UMBILICAL CORD BLOOD BANKING 1 (Feb. 2008), available at <http://www.acog.org/~media/Committee%20Opinions/Committee%20on%20Obstetric%20Practice/co399.pdf?dmc=1&ts=20120722T1521237632>. Studies show that cord blood does not need to match as closely as bone marrow. *Id.*

36. BE THE MATCH, *supra* note 28, at 8.

37. See Barnard, *supra* note 8.

38. AM. ACAD. OF PEDIATRICS, *supra* note 35, at 166. The plaintiffs in *Flynn* sought to compensate bone marrow and peripheral stem cell donors to increase the number of donors for these individuals. *Flynn v. Holder*, 684 F.3d 852, 855 (9th Cir. 2012).

39. Barnard, *supra* note 8, at 393 (citing *Fact Sheet, Bone Marrow Transplantation and Peripheral Blood Stem Cell Transplantation*, *supra* note 26.).

40. Barnard, *supra* note 8, at 393.

41. *Id.*

42. *Id.*

43. *Id.* at 394.

44. *Id.*

an apheresis machine which isolates the PBSCs.⁴⁵ To ensure a sufficient number of these cells for transplantation, donors are given drugs for several days prior to donation.⁴⁶ The collection process itself takes a few hours and does not require hospitalization.⁴⁷

2. Cord Blood Transplants

Cord blood is now commonly used as an alternative to bone marrow transplants or PBSC transplants and can treat more than seventy different diseases.⁴⁸ Cord blood is taken from the umbilical cord and placenta of a newborn baby after the delivery of the child.⁴⁹ Like PBSCs, cord blood contains hematopoietic stem cells that have the potential to be life-saving for people with some cancers, immune deficiencies, inherited disorders, and metabolic disorders.⁵⁰

In addition to being both extremely therapeutic and easy to collect, cord blood has wide usage because recipients of cord blood transplants are able to withstand a less perfect type match than recipients of bone marrow transplants.⁵¹ This is especially significant for racial minorities and mixed race individuals for whom it is very difficult to find exact bone marrow matches.⁵² Just like bone marrow cells, cord blood cells carry an HLA marker.⁵³ Because cord blood transplants require less exact matching, even with cord blood transplantation being in its relative infancy compared with marrow transplants, racial minorities and mixed race individuals have had better luck finding cord blood matches than bone marrow matches.⁵⁴

45. *Id.* at 395.

46. *Id.*

47. *Id.*

48. Jeannette Moninger, *The Cord Blood Controversy: Insurance—or Reassurance?*, PARENTS MAG., <http://www.parents.com/pregnancy/my-baby/cord-blood-banking/the-cord-blood-controversy/> (last visited Nov. 10, 2012).

49. THE AM. CANCER SOC'Y, *supra* note 25.

50. THE AM. ACAD. OF PEDIATRICS, *supra* note 35.

51. *Id.* at 165–66. Cord blood transplant recipients can withstand human leukocyte antigen mismatch and suffer much less graft-versus-host reaction than bone marrow transplant recipients. *Id.* at 166. Additionally, in comparison to bone marrow, the risk of graft-versus-host disease is diminished compared with similarly mismatched stem cells from the peripheral blood or bone marrow of a related or unrelated donor. *Id.*

52. *Cord Blood is Changing Lives*, *supra* note 11.

53. THE LEUKEMIA & LYMPHOMA SOC'Y, *supra* note 27, at 43.

54. *Reasons to Bank Cord Blood*, PARENT'S GUIDE TO CORD BLOOD

Cord blood transplants are also preferred over bone marrow or PBSC transplants when a patient does not have a lot of time due to the progression of his or her disease.⁵⁵ Cord blood transplants occur over a three-week period as opposed to the six weeks it takes if there is a PBSC or bone marrow match.⁵⁶

Cord blood contains a low number of stem cells acquired per unit compared with other sources of stem cells.⁵⁷ For this reason, cord blood transplants were often not used in large adults.⁵⁸ However, technology has progressed and now combined units of umbilical cord blood are used, which greatly increases the potential for cord blood transplants in a wider variety of patients.⁵⁹

B. The Process of Cord Blood Donation

In order to donate cord blood to most public banks, the expectant mother must be pregnant with a single baby, be at least eighteen years of age, and have no reason to expect delivery earlier than thirty-five weeks gestation.⁶⁰ The procedure to collect cord blood from the delivered placenta does not interfere with labor and delivery,⁶¹ and there are no risks

FOUNDATION, <http://parentsguidecordblood.org/reasons.php> (last modified May 30, 2012). Bone marrow should be “matched at least for the HLA-A, -B, -C and -DRB1 alleles. Since there are usually two alleles for each, in a perfect match, the donor will have the same eight alleles as the patient, an 8/8 match. A perfect match is most likely to occur among family members.” *Cord Blood Q & A: Why Do We Need to Have Cord Blood Donated to Public Cord Blood Banks?*, NAT’L CORD BLOOD PROGRAM, http://www.nationalcordbloodprogram.org/qa/why_do_we_need_it.html (last visited Nov. 10, 2012). In contrast, successful matches for cord blood have been 5/6 or 4/6 matches for HLA-A, -B and -DRB1 antigens. *Id.* Thus, patients who do not have a bone marrow match may have an easier time finding a cord blood match for transplant.

55. *Cord Blood Stem Cells Help Meet Minority Marrow Needs*, STEM CELL INST., (Mar. 1, 2010), <http://www.cellmedicine.com/cord-blood-stem-cells-help-meet-minority-marrow-needs/>.

56. *Id.*

57. THE AM. COLL. OF OBSTETRICIANS & GYNECOLOGISTS, *supra* note 35, at 1.

58. *Id.*

59. *Id.*

60. *The Arizona Public Cord Blood Banking Program—Frequently Asked Questions*, ARIZ. DEPT OF HEALTH SERVS., <http://azdhs.gov/biomedical/aztransnet/documents/ArizonaPublicCordBloodBankingProgram.pdf> (last visited Feb. 20, 2013).

61. *Eligibility Guidelines for Collecting Cord Blood Stem Cells*, CORD BLOOD BANKING (Aug. 10, 2011), <http://www.cordbloodbanking.com/tag/collecting-cord-blood/>.

to the mother or child when donating.⁶² After a baby is born, the umbilical cord is clamped.⁶³ To extract cord blood, a needle with a bag attached is inserted into the portion of the cord that is no longer attached to the baby.⁶⁴ After this, the bag is sealed, and the placenta is then delivered.⁶⁵ Cord blood cannot be used in certain limited circumstances, such as when the blood carries infection, in cases of premature birth, birth of multiple babies, or emergencies during labor and delivery.⁶⁶

After the cord blood is collected, the blood is placed in a tamper-proof, temperature-monitored container for transportation via land or air to the cord blood bank.⁶⁷ At the cord blood bank, the personnel then check the integrity of the cord blood donation and the accompanying paperwork.⁶⁸ The blood is then weighed and tested for extreme temperature changes since it was harvested.⁶⁹ The cord blood bank next separates the stem cells from the cord blood, tests the stem cells for potency, infectious diseases, and viability, identifies the genetic characteristics of the cells and then freezes and stores the unit of cells.⁷⁰ The information is then put into the database for future matching.⁷¹

C. *The Need for More Cord Blood*

There is a sheer lack of donated cord blood units. The NMDP's "Be the Match Registry" is the largest registry of potential marrow donors and donated cord blood units in the world.⁷² The Registry contains the information of almost 10.5 million potential donors, but only has a mere 185,000 available

62. *Cord Blood Donation*, NAT'L CORD BLOOD PROGRAM, www.nationalcordbloodprogram.org/donation/prospective_donor_faq.html (last visited Nov. 11, 2012).

63. *Eligibility Guidelines for Collecting Cord Blood Stem Cells*, *supra* note 61.

64. *Id.*

65. *Cord Blood Banking Frequently Asked Questions*, THE AM. COLL. OF OBSTETRICIANS AND GYNECOLOGISTS (Aug. 2011), <http://www.acog.org/~media/For%20Patients/faq172.pdf?dmc=1&ts=20120625T1219143933>.

66. *Id.*

67. U.S. GOV'T ACCOUNTABILITY OFFICE, GAO-12-23, NATIONAL CORD BLOOD INVENTORY: PRACTICES FOR INCREASING AVAILABILITY FOR TRANSPLANTS AND RELATED CHALLENGES 11 (Oct. 2011).

68. *Id.*

69. *Id.*

70. *Id.*

71. *Id.*

72. NAT'L MARROW DONOR PROGRAM & BE THE MATCH, *supra* note 8, at 1.

cord blood units.⁷³ Given how valuable cord blood is, this number is much too low, the numbers and percentages specifically of mixed race and minority donors and cord blood units are very low. The vast majority of cord blood units—over one hundred thousand—are from whites.⁷⁴ There are only about thirteen thousand black cord blood units, three hundred Native American cord blood units, eighteen thousand Asian cord blood units, thirty-four thousand Latino cord blood units, 150 Native Hawaiian cord blood units, and less than seventeen thousand mixed-race cord blood units.⁷⁵

The United States Congress, recognizing the need for genetically diverse and high quality units of cord blood, passed the Stem Cell Therapeutic and Research Act of 2005.⁷⁶ The goal of the Act was to bank an additional 150,000 new cord blood units.⁷⁷ Additionally, the Secretary of the Department of Health and Human Services (“HHS”) established the National Cord Blood Inventory (“NCBI”), a program that supports public cord blood banking for use in transplants.⁷⁸ One of the main goals of the NCBI is to increase the genetic diversity of cord

73. *Id.* at 3.

74. *Id.* at 2.

75. *Id.*

76. U.S. GOV'T ACCOUNTABILITY OFFICE, *supra* note 67, at 1; *see also* Stem Cell Therapeutic and Research Act of 2005, Pub. L. No. 109–129, 119 Stat. 2550 (codified as amended in 42 U.S.C. § 274(k)–(m)).

77. U.S. GOV'T ACCOUNTABILITY OFFICE, *supra* note 67, at 1. The Stem Cell Act authorized the appropriation of \$60 million in federal funds through 2010 in order to make more units of cord blood available for transplantation. *Id.*

78. *Id.* at 2. The Food and Drug Administration (“FDA”) also regulates cord blood banks. The FDA requires that cord blood banks register with the FDA and comply with current manufacturing, tissue handling, and storage practices and screen potential donors for certain diseases. *Id.* at 14. Additionally, now, all cord blood units must be approved by the FDA. *Id.* at 15. The Stem Cell Act created an Advisory Council to assist and advise the Secretary of Health and Human Services and Administrator of Health Resources and Services on how to perform the activities related to managing the National Cord Blood Inventory. *Id.* at 14. The Advisory Council consists of twenty-five members such as cord blood and bone marrow donor centers, recipients of transplants, transplant centers, and banks that partake in workgroups to develop and present recommendations on how the National Cord Blood Inventory should operate. *Id.* The GAO report contained recommendations from banks that adding more staff at collection sites during more hours of the day or more days of the week, providing recognition or feedback to motivate medical staff about cord blood collections, and lowering the age of consent for donating cord blood could all increase collections. *Id.* at 16. The GAO report acknowledges that competition from private banks and limited resources make increasing collections at existing sites more difficult. *Id.* Another suggestion in the GAO report to increase cord blood collections was to expand the number of collection sites. *Id.* at 17. These efforts could be focused on hospitals with a high number of minority births. *Id.*

blood units available to help ethnic and racial groups find matches for transplants.⁷⁹ In 2010, the Stem Cell Therapeutic and Research Reauthorization Act of 2010 authorized more funding to increase and support the growth of cord blood donations to public banks.⁸⁰

The Government Accountability Office recently submitted a Report to Congressional Committees on the NCBI.⁸¹ In the National Cord Blood Inventory, 1 percent of the cord blood units are from American Indian/Alaskan Natives donors, 10 percent from Asian donors, 10 percent from black/African American donors, 13 percent from Latino donors, and 59 percent from white donors.⁸² Clearly, there remains a substantial lack of minority cord blood donors in the United States.⁸³ More than 40 percent of minority patients suffering from a bone marrow disease requiring transplantation use cord blood transplants.⁸⁴ If the number of cord blood donations from

79. *Id.* at 2. In order to meet these goals, the Health Resources and Services Administration entered into thirteen contracts with cord blood banks. *Id.* By May 31, 2011, the banks had been reimbursed \$45.7 million for over 41,000 units of cord blood. *Id.* Under the practices used to increase racial and ethnically diverse cord blood donations, a new pilot program for remote collection of cord blood may help increase the opportunities to donors in locations where access to public banks is difficult. *Id.* at 11–12. According to the GAO report, the remote collections could not be added to the National Cord Blood Inventory because of FDA licensure requirements. *Id.* at 12. If the remote collection can be adjusted to meet the requirements of NCBI and FDA, this program could increase the number of cord units from sites around the country that do not have access or opportunity to do so now, which would likely increase the number of cord blood units from racial and ethnically diverse groups. Another practice used to increase racial and ethnically diverse cord blood donations is the awarding of contracts to banks through a competitive request-for-proposal process. *Id.* The Stem Cell Act required that the contract be for ten years and that no funds would be obligated under the contracts three years after they were entered into. *Id.* The contract also requires that the cord blood be available for transplant indefinitely or for as long as it is deemed viable by Health and Human Services. *Id.* As part of the competitive process, each bank puts forward a number of units based on ethnic and racial groups that the bank will provide to the National Cord Blood Inventory each year. *Id.* By doing so, Health Resources and Services Administration use these competitive measures to increase the diverse minority units available in the Inventory for transplant. *Id.* at 12–13. The Health Resources and Services Administration (HRSA) now pays banks higher rates for minority group units compared to the units collected from non-Latino Whites. *Id.* at 13.

80. *Id.* at 2.

81. *Id.*

82. *Id.* at 7.

83. *See id.*

84. Sara Farris, *Mothers Give the Gift of Life Twice with Cord Blood Donation*, UNIV. OF TEX. MD ANDERSON CANCER CTR. (Sept. 19, 2012, 11:08 AM), <http://www2.mdanderson.org/cancerwise/2012/09/mothers-give-the-gift-of-life-twice-with-cord-blood-donation.html>.

racially and ethnically diverse donors is increased, more matches can be made for minorities, increasing the likelihood that those patients will find a match that could save their lives.⁸⁵ As discussed later in this Article, the NCBI's goals could be achieved if a system of compensation for cord blood donors is instituted.⁸⁶

D. The Proliferation of Private Cord Blood Banks and the Lack of Public Cord Blood Banks: A Public Health Problem

Although the federal government has been advocating the establishment of larger and more widespread umbilical cord blood banks, there currently is not an easily accessible public cord blood banking option in most areas of the United States.⁸⁷ Cord blood donations are largely the domain of private cord banks, and there are currently only twenty-nine public cord blood banks in the United States.⁸⁸ Researchers have found that “the abundance of private cord blood banking options coupled with the lack of a public cord blood bank alternative in most areas of the United States prevents the public health benefits [of cord blood donation], such as improved access to stem cell transplant for underrepresented minorities, from being realized.”⁸⁹

The current scheme of cord blood donation in the United States is fraught with serious problems. First, pregnant women

85. See *Cord Blood Stem Cells Help Meet Minority Marrow Needs*, *supra* note 55.

86. See *infra* Part VI.B.

87. Anjali J. Kaimal et al., *Cost-effectiveness of Private Umbilical Cord Blood Banking*, 114(4) *OBSTETRICS & GYNECOLOGY* 848, 853 (2009).

88. *Find a USA Public Bank*, PARENT'S GUIDE TO CORD BLOOD FOUND., http://parentsguidecordblood.org/public_usa.php (last modified Oct. 25, 2012). Not all hospitals work with public banks. *Id.* For a list of hospitals that participate and work with cord blood banks, see *Participating Hospitals*, NAT'L MARROW DONOR PROGRAM, http://marrow.org/Get_Involved/Donate_Cord_Blood/How_to_Donate/Participating_Hospitals.aspx (last visited Feb. 8, 2013). “The first public bank was established at the New York Blood Center in 1991 and other public banks have since been established in various regions of the country.” *THE AM. COLL. OF OBSTETRICIANS & GYNECOLOGISTS*, *supra* note 35, at 1.

89. Kaimal et al., *supra* note 87. Even developing countries, such as Mexico, are beginning to establish public cord blood banks. See Micheal Boo, *Public Cord Blood Banking May Play an Important Role in the Emergence of Unrelated Transplant in Developing Countries*, 48 *TRANSFUSION* 207, 207 (Feb. 2008), <http://www.imss.gob.mx/salud/BancoSangre/Documents/RolBanco.pdf>. Unfortunately, even in these countries, private cord blood banks are preventing a robust public cord blood banking system. See Kaimal et al., *supra* note 87, at 848.

and prospective fathers are often uneducated about cord blood donation in general.⁹⁰ Often, public banking is not even mentioned to expectant families prior to the birth of their babies. Although twenty-seven states have passed legislation⁹¹ to encourage the discussion of the cord blood banking option, this appears to benefit the private cord banking industry instead of encouraging cord blood donation. Although some states follow the Institute of Medicine guidelines, which require discussion of all cord blood options, other states simply require education in general with no specifications.⁹²

Additionally, the majority of public and private hospitals in the United States do not have a direct connection to a public bank.⁹³ There are only a limited number of hospitals in the United States that participate in the NMDP's cord blood banking program.⁹⁴ In addition to these sites, the National Cord Blood Program also has a limited number of collection sites, and these are mostly in New York.⁹⁵ If a woman is not delivering in any of the NMDP participating hospitals, she has the option of donating to one of only four public banks that accept mail-in donations.⁹⁶ In contrast, representatives from private cord blood banks establish friendly relationships and leave promotional materials at obstetricians' offices.⁹⁷

90. MARY HAWS ET AL., DEPT OF MED. LAB. SCI., WEBER STATE UNIV., KNOWLEDGE AND PERCEPTIONS OF CORD BLOOD DONATION AMONG PREGNANT WOMEN 1–2, http://www.weber.edu/WSUIImages/DCHPResearch/mls_2011_12_projects/GRP4_OUR.pdf (last visited March 12, 2013).

91. *27 States Have Cord Blood Education Laws*, PARENT'S GUIDE TO CORD BLOOD FOUND., <http://parentsguidecordblood.org/news/12/> (last modified Mar. 28, 2012). These states include: Arizona, Arkansas, California, Colorado, Connecticut, Florida, Georgia, Illinois, Louisiana, Maryland, Massachusetts, Michigan, Missouri, New Jersey, New Mexico, New York, North Carolina, North Dakota, Ohio, Oklahoma, Pennsylvania, Rhode Island, Tennessee, Texas, Virginia, Washington, and Wisconsin. *Id.*

92. *Id.*

93. *Public and Private Cord Blood Banks*, SAVE THE CORD FOUND., http://savethecordfoundation.org/banking_list.php (last visited Mar. 8, 2013).

94. *Participating Hospitals*, *supra* note 88.

95. *Cord Blood Donation*, *supra* note 62. The NCBP's collection sites are New York-Presbyterian Hospital's Cornell Weill Medical Center; Brooklyn Hospital Center; Montefiore Medical Center/Albert Einstein College of Medicine of Yeshiva University Weiler Hospital; Mount Sinai Medical Center; North Shore University Hospital in Manhasset; Long Island Jewish (LIJ) Medical Center; Inova-Fairfax Hospital; and MacDonald Hospital for Women. *Id.*

96. *Donating at Other Hospitals*, NAT'L MARROW DONOR PROGRAM, http://marrow.org/Get_Involved/Donate_Cord_Blood/How_to_Donate/Donating_at_Other_Hospitals.aspx (last visited Feb. 8, 2013).

97. *See Sophie Ramsey, Docs Weigh in on Private Cord-Blood Banking*, CONSUMER NEWS (Mar 19, 2009), <http://news.consumerreports.org/health/2009/>

E. Private Cord Blood Banks: The Hype and the Reality

Despite the greater abundance of information on private cord blood banking over public, the realities of the process do not match the hype. Private banking is not cost-effective, will not likely be useful to those who bank the blood, and professional organizations are opposed to it.

1. Cord Blood Banking is Not Cost Effective

The private cord banking industry markets cord blood storage for future use as a sort of insurance policy⁹⁸—a private reserve of stem cells that parents can draw upon in the event that their child develops a bone marrow disease.

An illustrative example of private cord blood bank advertising to pregnant women is the Cord Blood Registry's ("CBR") website.⁹⁹ CBR's slogan is "Healthy Futures Born Here."¹⁰⁰ The website gives a one-sided narrative of private banking and gives inspiring real life stories of how private banking has saved lives.¹⁰¹ There is not one mention of public banking on the website. CBR private storage for cord blood and tissue costs a total of \$2,895 for the first year, which is made up of a one-time cord blood and tissue collection/processing fee of \$2,790, a one-time shipping fee of \$170, and an annual storage fee of \$260. However, the reality is that private cord blood banking does not assure a healthy future for a baby.

A recent study by University of California researchers found that privately storing umbilical cord blood was not cost-effective unless the family had a long history of blood disorders.¹⁰² This study found that the odds of privately stored umbilical cord blood being used for the family in the next twenty years was very small and not worth the expense of storing the cord blood privately for most families.¹⁰³

Researchers estimate that the chance that an individual

03/private-umbilical-cord-blood-banking.html.

98. Moninger, *supra* note 48.

99. *Cord Blood Banking at its Best*, CORD BLOOD REGISTRY, <http://www.cordblood.com/en/best-cord-blood-bank> (last visited Feb. 8, 2013).

100. *Id.*

101. *See Our Clients, Their Stories*, CORD BLOOD REGISTRY, <http://www.cordblood.com/en/benefits-cord-blood/our-clients-their-stories> (last visited Feb. 9, 2013).

102. Kaimal et al., *supra* note 87, at 848.

103. *Id.* at 853.

may actually use his or her own cord blood in lieu of receiving transplantation from another donor is one in five thousand per individual.¹⁰⁴ The cost of collection and storage usually comes with a hefty price tag. Private cord blood banking is not cost-effective because it costs an additional \$1,374,246 per life-year gained.¹⁰⁵ Additionally, a survey by the American Society for Blood and Marrow Transplantation found that only ninety-nine of the approximately 460,000 cord blood units banked in private cord blood banks were confirmed as being shipped for use in treatment.¹⁰⁶

2. Privately Banked Blood Will Likely Never be Useful to Those Who Banked It

As noted above, the cost-effectiveness of privately banking cord blood is reduced by the low likelihood that the blood will actually be useful to those who banked it. Parents who bank their baby's cord blood have a less than 0.04 percent chance of ever being able to use that blood to help their child and an only slightly higher chance for family members.¹⁰⁷

Because of the way cord blood banking is marketed, many parents who choose to invest in the significant cost of private banking do so because they believe that if their child develops a disease, this cord blood will be useful in curing their child's disease.¹⁰⁸ However, if that child develops a disease such as leukemia, using their own cord blood will most likely not be an option as the genetic predisposition to the disease is already in the cord blood.¹⁰⁹ The stored cord blood may only be useful for other siblings.¹¹⁰ Even members of the American Congress of Obstetricians and Gynecologists' ("ACOG") own ethics committee have stated that "there's no reason for parents to take on this additional financial burden when there's little chance of a child ever using his own cord blood."¹¹¹ Parents

104. *Private Cord Blood Banking: The Basics*, BABY CTR., http://www.babycenter.com/0_private-cord-blood-banking-is-it-for-you_1369773.bc (last updated June 2012).

105. Kaimal et al., *supra* note 87, at 848.

106. *Id.*

107. *Id.*

108. *Id.*

109. *Cord Blood Banking Pros and Cons*, M.A.Z.E. CORD BLOOD LABS., <http://www.mazecordblood.com/private-vs-public.htm> (last visited Feb. 8, 2013); *see also* Moninger, *supra* note 48.

110. *Cord Blood Banking Pros and Cons*, *supra* note 109.

111. Moninger, *supra* note 48.

have recently filed lawsuits after realizing the futility of cord blood banking when their child has been diagnosed with an illness caused by a genetic problem.¹¹²

3. Professional Organizations Oppose Private Cord Blood Banking for Most Individuals

Professional organizations discourage the use of private cord blood banking. The American Academy of Pediatrics discourages private cord blood storage and encourages public cord blood donation.¹¹³ In February 2008, ACOG released a policy about umbilical cord blood banking.¹¹⁴ It encourages obstetricians to provide a patient who requests information on umbilical cord blood banking with balanced and accurate information regarding the advantages and disadvantages of public versus private banking.¹¹⁵ It advises physicians to educate pregnant women about the “remote chance of an autologous unit of umbilical cord blood being used for a child or a family member (approximately 1 in 2,700 individuals).”¹¹⁶ ACOG further advises that cord blood collection not alter routine practice for the timing of umbilical cord clamping.¹¹⁷ Finally, ACOG advises that “physicians . . . who recruit pregnant women and their families for for-profit umbilical cord blood banking should disclose any financial interests or other potential conflicts of interest.”¹¹⁸

The American Association of Pediatrics (“AAP”) is similarly negative about the benefits of private cord blood

112. *See, e.g., id.* For example, the Dones chose to privately bank their son Anthony’s cord blood. *Id.* When Anthony was diagnosed with osteopetrosis, a potentially fatal disorder that affects bone formation, at four months of age, the Dones were shocked to discover the cord blood they had stored could not be used to save Anthony. *Id.* The cord blood could not be used for transplant because the cells had the same genetic defect that caused Anthony’s illness. *Id.* The Dones have filed a lawsuit against the private cord blood bank claiming false advertising and consumer fraud. *Id.* This is based on their claims that they were told in printed materials given to them by the private cord bank that storing the cord blood was akin to a life insurance policy that could save Anthony’s life should he need it in the future. *Id.* The bank never mentioned the possibility that the cells that were stored would contain the debilitating disease as well. *Id.*

113. *See* AMERICAN ACAD. OF PEDIATRICS, *supra* note 35, at 167.

114. THE AM. COLL. OF OBSTETRICIANS & GYNECOLOGISTS, *supra* note 35, at 1.

115. *Id.* at 2. The policy notes that the benefits of “long-term storage of autologous umbilical cord blood [have] been questioned.” *Id.*

116. *Id.*

117. *Id.*

118. *Id.*

banking.¹¹⁹ AAP warns, “Cord blood-banking recruitment practices should be developed with an awareness of the possible emotional vulnerability of pregnant women and their families and friends. Efforts should be made to minimize the effect of this vulnerability on cord blood-banking decisions.”¹²⁰

If cord blood transplants are to remain a viable alternative to bone marrow and PBSC transplants, collection and banking procedures will need to be addressed. Although NOTA, which is discussed in the following sections, specifically addresses organ transfer and donation, it is silent as to cord blood, leaving questions about collection and banking open for debate, especially after the *Flynn v. Holder* decision.

II. THE NATIONAL ORGAN TRANSPLANT ACT OF 1984 AND THE POLICY REASONS BEHIND THE BAN ON COMPENSATION FOR ORGANS

Under NOTA,¹²¹ which was enacted in 1984, it is unlawful for any person to knowingly transfer any human organ for valuable consideration for use in human transplantation if the transfer affects interstate commerce.¹²² NOTA defines “human organ” as any human kidney, liver, heart, lung, pancreas, bone marrow, cornea, eye, bone, and skin or any subpart thereof or any other human organ specified by the Secretary of Health and Human Services by regulation.¹²³ When the statute speaks of “valuable consideration”¹²⁴ it does not include reasonable

119. See AM. ACAD. OF PEDIATRICS, *supra* note 35, at 166.

120. *Id.* at 167–68.

121. 42 U.S.C. § 274e (2007).

122. *Id.* § 274e(a). Some countries do allow compensation for organs. Compensation for living organ donors is legal in Iran. Lisa M. Derco, Note, *America's Organ Donation Crisis: How Current Legislation Must be Shaped by Successes Abroad*, 27 J. CONTEMP. HEALTH L. POL'Y 154, 163–64 (2010). This is done through a state regulated system. *Id.* at 163. Through this system, donors receive \$1,200 as well as health insurance from the government for their donation. *Id.* at 164. Additionally, donors receive compensation from the donee. *Id.* If the donee cannot afford to pay this compensation then “several charities have been established to provide compensation to the donor.” *Id.* This practice has led to Iran being the only country in the world that does not have a shortage of donated organs. *Id.* at 163; see also Alex Tabarrok, *The Meat Market*, WALL ST. J., Jan. 8, 2010, <http://online.wsj.com/article/SB10001424052748703481004574646233272990474.html>.

123. 42 U.S.C. § 274e(c)(1) (2007).

124. Although live organ donations are not compensated in most countries, some countries allow for the medical expenses that were incurred during the transplant to be reimbursed. See Derco, *supra* note 122; see also Amnon Meranda, *Knesset Approves Organ Donation Law*, YNETNEWS.COM (March 25, 2008, 2:00

payments that are associated with the procedure itself.¹²⁵ Additionally, payments that are meant to reimburse the donor for travel expenses and lost wages are allowable.¹²⁶

The legislative history of NOTA states that “human body parts should not be viewed as commodities.”¹²⁷ However, it does not specifically state the reasons for this view. In *Flynn v. Holder*, the Ninth Circuit presented possible policy reasons for this stance.¹²⁸ First, the court supposed that Congress might have been concerned that poor patients could be induced to sell their organs creating medical risks or pain for poor donors.¹²⁹ Second, the court theorized that patients needful of transplants might be threatened by matching donors to give them exorbitant amounts of money or face death.¹³⁰ The Ninth Circuit also suggested that Congress might have thought that the practice of extracting organs by fraud or force could be stimulated.¹³¹ Finally, the court presented the notion that Congress may have worried that this practice could “degrade the quality of the organ supply, by inducing potential donors to lie about their medical histories in order to make their organs

PM), <http://www.ynetnews.com/articles/0,7340,L-3523461,00.html>; see also Benny Moshe & Hana Levi Julian, *Organ Donor Compensation Bill Passes Knesset Committee*, ISRAELI NAT'L NEWS (Jan. 7, 2010, 4:28 PM), <http://www.israelnationalnews.com/News/News.aspx/135415>. In the United States, under 42 U.S.C. § 274e, “valuable consideration” for the selling or transplanting of organs is prohibited; however, reasonable payments that reimburse the donor for the medical expenses of the transplant are permitted. See 42 U.S.C. § 274e(a), (c)(2) (2007) (noting that these costs are not prohibited and by inference would be permitted).

125. 42 U.S.C. § 274e(c)(2). It is important to note that this law does not apply to human organ paired donation. *Id.* § 274e(a). Human organ paired donation is described as when one donor (donor 1) wants to donate a human organ to a particular patient (patient 1) but the donor is biologically incompatible as a donor for the patient. *Id.* § 274e(c)(4)(A). There is also a second donor (donor 2) who wants to donate a human organ to a different particular patient (patient 2) but is also biologically incompatible as a donor for the patient. *Id.* § 274e(c)(4)(B). If donor 1 is biologically compatible as a donor to patient 2 and donor 2 is a biologically compatible donor for patient 1, the statute does not apply. *Id.* § 274e(a).

126. 42 U.S.C. § 274e(a), (c)(2).

127. S. REP. NO. 98-382, at 17 (1984), reprinted in 1984 U.S.C.C.A.N. 3975, 3982.

128. *Flynn v. Holder*, 684 F.3d 852, 860 (9th Cir. 2012).

129. *Id.*; see also Jennifer M. Smith, “Dirty Pretty Things” and the Law: Curing The Organ Shortage & Health Care Crises in America, 12 CHAP. L. REV. 361, 368–69 (2008) (arguing that the supply of living donors will largely come from the poor segment of society—a segment that is often exploited).

130. *Flynn*, 684 F.3d at 860.

131. *Id.*

marketable.”¹³²

In addition to these policy arguments, the Ninth Circuit also presented possible philosophical reasons for the prohibition on compensation of organ donations¹³³—namely, that commerce regarding organs “is generally seen as revolting.”¹³⁴ The Ninth Circuit attributed this to cultural taboos.¹³⁵ With regard to the argument that certain groups will be exploited if compensation for organ donors were allowed, some argue that “there is a lack of empirical evidence to conclusively establish that offering economic incentives will promote organ donations. Yet, there is clear evidence demonstrating [that] economic incentives for donating parts of the human body will lead to exploitation of underprivileged groups.”¹³⁶ However, the argument that this compensation scheme will lead to exploitation of underprivileged groups is harder to make in the bone marrow context. Supporters of the ban on compensation ostensibly seek to protect ethnic minority groups from exploitation; however, these are the very groups that are the most disadvantaged by the status quo lack of donors.¹³⁷

It has further been suggested that if donors were compensated, this new marketplace would drive out altruistic donors, thereby decreasing both the supply and quality of donated organs.¹³⁸ However, financially motivated and

132. *Id.*

133. *Id.* at 861. Some countries, like Israel, have created ways for donors to be compensated. Meranda, *supra* note 124. In Israel, a recently enacted law allows for a person who has made living organ donations of a kidney or part of a liver to attain the status of “chronic patient.” *Id.*; see also Moshe & Julian, *supra* note 124. This means that the donor does not “have to pay the self-participation fee for any medical service resulting from the donation.” Meranda, *supra* note 124. Furthermore, the donor is compensated approximately \$5,100 from the State. *Id.* This money is viewed as a “‘safety net’ against financial and health damages that may be caused by the organ donation.” Moshe & Julian, *supra* note 124. Singapore now compensates organ donors as well. Cody Corley, *Money as a Motivator: The Cure to Our Nation’s Organ Shortage*, 11 HOUS. J. HEALTH L. & POL’Y 93, 112 (2010). The country plans to compensate “as much as US \$36,000 to individuals that are willing to donate their organs.” *Id.*

134. *Flynn*, 684 F.3d at 861.

135. *Id.*

136. Jennifer L. Hurley, *Cashing In On the Transplant List: An Argument Against Offering Valuable Compensation for the Donation of Organs*, 4 J. HIGH TECH. L. 117, 132–33 (2004) (arguing that in the past, blood and plasma donors have been unemployed, indigent, and substance-addicted).

137. See Young, *supra* note 17, at 1228–29.

138. *Id.* at 1228. The demand for bone marrow in a market that outlaws compensation for donors has led to unorthodox methods of procuring donations. In

altruistic donors can co-exist.¹³⁹ Moreover, when looking at the level of blood donations that existed before and after compensation was allowed, the total amount of donations increased.¹⁴⁰ Arguably, this shows that even if the number of altruistic organ donations dropped, the total number of donations could still rise.¹⁴¹

Another argument that has been presented is that if an open market were created for organs, then poor people would

2010, the Caitlin Raymond International Registry and UMASS Memorial Health Ventures Inc. hired models to recruit potential bone marrow donors. Denise Lavoie, *Bone Marrow Donor Recruiting Cases Settled*, CBS BOSTON (Feb. 2, 2012, 8:37 PM), <http://boston.cbslocal.com/2012/02/02/bone-marrow-donor-recruiting-cases-settled/#.Tyv3jt6ferk.email>. Wearing high heels and short skirts, these fashion models attempted to “recruit potential registrants during donor drives at malls, festivals and sporting ventures.” *Id.* Afterwards, both entities were accused of “improperly waiv[ing] copayments and deductible amounts for the testing of potential donors, g[iving] away free T-shirts and h[olding] free raffles for big-screen televisions and golf clubs.” *Id.* These activities led to claims of improper marketing practices for which these entities paid \$770,000 to the states of Massachusetts and New Hampshire. *Id.* Although certainly questionable, these practices were effective. *Id.* Additionally, Caitlin Raymond International Registry and UMass Memorial Health Ventures Inc. were charged with inflating the rates of individual donor tests. *Id.* While these tests only cost \$50 to administer, the price charged by UMass Memorial ranged from network rates of several hundred dollars to up to more than \$4,000. *Id.* “[D]onor tests performed by UMass Memorial increased significantly, from about 7,000 in 2008 to more than 40,000 in 2010.” *Id.* Remarking on the issue, Douglas Brown, the senior vice president and general counsel of UMass Memorial Healthcare Inc., said that it was regrettable that certain “practices may have undermined the public perception of the life-saving importance of donor recruitment.” *Id.* However, Brown also stated that these practices did not cause anyone any harm. *Id.* Furthermore, Brown also pointed out that “48 patients received transplants from donors in the past year as a result of the registry’s past recruitment efforts.” *Id.*

139. Young, *supra* note 17, at 1228 (citing DAVID PRICE, *LEGAL AND ETHICAL ASPECTS OF ORGAN TRANSPLANTATION* 397 (2000)). In fact, some, like constitutional scholar Eugene Volokh, argue that allowing payment for organs may be a type of medical self-defense. Allan J. Jacobs, *Is State Power to Protect Health Compatible with Substantive Due Process Rights?*, 20 *ANNALS HEALTH L.* 113, 119 (2011). Volokh argues that the “common law right of self-defense and constitutional guarantees of substantive due process should” prevent the government from regulating “therapeutic modalities in some clinical circumstances.” *Id.* Additionally, Volokh has also argued that the Supreme Court has already recognized medical self-defense in the context of abortion. Eugene Volokh, *Medical Self-Defense, Prohibited Experimental Therapies, and Payment for Organs*, 120 *HARV. L. REV.* 1813, 1824 (2007). This concept has been described as an apparent right to defend oneself through the use of medical care. *Id.* Although the Supreme Court has only recognized the medical self-defense right in abortion cases, Volokh has argued that it is logical to extend this right when people need to medically defend themselves through an organ transplant. *Id.* at 1826.

140. See Young, *supra* note 17, at 1235 n.197.

141. *Id.*

be denied access to organs.¹⁴² This argument has been attacked with the assertion that “the use of money to *acquire* organs from donors and the use of money to allocate organs to waiting recipients” are two different things.¹⁴³ Therefore, “financial incentives can be incorporated readily within the current system without any alteration in the manner through which transplantable organs are distributed to patients. The only difference would be that more organs would become available for distribution.”¹⁴⁴

III. PAYMENT ALLOWED FOR BLOOD, SPERM, AND EGGS UNDER NOTA: WHY?

Beginning in the 1910s and lasting until the 1970s “a significant percentage of the United States’ blood supply was derived from paid human donors.”¹⁴⁵ The first documented blood transfusion took place in 1818.¹⁴⁶ However, the results of early transfusions were normally unsuccessful.¹⁴⁷ It was not until the discovery of multiple blood groups in the early twentieth century that transfusions became more reliable, opening the door to blood donations and blood banks.¹⁴⁸ The revolutionary Blood Transfusion Betterment Association (“BTBA”) was founded in 1929 in New York¹⁴⁹ to provide blood to New York and the surrounding areas.¹⁵⁰ The donors were compensated per hundred cubic centimeters provided.¹⁵¹

Technological advances and increased knowledge of blood and blood storage led to the practice of civilians donating blood

142. See Corley, *supra* note 133, at 105–06 (arguing against this assertion).

143. *Id.*

144. *Id.* at 106 (citing T. Randolph Beard & David L. Kaserman, *On the Ethics of Paying Organ Donors: An Economics Perspective*, 55 DEPAUL L. REV. 827, 831 (2006)).

145. Julia D. Mahoney, *The Market for Human Tissue*, 86 VA. L. REV. 163, 171 (2000).

146. *Id.* at 171 n.23.

147. *Id.*

148. See generally *id.*

149. *The Charles R. Drew Papers: Becoming “the Father of the Blood Bank,” 1938–1941*, NAT’L LIBR. OF MED., <http://profiles.nlm.nih.gov/ps/retrieve/Narrative/BG/p-nid/338> (last visited Nov. 14, 2012) [hereinafter *Charles R. Drew Papers*].

150. *Blood Transfusion Betterment Association*, 6 BULL. OF THE N.Y. ACAD. OF MED. 682, 682 (1930), available at <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC2096130/>.

151. *Id.* at 684.

and supplying it to forward medical installations.¹⁵² This program was first used in Spain during the Spanish Civil War,¹⁵³ and a similar program was instituted by the United States at the onset of World War II.¹⁵⁴ A relief program called “Blood for Britain” collected blood in American hospitals and shipped it to England.¹⁵⁵ This program was also intended to gather the information that would be necessary to implement “a nationwide blood banking program if the U.S. entered the war.”¹⁵⁶ In addition to the Blood for Britain campaign, in 1940, the Red Cross began looking for civilian groups to provide blood to ensure a supply would be available to the armed forces if there were ever a national emergency.¹⁵⁷

Throughout World War II the number of donors depended “largely upon the ebb and flow of battle.”¹⁵⁸ During times of lower military activity, it was difficult for the program to obtain an adequate number of donors.¹⁵⁹ Although the donors did not receive any payment for their service, they were given an emblem and a certificate signifying their donation.¹⁶⁰

After World War II, human sperm also began to be seen as a marketable commodity.¹⁶¹ Much like blood donors, donors of human sperm were compensated for their donations.¹⁶² “[A]lthough artificial insemination and blood transfusions did not gain immediate public acceptance,” the objections that were raised by the public centered on the practices themselves, rather than the compensation of donors.¹⁶³ However, these sentiments did not prevail, and criticism of donors of bodily fluids centered on the commodification of these donations.¹⁶⁴

152. See Brigadier General Douglas B. Kendrick, *Blood Program in World War II*, U.S. ARMY MED. DEPT 11, available at <http://history.amedd.army.mil/booksdocs/wwii/blood/DEFAULT.htm> (last visited Feb. 12, 2013).

153. *Id.*

154. *Charles R. Drew Papers*, *supra* note 149.

155. *Id.*

156. *Id.*

157. Kendrick, *supra* note 152, at 101.

158. *Id.* at 119–20.

159. *Id.* at 119.

160. *Id.* at 148. Another non-monetary incentive to donate blood was the concept of “blood-time,” where a number of states created “blood-time” programs under which inmates that donated blood were able to serve reduced sentences. See Jamila Jefferson-Jones, *The Exchange of Inmate Organs for Liberty: Diminishing the “Yuck Factor” in the Bioethics Repugnance Debate*, 16 J. GENDER RACE & JUST. 105, 132 (2013).

161. Mahoney, *supra* note 145, at 171.

162. *Id.*

163. *Id.*

164. See Kenneth Baum, *Golden Eggs: Towards the Rational Regulation of*

In fact, many of the arguments that are currently used against the commodification of organs were used against the commodification of donating blood, sperm, and eggs. In the case of blood, when commercial blood banks first began paying people for their blood, there were many opponents who claimed that this commodification would “repress altruism, increase the risks of unethical medical practice, and exploit the poor to provide for the rich.”¹⁶⁵

Some argue that paying people for their blood would result in a decrease in the number of charitable donations.¹⁶⁶ In the book *The Gift Relationship*, Roger Titmuss argued that by paying people for their blood, “the altruistic motivations that lead individuals to donate their blood for free” were undermined.¹⁶⁷ This, he hypothesized, would lead to “[i]ndividuals who would have otherwise donated their blood for free [being] persuaded by self-interest to ask for the compensation they now thought they deserved.”¹⁶⁸ Titmuss claimed that “offering material rewards for blood donations might backfire and lower donations.”¹⁶⁹ However, a 2011 study involving nearly one hundred thousand individuals and seventy-two blood drives concluded that “providing material rewards led to a large and significant increase in the propensity to donate.”¹⁷⁰ Furthermore, this effect increased when the incentive for donating increased.¹⁷¹

Oocyte Donation, 2001 BYU L. REV. 107, 136 (2001).

165. Corley, *supra* note 133, at 111 (quoting Gail L. Daubert, *Politics, Policies, and Problems with Organ Transplantation: Government Regulation Needed to Ration Organs Equitably*, 50 ADMIN. L. REV. 459, 481 (1998)).

166. See Baum, *supra* note 164, at 136–37.

167. *Id.* at 137.

168. *Id.*

169. Nicola Lacetera et al., *Rewarding Altruism? A Natural Field Experiment* 26 (Nat'l Bureau of Econ. Research, Working Paper No. 17636, 2011) (discussing Titmuss's arguments on payment for blood donations). *But see* Baum, *supra* note 164, at 137 (“Whether or not such a shift would lead to an overall increase or decrease in donations is arguable and likely depends on the amount of compensation provided. But Titmuss was concerned with more than just decreasing numbers of blood donors. He was also concerned with the broader social implications that such a shift would endorse.”).

170. Lacetera et al., *supra* note 169, at 2, 26.

171. *Id.* It has been suggested that this trend also exists with egg donors. Egg donations are accompanied with a degree of risk not found in blood donations. Russell Korobkin, *Buying and Selling Human Tissues for Stem Cell Research*, 49 ARZ. L. REV. 45, 60 (2007). “The procedure is painful, is accompanied by the risk of bleeding and infection, and carries a small but non-trivial risk of substantial medical complications.” *Id.* As such, “there are likely to be far fewer altruistic egg donors.” *Id.*

Additionally, some felt that by offering financial incentives, the quality of donated blood would suffer.¹⁷² This idea was predicated on the belief that this lure of money would attract “poor individuals harboring infectious diseases [who] would have reason not to disclose their medical history.”¹⁷³ It was thought that if these individuals donated blood, the donated blood “could harm or even kill its recipient.”¹⁷⁴ However, with modern technology, blood banks have “extremely accurate screening techniques for the major blood-borne infectious diseases.”¹⁷⁵ Similarly, egg donors are “carefully screened through histories, physicals, . . . and genetic testing.”¹⁷⁶ Regardless of this initial reluctance to embrace the commodification of blood donors, “commercial blood banks are now widely accepted as commonplace and viewed as a necessary tool for . . . hospitals.”¹⁷⁷

IV. *FLYNN v. HOLDER*: OPENING UP THE POSSIBILITY FOR COMPENSATION FOR CERTAIN TYPES OF BODILY MATERIAL

The *Flynn v. Holder*¹⁷⁸ decision is significant because it is the first time the Ninth Circuit has interpreted NOTA and examined whether a particular bodily material falls within its purview. In *Flynn*, the District Court dismissed the plaintiffs’ claims that NOTA’s ban on payment for bone marrow and PBSCs was unconstitutional.¹⁷⁹ However, upon appeal, the Ninth Circuit stated that payment for PBSCs did not violate NOTA.¹⁸⁰ The *Flynn* court held that NOTA was constitutional, making this decision through its interpretation of the statute itself.¹⁸¹ Although some scholars have read *Flynn* as a narrow decision that will not lead to creation of markets beyond PBSCs obtained through apheresis,¹⁸² this Article contends that *Flynn* opens up the possibility that additional bodily material, such as

172. Baum, *supra* note 164, at 140.

173. *Id.*

174. *Id.*

175. *Id.*

176. *Id.*

177. Corley, *supra* note 133, at 111.

178. 684 F.3d 852 (9th Cir. 2012).

179. *Id.* at 855.

180. *Id.* at 865.

181. I. Glenn Cohen, *Selling Bone Marrow—Flynn v. Holder*, 366 NEW ENG. J. MED. 296, 296 (2012), available at <http://www.nejm.org/doi/pdf/10.1056/NEJMp1114288>.

182. See, e.g., *id.*

cord blood, may be exempted from NOTA. This section discusses the key points that were raised in *Flynn*. In Part VI, *Flynn*'s reasoning is applied to cord blood. The Article concludes that, based on the reasoning in *Flynn*, cord blood payment would be allowed under NOTA.

A. *Plaintiffs' Arguments*

Until recently, NOTA had been interpreted as forbidding compensation for organs, including bone marrow.¹⁸³ The *Flynn v. Holder* case involved several individuals who challenged this prohibition on compensation for bone marrow donations as unconstitutional.¹⁸⁴ The plaintiffs included parents of children who would benefit from bone marrow donations; a physician who provided bone marrow transplants; a parent of a mixed-race child who struggled to find matching donors; an African American man who suffered from leukemia; and, most importantly, MoreMarrowDonors.org (“MMD”), a California nonprofit corporation that sought to operate a program that would incentivize bone marrow donations.¹⁸⁵

NOTA makes it a crime to compensate the donation of a “human organ.”¹⁸⁶ The plaintiffs in *Flynn v. Holder* argued that NOTA should not be applied to bone marrow, as bone marrow donors suffer no permanent harm, experience “no significant risk, and [the body] quickly regenerates what is donated.”¹⁸⁷ This claim centered on the argument that the application of NOTA to bone marrow violated the Equal Protection Clause of the Constitution.¹⁸⁸ The plaintiffs argued that because bone marrow donations can be accomplished through apheresis, “there is no rational basis for allowing compensation for blood, sperm, and egg donations while disallowing compensation for bone marrow donations.”¹⁸⁹ Specifically, the plaintiffs sought declaratory and injunctive relief so that a pilot program called “MoreMarrowDonors.org” could begin offering financial

183. See 42 U.S.C. § 274e (2007).

184. *Flynn*, 684 F.3d at 855.

185. *Id.* at 855–56. All of the plaintiffs were connected to MMD in some manner. See *id.* at 858.

186. See 42 U.S.C. § 274e.

187. *Flynn*, 684 F.3d at 858.

188. *Id.*

189. *Id.* “The Equal Protection Clause . . . requires the state to articulate a rational basis for distinctions that it makes in the law.” Cohen, *supra* note 181, at 296.

incentives to minority and mixed-race donors of bone marrow.¹⁹⁰ MMD sought to make bone marrow donation more attractive by providing compensation to donors.¹⁹¹ MMD was hoping to offer \$3,000 awards in the form of scholarships, housing allowances, or charitable donations to potential donors.¹⁹²

The plaintiffs further argued that all bone marrow donors, regardless of the method of transplant, should be allowed to receive compensation.¹⁹³ They contended that donors should receive compensation if they donated bone marrow or PBSCs, regardless of the method used to retrieve the material.¹⁹⁴

In attempt to show a violation of the Equal Protection Clause in the application of NOTA to apheresis bone marrow donation, the plaintiffs claimed: (1) there is no logical connection to any rational basis; or (2) the distinction between blood donations and apheresis bone marrow donation “produces effects so irrational as to be unconstitutional.”¹⁹⁵

The plaintiffs maintained that there was no logical connection to the argument that Congress may have felt that it is morally and ethically wrong to sell body parts.¹⁹⁶ This is because there is no rational basis for the arbitrary distinction that it is “perfectly legal to provide scholarships to donors of mature blood cells, but makes it a major federal crime to

190. *Flynn*, 684 F.3d at 858. Such an act would be “considered a federal crime under NOTA.” *9th Circuit Lifts Ban on Selling Bone Marrow*: *Flynn v. Holder*, 19 No. 8 WESTLAW J. HEALTH L. 8, at 10 (Dec. 29, 2011).

191. *Flynn*, 684 F.3d at 858.

192. *Id.*

193. *Id.* at 859.

194. *Id.* The plaintiffs also argued in their brief that even though the rational basis test is deferential to the government there are three circumstances in which the Supreme Court has held that a statutory classification lacks a rational basis and therefore violates equal protection. Brief of Appellants at 25, *Flynn v. Holder*, 684 F.3d 852 (9th Cir. 2012) (No. 10-55643). First, when there is “[n]o logical connection between a statutory classification and any hypothetical rational basis,” there is no rational basis. *Id.* at 26 (citing *Zobel v. Williams*, 457 U.S. 55, 61–62 (1982)). Secondly, when the effects of the statutory classification “are so manifestly irrational that no rational legislator could have intended them” the legislation fails the rational basis test. *Id.* at 28 (citing *Allegheny Pittsburg Coal Co. v. Cnty. Comm’n*, 488 U.S. 336 (1989)). Finally, the plaintiffs argued that “[t]he Supreme Court also rejects asserted rational bases that are motivated by illegitimate interests such as raw animus toward a disfavored group.” *Id.* at 29 (citing *City of Cleburne v. Cleburne Living Ctr.*, 473 U.S. 432 (1985)).

195. *Id.* at 32. The plaintiffs then argued that the possible bases “that the district court cited in support of NOTA’s *facial* validity do not support NOTA *as applied* to Appellants’ pilot program for the strategic compensation of marrow-cell donors.” *Id.* (emphasis in original).

196. *Id.* at 32–33.

provide scholarships to donors of immature blood cells.”¹⁹⁷

They further maintained that there was no logical connection to the argument that Congress could have been concerned that individuals, particularly the poor, will be coerced by financial pressure into selling their organs.¹⁹⁸ To advance this argument, the plaintiffs argued that there is no fear of this financial pressure forcing people to donate bone marrow since bone marrow is a renewable resource.¹⁹⁹ Therefore, donors do not lose anything and are not in the same position to be harmed as they would be if they were donating a kidney.²⁰⁰

Finally, the plaintiffs reasoned that the court should not ignore the change in circumstances from when NOTA was originally written.²⁰¹ Essentially, the court should take into account the fact that Congress could not have been referring to apheresis when NOTA was written as the procedure did not exist at that time.²⁰² The plaintiffs urged that the Ninth Circuit take this change in circumstances into account.²⁰³

B. Defendant's Response

The Attorney General, as defendant, argued simply “that the statute plainly classifie[d] ‘bone marrow’ as an organ for which compensation is prohibited.”²⁰⁴ The defendant also

197. *Id.* at 33; see also *Cancer Patients Win Bone Marrow Legal Fight Against U.S. Attorney General*, INST. FOR JUSTICE (Dec. 1, 2011), <http://www.ij.org/bone-marrow-release-12-1-2011-2>.

198. Brief of Appellants, *supra* note 194, at 33–34.

199. *Id.* at 34. Apheresis only impacts the donor's blood and is replaceable. *Id.*

200. *Id.* The plaintiffs went on to argue that there is no logical connection to the concern that the rich will be at a substantial advantage for purchasing organs because the donations the plaintiffs are planning on facilitating are shielded from market-like transactions. *Id.* at 34–35. In addition to these and other arguments, the plaintiffs also contended that their equal protection claim can be bolstered because NOTA as applied to them creates effects so irrational as to be unconstitutional. *Id.* at 32. One of these arguments is directed at the District Court's argument that Congress could have been concerned “[t]hat [a]llowing [f]inancial [i]ncentives [w]ould [c]reate [a] [p]owerful [i]ncentive [f]or [a] [p]otential [d]onor [t]o [p]rovide [a]n [i]naccurate [m]edical [h]istory.” *Id.* at 37. In response to this argument, the plaintiffs argued that if this were to happen, the recipients of the marrow cells would have the possibility of an infection. *Id.* at 38. However, if the recipient does not receive any bone marrow cells, the outcome is much worse: death. *Id.*

201. *Id.* at 40–43.

202. *Id.*

203. *Id.*

204. *Flynn v. Holder*, 684 F.3d 852, 858 (9th Cir. 2012).

argued that there is a rational basis for distinguishing between blood donations and blood stem cell apheresis donations.²⁰⁵ The grounds for this argument were that (1) it is harder to find matches for bone marrow transplants there will be a greater chance of exploitative market forces to take hold, and (2) bone marrow transplants have increased health risks over blood donations.²⁰⁶

The Attorney General stated in his reply brief that there is no merit to the plaintiffs' argument that Congress could not rationally exclude blood from the scope of NOTA without also excluding bone marrow.²⁰⁷ In addition, the Attorney General argued that the apheresis method is more involved than donating blood.²⁰⁸

C. *The Ninth Circuit's Decision*

Ultimately, the Ninth Circuit held for the plaintiffs, finding that NOTA did not cover stem cell extraction by apheresis and thus compensation was allowed.²⁰⁹

The court first struck down the plaintiffs' challenge of the constitutionality of the compensation ban on bone marrow via the aspiration method.²¹⁰ The court reasoned that because bone marrow is specifically listed as a "human organ" in NOTA, the ban applies to it.²¹¹

205. *Id.* at 859.

206. *Id.* However, the government did not take this argument from assertions made in the complaint. *Id.* Instead, the government took this argument from a patient handout called "Now That You Are a Match," which was published by the National Marrow Donor Program. *Id.* The complaint stated that there was no significant risk. *Id.* The Ninth Circuit held that because this case was dismissed on a 12(b)(6) motion, the complaint controls. *Id.*

207. Brief for the Appellee at 15, *Flynn v. Holder*, 684 F.3d 852 (9th Cir. 2012) (No. 10-55643). This is because "mere underinclusiveness is not fatal to the validity of a law' under the Fifth Amendment's guarantee of equal protection." *Id.* (quoting *Atonio v. Wards Cove Packing Co.*, 10 F.3d 1485, 1495 (9th Cir. 1993) (quoting *Nixon v. Adm'r of Gen. Services*, 433 U.S. 425, 471 n.33 (1977))).

208. *Id.* at 17-18. This is because five days of injections are needed before the procedure and "a not insignificant portion of donors require the insertion of a central venous line to donate using apheresis, which has its own risks and requires a local anesthesia." *Id.* Therefore, "Congress violated no constitutional restraint by declining to treat bone marrow [sic] donations in the same manner as blood donations." *Id.* at 20. Finally, the Attorney General argued that Congress revisited the statute in 2007, long after the apheresis procedure began to be used and that Congress neglected to change the provision. *Id.* at 19.

209. *Flynn*, 684 F.3d at 865.

210. *Id.* at 859.

211. *Id.* at 859-60. The Ninth Circuit found it irrelevant for this point that

The court then addressed the plaintiffs' "no rational basis" argument under the Equal Protection Clause by delineating between two classes of rational basis at issue: (1) policy concerns and (2) philosophical concerns.²¹² The Ninth Circuit held that the policy concerns were obvious as Congress could have had a legitimate concern to protect poor people from being induced to sell their organs.²¹³ The court also stated that Congress could have had philosophical concerns for prohibiting the compensation of organ donors²¹⁴—namely, people have an "instinctive revulsion" at the concept of the removal of flesh from a human being for use by another and particularly the "commodification" of such conduct.²¹⁵

The court further noted that Congress need only show a rational basis, not a persuasive basis for their distinction, and Congress had done so.²¹⁶ Therefore, "the prohibition on compensation for bone marrow donations by the aspiration method [did] not violate the Equal Protection Clause."²¹⁷

The Ninth Circuit additionally stated that there was no need to answer any constitutional question relating to the apheresis method.²¹⁸ The court found that Congress did not intend to address the method as NOTA contained no express prohibition against it, considering that the method did not even exist when the statute was passed.²¹⁹

The court then examined the text of NOTA to determine possible implications about extraction of stem cells by the apheresis method.²²⁰ The statute prohibits compensation not

Congress viewed certain types of regenerable tissue as falling outside the statutory definition of "human organ." *Id.*

212. *Id.* at 860.

213. *Id.* The Ninth Circuit noted "that although blood can legally be sold, certain differences between blood and bone marrow justify the view of Congress that providing financial incentives would reduce altruistic donation and undermine voluntary donation." Cohen, *supra* note 181, 297.

214. *Flynn*, 684 F.3d at 861.

215. *Id.*

216. *Id.* at 861–62.

217. *Id.* at 862.

218. *Id.*

219. *Id.*

220. *Id.* The Ninth Circuit did not consider whether the compensation of donations procured through the apheresis method violated the Equal Protection Clause of the Constitution. Had they chosen to decide this issue on those grounds, the Ninth Circuit would need to have decided whether allowing the compensation for blood donations but not for apheresis donations was rationally related to a legitimate government purpose. Even though the Ninth Circuit did not decide the case on these grounds, both the plaintiffs and the Attorney General argued extensively about whether the NOTA ban on bone marrow donations via

only for donation of an organ but also any subpart thereof.²²¹ The Ninth Circuit rejected the Attorney General's argument that hematopoietic stem cells (which are located in the veins) should be treated as "bone marrow," reasoning that once these stem cells are in the bloodstream, they are a "subpart" of the blood, not the bone marrow.²²² The Ninth Circuit therefore concluded that the PBSC apheresis method of bone marrow transplantation is not the transfer of an organ or a subpart thereof.²²³ Accordingly, they held that NOTA does not criminalize the compensation of the donor when this method is used.²²⁴

The Obama administration petitioned the Ninth Circuit for a rehearing, arguing that the Ninth Circuit ignored the intent of Congress to shield all organ sales from "market forces."²²⁵ In

apheresis violated the Equal Protection Clause in their respective briefs. *See* Brief of Appellants, *supra* note 194, at 12; Brief for the Appellee, *supra* note 207, at 11. In attempting to argue this position, the plaintiffs contended in their brief to the Ninth Circuit that NOTA as applied to them is unconstitutional. Brief of Appellants, *supra* note 194, at 14. The district court dismissed the plaintiffs' equal protection claim based on the conclusion that rational basis review permits only facial challenges of law, rather than as-applied challenges. *Id.* at 15. The plaintiffs argued that this was in error as both the Ninth Circuit and the Supreme Court regularly hear as-applied challenges in the rational-basis context. *Id.* at 15–16. The Ninth Circuit apparently did not disagree as they heard the case while making essentially no mention of as-applied challenges in the opinion.

221. 42 U.S.C. § 274e (2007).

222. *Flynn*, 684 F.3d at 863.

223. *Id.* at 865.

224. *Id.* It has been said that the Ninth Circuit's decision is "both a win and a loss for advocates of organ markets." *See* Cohen, *supra* note 181, at 297. The decision is a win given that "patients can now buy and sell peripheral-blood stem cells derived through apheresis." *Id.* However, the win was achieved through the Ninth Circuit's interpretation of NOTA. *Id.* Congress could always change the statute, as the Ninth Circuit did not make its ruling based on the plaintiff's Equal Protection Clause argument. *Id.* Because of the narrowness in this holding, "[n]othing in the Ninth Circuit decision foreshadows the creation of markets in any other types of organs." *Id.*

225. Carol J. Williams, *Court Asked to Reconsider Ruling On Bone Marrow Compensation*, L.A. TIMES (Jan. 18, 2012, 4:45 PM), <http://latimesblogs.latimes.com/nationnow/2012/01/bone-marrow-compensation.html>; *see also* Appellee's Petition for Rehearing & Rehearing En Banc at 10, *Flynn v. Holder*, 684 F.3d 852 (9th Cir. 2012). Additionally, the appeal stated that the panel erred when it created a distinction between donations of cells from fatty tissue and donations of cells from peripheral blood. Appellee's Petition for Rehearing & Rehearing En Banc, *supra*, at 2. The Attorney General argued that because Congress made no distinction, the panel erred in creating one. *Id.* at 8–9. The Attorney General further argued that this error undermines the scheme that Congress created. *Id.* at 12. Furthermore, the petition stated that even the plaintiffs did not claim that the statute is limited to only bone marrow cells obtained from fatty tissue. *Id.* at 8. The petition argued that the plaintiffs' claim

March 2012, the Ninth Circuit denied the government's petition for rehearing and rehearing en banc.²²⁶ In that denial, the Ninth Circuit rejected the government's argument that because Congress defined "bone marrow" in another statute to include cells found in peripheral blood, "bone marrow" should be given the same meaning in NOTA.²²⁷ Because the Attorney General did not petition the Supreme Court to review *Flynn*, the Ninth Circuit's holding will stand.²²⁸

D. *The Aftermath*

Although advocates of a market-based system for bone marrow, organ, or tissue donation were hopeful that *Flynn* would open the door to such markets, the decision was more limited in its holding than those advocates had hoped.²²⁹ Although patients can now both buy and sell peripheral blood stem cells that were derived through apheresis, the Ninth Circuit came to this conclusion through its interpretation of NOTA, while still upholding the statute as a whole.²³⁰ Because Congress could always change the statute, *Flynn* would have had a more far-reaching impact had the Ninth Circuit struck down the statute or a portion thereof based on the plaintiffs'

was based on equal protection issues and centered on the argument that "Congress *should* have limited the scope of the Transplant Act and that it was irrational not to do so." *Id.* at 8. The government argued that the Ninth Circuit panel took it upon themselves to evaluate medical policy and medical science and their interpretation is "directly at odds with Congress's own evaluation." *Id.* at 9. The petition then stated that "Congress addressed scientific developments in transplant methods in the 2005 Amendments [to the Transplant Act] and defined 'bone marrow' to include 'the cells found in adult bone marrow *and* peripheral blood.'" *Id.* The petition stated that this definition covers the process of apheresis. *Id.* at 9.

226. *Flynn v. Holder*, 665 F.3d 1048 (9th Cir. 2011), *amended and superseded on denial of rehearing by* 684 F.3d 852 (9th Cir. 2012).

227. *Flynn v. Holder*, 684 F.3d at 854.

228. Nicholas J. Diamond, *Is It Time to Reconsider the National Organ Transplant Act?*, SCI. PROGRESS (July 16, 2012), <http://scienceprogress.org/2012/07/is-it-time-to-reconsider-the-national-organ-transplant-act/>. The Ninth Circuit is bound by the *Flynn* decision. The Ninth Circuit is comprised of the states of Alaska, Arizona, California, Hawaii, Idaho, Montana, Nevada, Oregon, and Washington and the Guam territory. *Map of the Ninth Circuit*, U.S. COURTS FOR THE NINTH CIRCUIT, http://www.ca9.uscourts.gov/content/view.php?pk_id=0000000135 (last visited Mar. 15, 2013). It is by far the largest Circuit in the United States. U.S. COURTS FOR THE NINTH CIRCUIT, <http://www3.ce9.uscourts.gov> (last visited Mar. 15, 2013).

229. Cohen, *supra* note 181, 296.

230. *Id.* at 297.

equal protection argument.²³¹ Although some scholars argue that “[n]othing in the Ninth Circuit decision foreshadows the creation of markets in any other types of organs,”²³² Part V of this Article explores how the Ninth Circuit’s discussion of bone marrow obtained through apheresis could also be applied to cord blood. *Flynn* could reasonably be read as allowing payment for cord blood, which could have a potentially great impact on public health.

V. CRITICISMS OF FUTURE IMPLICATIONS AFTER THE *FLYNN* DECISION

Much of the criticism of the *Flynn* decision mirrors the arguments made by the Attorney General regarding the policy behind NOTA’s ban on compensation for organs. That is, opponents of any market-based system worry about the commodification and coercion that could occur if individuals who possessed matching bone marrow types were allowed to name their price for their much-needed bone marrow.²³³

However, since *Flynn* was decided, a new concern has arisen about allowing compensation for bone marrow in the United States. This concern is what effect such payment would have on the international community of bone marrow donors and registries.²³⁴ After the *Flynn v. Holder* ruling, the nine states bound by the decision no longer conform to international donor standards that do not accept bodily material that has been paid for.²³⁵ This is significant because more than half of the bone marrow transplants in 2011 made possible by NMDP

231. *Id.*

232. *Id.*

233. See discussion *supra* Part II.

234. Michael Boo, *The Dangers of Repealing Bone Marrow Compensation Restrictions*, U.S. NEWS & WORLD REPORT (Apr. 19, 2012), <http://www.usnews.com/opinion/articles/2012/04/19/the-dangers-of-repealing-bone-marrow-compensation-restrictions>.

235. *Id.* The World Marrow Donor Association (WMDA) fosters international collaboration for hematopoietic stem cell transplants worldwide. *About WMDA, Who We Are*, WORLD MARROW DONOR ASSOC., <http://www.worldmarrow.org/> (last visited May 24, 2013). The WMDA International Standards for Unrelated Hematopoietic Stem Cell Donor Registries requires that “donations must be voluntary.” *WMDA International Standards for Unrelated Hematopoietic Stem Cell Donor Registries*, WORLD MARROW DONOR ASSOC. 7 (2012), http://www.worldmarrow.org/fileadmin/Committees/STDC/20120101-STDC-WMDA_Standards.pdf. The standards further state that “[d]onors must not be paid for their donation but may be reimbursed for expenses incurred during the donation process.” *Id.*

involved an international donor or international patient.²³⁶ Some worry that compensation for bone marrow donation could have a severe impact on both the United States and international community if international registries excluded the United States where PBSC payments were allowed.²³⁷ These advocates of an altruistic donor system claim that such a system is far superior to one motivated by financial incentives and that interpreting the current federal law to allow compensation of marrow donors “carries serious risks.”²³⁸ By allowing payment for bone marrow (technically, stem cells) extracted by apheresis, patients may not be able to use the worldwide search process that is considered imperative to help increase access to donors.²³⁹

Those who advocate bone marrow markets argue that international organizations have often followed the United States’ lead when dealing with novel technological and scientific issues.²⁴⁰ In fact, the United States has the largest bone marrow registry in the world.²⁴¹ Advocates of a market-based system in bone marrow argue that the United States should not worry about following others’ leads, but rather be a pioneer in allowing compensation for bone marrow.²⁴² Additionally, it is unlikely that there will be a significant change in bone marrow donations just based on the *Flynn* decision. In fact, the plaintiffs in *Flynn* were not seeking any type of monetary compensation for bone marrow. Rather, as discussed earlier, MMD was proposing scholarship programs that would compensate bone marrow donors with a \$3,000 scholarship.²⁴³

236. Boo, *supra* note 234.

237. *Id.*

238. *Id.*

239. *Leading Global Cell Therapy Organizations Support DOJ Appeal of Ruling on Donor Compensation*, NAT’L MARROW DONOR PROGRAM (Feb. 2, 2012), http://marrow.org/News/News_Releases/2012/Coalition_says_PBSC_donor_compensation_poses_health_risks_to_patients_and_donors.aspx. There is also a concern that those wishing to sell their bone marrow are “more likely to withhold medical details and information that could harm patients.” *Id.* Also, there is a concern that compensation could deter altruistic donors. *Id.*

240. See Patty B. Wight, *Bone Marrow Transplant Donors Compensation Case*, THE ME. PUB. BROAD. NETWORK (Apr. 24, 2012), <http://www.mpbn.net/News/MPBNNews/tabid/1159/ctl/ViewItem/mid/3762/ItemId/21510/Default.aspx>.

241. *Id.*

242. See *id.*

243. *Id.*; *Flynn v. Holder*, 684 F.3d 852, 858 (9th Cir. 2012).

VI. A NEW FRONTIER?: COMPENSATION FOR CORD BLOOD
AFTER *FLYNN V. HOLDER*

The lack of minority or mixed-race bone marrow, PBSC, or cord blood donors is a significant public health problem in the United States that has not been addressed adequately. Rather than just focusing on bone marrow and PBSC donors, it is prudent to focus on increasing cord blood donations as a method of overcoming this problem. This Article argues that the Ninth Circuit's ruling in *Flynn* that compensation for PBSCs is acceptable in some circumstances would also allow compensation for cord blood. If cord blood compensation is allowed and structured properly, the health outcomes of those who are unable to find a bone marrow match or cord blood match could be significantly improved.

This Section proceeds as follows. Part A analyzes how *Flynn* leaves open the possibility that cord blood compensation is allowed under NOTA. Part B proposes schemes whereby public cord blood donations could be increased with prudent compensation schemes.

A. *Reading Between the Lines: Flynn and Cord Blood Compensation*

The holding in *Flynn* applies to cord blood because (1) cord blood, unlike bone marrow, is not explicitly mentioned by statute or by HHS regulation; (2) the procedure to utilize cord blood was not in practice at time of NOTA passage and could therefore not have been contemplated by Congress; (3) when Congress revisited NOTA and passed later amendments, it chose not to modify the statute to explicitly include cord blood; and (4) the long-standing view that blood should not be covered by NOTA's prohibitions applies equally to cord blood.

As discussed in Part II, NOTA makes it a crime 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."²⁴⁴ Under NOTA, human organs include "the human . . . kidney, liver, heart, lung, pancreas, bone marrow, cornea, eye, bone, and skin . . . and any other human organ . . . specified by the

244. 42 U.S.C. § 274e (2007).

Secretary of Health and Human Services by regulation.”²⁴⁵ The Secretary of Health and Human Services specified other human organs by adding, through regulations, “intestine, including the esophagus, stomach, small and/or large intestine, or any portion of the gastrointestinal tract.”²⁴⁶

In *Flynn*, the Ninth Circuit held that compensation for PBSCs extracted through apheresis was not prohibited by NOTA.²⁴⁷ The court found that NOTA was constitutional with regard to banning compensation for bone marrow extracted via aspiration because bone marrow was specifically listed as a “human organ” in NOTA.²⁴⁸ In contrast, neither the umbilical cord nor umbilical cord blood is mentioned in NOTA.

Further, the Ninth Circuit held that NOTA contained no prohibition against extraction of PBSCs through apheresis because this method did not exist when Congress passed NOTA.²⁴⁹ The Ninth Circuit went on to say that Congress therefore did not intend to address the apheresis method.²⁵⁰ These findings are equally true about cord blood donation. NOTA was approved in 1984,²⁵¹ and the first cord blood transplant did not occur until October 1988.²⁵² Therefore, using *Flynn*’s reasoning, similar to apheresis, Congress could not have intended to include cord blood in its prohibition on payment for organs.

When NOTA was amended in 1988²⁵³ and 1990, PBSC retrieval via apheresis and cord blood donations had begun to take place.²⁵⁴ However, the amendments did not mention either PBSCs extracted via apheresis nor umbilical cord blood.²⁵⁵ The Ninth Circuit held in *Flynn* that because it was

245. *Id.*

246. 42 C.F.R. § 121.13 (2007).

247. *Flynn*, 684 F.3d at 865.

248. *Id.* at 859–60.

249. *Id.* at 862.

250. *Id.*; see also *supra* text accompanying note 220.

251. National Organ Transplant Act, Pub. L. 98-507, 98 Stat. 2339 (1984) (codified as amended at 42 U.S.C. § 274e (2006)).

252. Hal E. Broxmeyer, *Cord Blood Transplantation: A Mini Review Celebrating the 20th Anniversary of the First Cord Blood Transplant*, THE HEMATOLOGIST, Jan–Feb. 2009, available at <http://www.hematology.org/Publications/Hematologist/2009/2199.aspx>.

253. Organ Transplant Amendments Act of 1988, Pub. L. 100–607, Tit. IV, 102 Stat. 3114 (1988) (codified as amended at 42 U.S.C. § 274 (2007)).

254. Martin Körbling & Emil J. Freireich, *25 Years of Peripheral Blood Stem Cell Transplantation*, BLOOD 8, available at <http://bloodjournal.hematologylibrary.org/content/early/2011/04/01/blood-2010-12-322214.full.pdf>.

255. Organ Transplant Amendment Act Tit. IV, 102 Stat. 3114.

not specifically mentioned, PBSCs extracted via apheresis were not covered under NOTA's prohibitions.²⁵⁶ Although the court was not asked by the plaintiffs in *Flynn* to interpret cord blood under NOTA, based on the court's own reasoning it seems likely that the court would have ruled the same way—finding that it is not covered because it is not mentioned in NOTA or its amendments.

Additionally, the Organ Transplant Amendments Act of 1988 amended NOTA to add a prohibition on fetal organs but did not mention umbilical cords or umbilical cord blood.²⁵⁷ NOTA specifies organs and does not mention umbilical cords or cord blood.²⁵⁸ Although NOTA contains language describing the 'human organ' to include "any subpart thereof and any other human organ (or any subpart thereof, including that derived from a fetus),"²⁵⁹ the defendant in *Flynn* unsuccessfully argued that PBSCs were a "subpart thereof" of bone marrow and therefore compensation for them should not be allowed.²⁶⁰ The Ninth Circuit reasoned that this would be too expansive a definition and would include blood as well, which is not covered by NOTA.²⁶¹ Even more than PBSCs, cord blood does not fit into any of the definitions of any of the organs named in NOTA. Peripheral stem cells are a subpart of bone marrow, but the Ninth Circuit rejected this interpretation of NOTA because it would then also include blood, which is a subpart of each organ.²⁶² In contrast, cord blood is not a subpart of any organ. Again, the Ninth Circuit's reasoning about blood is very applicable to cord blood. Cord blood is just blood that is derived from the umbilical cord.²⁶³ If blood is exempted from NOTA, cord blood should be as well.

Some may argue that the umbilical cord is an organ. NOTA does not define an organ, but it gives examples of organs, which do not include the umbilical cord. In medical terminology, an organ is defined as "a differentiated structure (as a heart or kidney) consisting of cells and tissues and

256. *Flynn v. Holder*, 684 F.3d 852, 865 (9th Cir. 2012).

257. Organ Transplant Amendments Act of 1988, Pub. L. 100-607, Tit. IV, 102 Stat. 3114 (1988) (codified as amended at 42 U.S.C. § 274 (2007)).

258. 42 U.S.C. § 274e (2007).

259. *Id.* § 274e(c)(1).

260. *Flynn*, 684 F.3d at 865.

261. *Id.*

262. *Id.* at 863.

263. THE AM. COLL. OF OBSTETRICIANS & GYNECOLOGISTS, *supra* note 35, at 1.

performing some specific function in an organism.”²⁶⁴ The umbilical cord is defined not as an organ but as “a cord arising from the navel that connects the fetus with the placenta and contains the two umbilical arteries and the umbilical vein.”²⁶⁵ The umbilical cord seems to be more akin to a blood vessel than to an organ. Arguably, the umbilical cord could be considered an organ because it is a differentiated structure that connects the fetus to the pregnant woman. However, its function ceases once the newborn is delivered.²⁶⁶ In fact, the cord is clamped and in 97 percent of cases, the remaining umbilical cord is discarded.²⁶⁷ At this point, it could be argued that the umbilical cord is no longer “performing some specific function” in the human body, and is no longer even a part of the human body, and thus cannot be considered an organ. Unlike a kidney or heart that also ceases to perform a specific function once it has been removed, the umbilical cord cannot resume its prior functioning even if it could be transplanted to another person, thus further supporting the argument that it should be not classified as an organ.

Even if one is not persuaded that the umbilical cord is not an organ, it is actually not the umbilical cord for which compensation would be theoretically given. What is valuable is the cord blood, defined as “blood from the umbilical cord of a fetus or newborn.”²⁶⁸ In *Flynn*, the Ninth Circuit rejected the Attorney General’s argument that hematopoietic stem cells (which are located in the veins) should be treated as “bone marrow” because the statute prohibits compensation not only for donation of an organ but also any subpart thereof.²⁶⁹ The Ninth Circuit reasoned that if the language of the statute were permitted to be interpreted this way, then blood would fall under the category of “human organ” as red and white blood cells that flow in the veins come from the bone marrow, just as

264. *Organ*, MERRIAM-WEBSTER, <http://www.merriam-webster.com/medical/organ> (last visited Nov. 14, 2012).

265. *Umbilical Cord*, MERRIAM-WEBSTER, <http://www.merriam-webster.com/medical/umbilical%20cord> (last visited Nov. 14, 2012).

266. Dr. Allan Bruckheim, *Q. What Happens to the Umbilical Cord Inside a Mother Once . . .*, CHI. TRIB. (Oct. 25, 1994), http://articles.chicagotribune.com/1994-10-25/news/9410260009_1_umbilical-cord-uterus-placenta.

267. *Frequently Asked Questions*, SAVE THE CORD FOUND., http://www.savethecordfoundation.org/what_faq.php (last visited Mar. 7, 2013).

268. *Cord Blood*, MERRIAM-WEBSTER, <http://www.merriam-webster.com/medical/cord%20blood> (last visited Nov. 14, 2012).

269. *Flynn v. Holder*, 684 F.3d 852, 863 (9th Cir. 2012).

hematopoietic stem cells do.²⁷⁰ It reasoned that once these stem cells are in the bloodstream, they are a “subpart” of the blood, not the bone marrow.²⁷¹ The Ninth Circuit then stated that “[t]he word ‘subpart’ refers to the organ from which the material is taken, not the organ in which it was created.”²⁷² It reasoned that the PBSC apheresis method of bone marrow transplantation is not the transfer of an organ or a subpart thereof.²⁷³ Accordingly, the statute does not criminalize the compensation of the donor when this method is used.²⁷⁴ This reasoning would apply to cord blood as well. The legislative history of NOTA notes that the definition of “human organ” specifically does not include blood.²⁷⁵ This should be read to include cord blood, as cord blood is merely blood that is located within the umbilical cord. Since it is arguably more valuable due to its stem-cell-rich content, that should be even more reason why it would not be included in NOTA’s prohibitions.

The legislative history of NOTA states 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.”²⁷⁶ There may be a concern that cord blood is not replenishable, unlike PBSCs, sperm, eggs, or hair. The legislative history of NOTA does note that these exceptions to NOTA are for replenishable body parts.²⁷⁷ However, a reasonable interpretation of the “which can be replenished and whose donation does not compromise the health of the donor” language is that the concern over bodily material being replenishable is just to ensure that the donor is no worse off by having donated that material. Under NOTA, it appears unacceptable to allow payment for bodily material that, if donated, would put the donor in a worrisome

270. *Id.*

271. *Id.*

272. *Id.*

273. *Id.*

274. *Id.* at 865; *see also supra* note 224 and accompanying text.

275. H.R. REP. NO. 98-1127, at 16 (1984) (Conf. Rep.).

276. S. REP. NO. 98-382, at 16–17 (1984), *reprinted in* 1984 U.S.C.C.A.N. 3975, 3982.

277. H.R. REP. NO. 98-1127, at 16 (1984) (Conf. Rep.) (“The term ‘human organ’ is not intended to include replenishable tissues such as blood or sperm.”); *see also* J. Brad Reich & Dawn Swink, *You Can’t Put the Genie Back in the Bottle: Potential Rights and Obligations of Egg Donors in the Cyberprocreation Era*, 20 ALB. L.J. SCI. & TECH. 1, 24 (2010) (noting that NOTA does not prohibit payment for human eggs).

state of health. The Committee seems concerned that the health of an individual is not permanently compromised in some way.²⁷⁸ In essence, this concern presupposes an ongoing need for similar material from the donor. Obviously, this is not the case with a discarded umbilical cord.

One argument against compensation being allowable under NOTA may be that cord blood stem cells are not regenerated within the body of the donor. The concern seems to be about making the individual “whole” or the same as they were before they donated. Therefore, one could argue that this resembles an organ for which one cannot be compensated under NOTA. However, cord blood is not retrieved from a baby directly. There is no need for regeneration, as it is already cut from the body of the newborn. If anything, there is more of an argument to allow cord blood compensation than any other type of blood product because there is no impact on the donor.²⁷⁹ NOTA’s legislative history suggests that payment was allowed for hair, blood, eggs, and sperm because the human body replaces these materials within a certain period of time and the individual is not any worse off.²⁸⁰ In contrast, organs for which payment is not allowed, such as kidneys, do not regenerate. But, cord blood does not even need to be replenished, taking it one step further away from the underlying health concerns for organs or replenishable bodily materials. The reality is that individuals who donate, or even are paid for their cord blood, do not have their health compromised in any way.

Further, at the time NOTA was enacted, cord blood transplants were not standard practice and cord blood uses were just beginning to be explored.²⁸¹ Therefore, the language in the statute or legislative history could not have contemplated cord blood. In 1984, it is probable that the only bodily materials that could have been used without compromising the health of the individual were replenishable materials, such as blood, sperm, and eggs.²⁸² That, coupled with the exceptions for blood compensation under NOTA, makes it more likely that NOTA would be interpreted not to

278. See H.R. REP. No. 98-1127, at 16 (1984) (Conf. Rep.).

279. *Frequently Asked Questions*, *supra* note 267 (noting that “donation of the cord blood does not harm the baby or the mother”).

280. See H.R. REP. No. 98-1127, at 16.

281. See *supra* notes 251–54 and accompanying text.

282. This author contends.

cover cord blood.²⁸³

Using *Flynn's* reasoning with regard to PBSCs extracted through apheresis, this Article contends that cord blood is more similar to hair, blood, eggs, sperm, and PBSCs, which are all exempted from NOTA's compensation requirements. Therefore, NOTA would arguably allow compensation for cord blood.

B. An Easy Answer? Compensating Cord Blood Donors

If compensation for cord blood is permitted under NOTA, there are still several questions to be answered: How should donors be compensated? Is compensation alone enough to address the public health need for cord blood? Is the current collection and banking process sufficient even with compensation? The following section of this Article addresses these and other questions regarding cord blood compensation.

1. How to Compensate Cord Blood Donors

There are a variety of possible forms that compensation for cord blood could take. The most obvious model would be to have existing organizations that advocate for more bone marrow and PBSC donors, such as MMD, offer financial incentives to minority and mixed-race cord blood donors. In *Flynn*, MMD sought to make bone marrow donation more attractive by providing compensation to potential bone marrow and PBSC donors.²⁸⁴ MMD proposed offering \$3,000 awards in the form of scholarships, housing allowances, or charitable donations to potential donors.²⁸⁵ *Flynn* allowed MMD to proceed with its plans to recruit potential donors of PBSC.²⁸⁶ MMD proposed to offer compensation only to minorities and mixed-race individuals in the first phase of the program due to the dearth of donors in these populations.²⁸⁷ MMD could offer similar compensation to ethnic minority or mixed-race pregnant women who agree to donate their cord blood to a public bank. MMD structured its proposed compensation program to allay concern that compensation would change clinical behavior or be

283. Jennifer Kulynych, *Blood as a Biological "Drug": Scientific, Legal, and Policy Issues in the Regulation of Placental and Umbilical Cord Stem Cell Transplantation*, 32 U. RICH. L. REV. 407, 439 (1998).

284. *Flynn v. Holder*, 684 F.3d 852, 858 (9th Cir. 2012).

285. *Id.*

286. *Id.*

287. *Id.*

subject to manipulation.²⁸⁸ In the case of cord blood, this is not a concern. Once the cord is cut from the mother, she and her baby are no longer involved in any potential clinical matching or anything related to the donation. The cord blood extraction occurs after delivery, and the cord blood is sent to a public bank. MMD would not need to be involved in matching donors and recipients. MMD and similar organizations could facilitate the public donation process for pregnant women in addition to providing stipends. To receive compensation, pregnant women wishing to donate their baby's cord would need to have the requisite medical tests and meet the same standards that all donors to public cord banks must meet.²⁸⁹ Unlike in PSBC or bone marrow transplants, there are no behavioral questions that could be manipulated because of the possibility of compensation because the cord is going to be discarded anyway.²⁹⁰

Instead of scholarships as proposed by MMD, cord blood donors could receive a stipend towards their medical expenses or a savings bond for their child. This may help convince women to donate their cord blood as it will benefit their child in the future. This could be a true insurance policy, as opposed to the fictional insurance policy noted earlier in this Article that is marketed by private cord blood banks.

It may be worthwhile to create a tax credit for those who participate in public cord donations. The costs of private cord blood banking are considered a medical expense which may be deducted from a family's salary.²⁹¹ Currently, there is no such tax advantage for donating cord blood. Structuring cord blood donation to public banks as tax credits could serve as an incentive for expectant mothers to donate their valuable cord blood.

Whatever the form, compensation could increase interest in cord blood donation. However, compensation alone will likely not be the most compelling answer to this public health

288. *Id.*

289. See NAT'L MARROW DONOR PROGRAM & BE THE MATCH, *Learn if You Can Donate Cord Blood*, https://secure.marow.org/Get_Involved/Donate_Cord_Blood/How_to_Donate/Learn_if_You_Can_Donate_Cord_Blood.aspx (last visited Mar. 28, 2013) (giving checklist for determining eligibility for public cord blood donation).

290. See *Frequently Asked Questions*, *supra* note 267.

291. John Hewitt, *Is Cord Blood Banking Tax Deductible?*, ESSORTMENT, <http://www.essortment.com/cord-blood-banking-tax-deductible-51235.html> (last visited Nov. 14, 2012).

concern.

2. Need for a Public Health Education Campaign on Cord Blood Donation

One of the most effective tools of public health is education. The public, and especially pregnant women, needs to be made aware of the scientific benefits of cord blood and the ease of cord blood donation. The proliferation of private cord blood banks that encourage private storage has led to those who are aware of the importance of stem cells to privately bank cord blood, rather than donate their cord blood to public banks.²⁹² As opposed to the thousands of dollars spent to store cord blood, donation to a public bank is free.²⁹³ If more expectant mothers, especially those who are carrying mixed-race or ethnic minority babies, were made aware of the dire shortage of cord blood units by these groups, they would likely be more apt to donate.²⁹⁴ Public health education is required so that pregnant mothers are told that by donating their baby's cord blood to a public bank, they may be helping people in need of potentially life-saving cord blood.²⁹⁵

Despite the lack of a proven scientific basis for private cord blood banking, private cord blood banking seems to be flourishing,²⁹⁶ while the growth of a public banking system has been painstakingly slow.²⁹⁷ Researchers in this area advocate patient education as “the key to shifting the focus to a public cord blood banking system.”²⁹⁸ Because private cord blood banks have a “significant conflict of interest” in providing balanced scientific data about cord blood banking, obstetricians should “provide evidence-based information to patients.”²⁹⁹ Pregnant women should be made aware that public cord blood

292. This author contends.

293. *Frequently Asked Questions*, *supra* note 267.

294. This author contends.

295. *Cord Blood Banking Pros and Cons*, *supra* note 109.

296. Theresa Agovino, *Cord Blood Banking Industry Flourishes*, NBC NEWS, (Apr. 12, 2004), http://www.nbcnews.com/id/4702857/ns/health-cloning_and_stem_cells/t/cord-blood-banking-industry-flourishes/#.URAPvx0727w.

297. See *Current State-by-State Banking and Legislation Options*, SAVE THE CORD FOUND., http://savethecordfoundation.org/banking_map.php?state=FL#statedata (last visited Mar. 28, 2013) (giving links to individual state listings of public versus private cord blood bank options, which reveal a significantly larger number of private banking options).

298. Kaimal et al., *supra* note 87, at 853–54.

299. *Id.* at 854.

banking is a better scientific alternative to private cord blood storage.³⁰⁰

Some pregnant women may be concerned about whether cord blood donation will harm the baby in any way. Pregnant women should be made aware that their babies' cord blood is extracted with no pain to their babies.³⁰¹ The cord blood, which is normally discarded along with the cord, would be a potential source of life for those sick individuals who are in need of a stem cell transplant.

One issue that may need to be addressed in a public health education campaign is the distrust by many African Americans of the public health system in general³⁰² due to the checkered history of public health disasters such as the Tuskegee Syphilis Study,³⁰³ forced sterilizations and Norplant,³⁰⁴ and even more recently, the use of stored blood spots for DNA research.³⁰⁵ Issues of racial distrust must be proactively addressed. Literature in the form of "Q and As" addressing these issues may be helpful to quell fears of some that their babies' cord blood will be used for purposes other than donation. A comprehensive public health education campaign, acknowledging this distrust and explaining the benefits of cord blood and of public cord blood banking, would likely increase donors.

3. Additional Issues to Be Addressed to Bolster Cord Blood Donation

Cord blood donation should be encouraged, not made to be a chore. Given that the *Flynn* decision seems to allow compensation for cord blood, this compensation could be used to incentivize public donations. We would go far in addressing the lack of minority and mixed-race bone marrow matches by making it seamless and easy for pregnant women to donate cord blood. Having pregnant women who are interested in cord blood donation jump through hoops to do something worthwhile, painless, and easy helps to explain in part why

300. See AM. ACAD. OF PEDIATRICS, *supra* note 35, at 166.

301. See *Frequently Asked Questions*, *supra* note 367.

302. See Vernellia R. Randall, *Slavery, Segregation and Racism: Trusting the Health Care System Ain't Always Easy! An African American Perspective on Bioethics*, 15 ST. LOUIS U. PUB. L. REV. 191, 191 (1996).

303. *Id.* at 197–98.

304. *Id.* at 223–25.

305. *Id.* at 215–27.

cord blood donations to public banks are so rare. This could be changed if pregnant women were offered modest incentives to donate their baby's cord blood. As stated above, this could take the form of a minimal credit (such as \$100 or \$200) towards their medical expenses or a savings bond or scholarship for their babies to use in the future.

There is a lack of knowledge among expectant women about cord blood donation.³⁰⁶ Many women and health care providers are not always aware of the possibility to donate their cord blood.³⁰⁷ There are no glossy pamphlets in most obstetricians' offices or hospitals espousing the benefits of cord donation to compete with the literature given by the private cord blood banks.³⁰⁸ In the last several years, twenty-seven states have passed legislation to encourage physicians to discuss cord blood donation and banking with pregnant women.³⁰⁹ However, the reality is that public cord blood banks do not operate all over the United States, while private cord banks do.³¹⁰ Another issue is that the process to donate cord blood is often complicated.³¹¹ It is not the routine practice currently to expect that most mothers will donate their babies' cord blood. Unless a woman happens to be delivering in one of the very few hospitals that is set up for public donations, a woman who does decide to donate must prepare far in advance.³¹² She must request a packet of materials from public banks and these must be completed before labor and delivery.³¹³ This complicated and sometimes confusing process for an expectant mother is an additional hassle that prevents more women from donating cord blood.³¹⁴

ACOG should consider making cord blood donation a standard practice in each delivery. ACOG releases practice guidelines for each aspect of labor and delivery and has

306. MARY HAWS ET AL., *supra* note 90, at 1.

307. *Id.* at 1–2.

308. *See* Ramsey, *supra* note 97.

309. *27 States Have Cord Blood Education Laws*, *supra* note 91.

310. *See Find a USA Public Bank*, *supra* note 88.

311. *See How to Donate Cord Blood*, NAT'L MARROW DONOR PROGRAM, http://marrow.org/Get_Involved/Donate_Cord_Blood/How_to_Donate/How_to_Donate.aspx (last visited Mar. 15, 2013).

312. *See id.*

313. *Id.*

314. Kenny Goldberg, *Women Encouraged To Donate Their Baby's Cord Blood*, KPBS (Apr. 10, 2012), <http://www.kpbs.org/news/2012/apr/10/women-encouraged-donate-their-babys-cord-blood/>.

previously considered the issue of cord blood banking.³¹⁵ However, ACOG should be encouraged to go further. ACOG has the power and expertise to deem that unless a pregnant woman decides to opt out of donating her cord blood, the standard practice will be to presume donation³¹⁶ and give compensation to cover the costs of collection. This would have an incredible effect of vastly increasing the public cord blood supply in the United States. Rather than the arduous opt-in procedure that currently exists and dissuades all but the most committed altruistic cord blood donors, an opt-out policy would increase the number of cord blood donations. Additionally, this would not prevent anyone who wishes to privately bank their baby's cord blood from doing so. Individuals may still choose to privately donate instead.

Currently, almost 97 percent of cord blood is discarded as medical waste.³¹⁷ Therefore, the routine practice is to discard the umbilical cord. However, if ACOG advocates a change in the routine practice, the percentage of donated cord blood would rise dramatically. The revised routine practice could be to preserve the cord blood, while still allowing the patient the choice of public donation or private banking (if, for example, there is a family member with an illness that could be helped by cord blood). Because extracting the cord blood from the cut umbilical cord takes additional time,³¹⁸ there could be reimbursement or compensation incentives put into place so that physicians and nurses would be paid for this extraction. All of these suggestions would significantly increase the potential for matching cord blood for ethnic minorities and mixed-race individuals. By simplifying the process to donate cord blood and making it the routine practice, the number of donations would increase, which would increase minority donations available for transplants.³¹⁹

315. See *Resources & Publications*, THE AM. COLL. OF OBSTETRICIANS & GYNECOLOGISTS, http://www.acog.org/Resources_And_Publications (last visited Mar. 7, 2013).

316. See *generally Fact Sheet*, THE AM. COLL. OF OBSTETRICIANS & GYNECOLOGISTS, <http://www.acog.org/~media/About%20ACOG/ACOGFactSheet.pdf?dmc=1&ts=20130307T2117021760> (last visited Mar. 7, 2013).

317. JoNel Aleccia, *Cord Blood Donation Surges as Hospitals Launch Public Collection Programs*, NBC NEWS (May 2, 2012, 8:17 AM), http://vitals.msnbc.msn.com/_news/2012/05/02/11490071-cord-blood-donation-surges-as-hospitals-launch-public-collection-programs?lite.

318. See *Private Cord Blood Banking: The Basics*, *supra* note 104.

319. *Donating to a Public Cord Blood Bank*, SAVE THE CORD FOUND., http://www.savethecordfoundation.org/banking_public.php (last visited Feb. 10,

Existing public health screening models could be modified to accommodate cord blood donation. For example, unless a mother decides to proactively opt-out of testing, in every state, every newborn is subjected to a heel prick so that the baby's blood may be screened for a slew of metabolic and other diseases.³²⁰ This opt-out model of newborn screening could be used to formulate an opt-out model of cord blood donation. As of now, women and families who wish to donate cord blood must proactively seek out ways to donate to a public bank.³²¹

CONCLUSION

Although this Article advocates for an increased emphasis for public banking, it is important to acknowledge the downsides to donating to a public bank. One of the most obvious downsides is that once cord blood is donated to a public bank, public banks own the donated cord blood.³²² Thus, that cord blood may not be available for one's own family member should a need arise.³²³ If a family member or a sibling needs the cord blood in the future, it will not be readily available.³²⁴ Although it is unlikely that one's own cord blood would be useful to that individual if he or she suffers from a disease,³²⁵ the use of cord blood from one's immediate family doubles the chance of a successful transplant.³²⁶ Theoretically, minorities and mixed-race individuals may be more worried about the lack of stem cell matches and may wish to store their baby's cord blood at a private facility for future use.³²⁷ However,

2013).

320. *Newborn Screening Tests*, MEDLINEPLUS, <http://www.nlm.nih.gov/medlineplus/ency/article/007257.htm> (last visited Mar. 28, 2013).

321. *Frequently Asked Questions*, *supra* note 267. Public cord blood banks generally do not charge to harvest the cord blood. *Id.* However, physicians may choose to charge a collection fee not covered by insurance. *Cord Blood Banking Pros and Cons*, *supra* note 109. Some physicians have waived any collection fee for public bank donations. *Id.* However, if cord blood donation becomes more prevalent, this could change. Harvesting cord blood from the cut cord does take away time from staff to do other things, and physicians or hospitals could charge to harvest the cord blood. One of the ways compensation could be used would be to pay hospitals and physicians a fee to cover the cost of this extra time.

322. *Cord Blood Banking Pros and Cons*, *supra* note 109.

323. *Id.*

324. *Id.*

325. *Id.*; Moninger, *supra* note 48.

326. *Cord Blood*, WOMEN'S HEALTH OF MANSFIELD PA., <http://www.womenshealthofmansfield.com/cord-blood/> (last visited Feb. 10, 2013).

327. *See Cord Blood Banking Pros and Cons*, *supra* note 109.

currently, there are a very small percentage of minorities who store their babies' cord blood.³²⁸

This Article does not propose eliminating private banking. If this concern is worrisome for individuals, they may still choose to privately bank their babies' cord blood. This Article proposes methods, including compensation, to encourage cord blood banking in general, particularly to the vast majority of the public that allows their babies' cord blood to be discarded. Because *Flynn* seems to allow payment for cord blood, public health officials, professional organizations, and nonprofits should work together to devise compensation schemes that would increase the public cord blood supply in the United States.

328. NAT'L MARROW DONOR PROGRAM & BE THE MATCH, *supra* note 8, at 2.