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IN THE UNITED STATES DISTRICT COURT

CENTRAL DISTRICT OF CALIFORNIA

CV09 07772 VBF AJWx

DOREEN FLYNN, JOHN WAGNER, M.D., AKIIM DESHAY, MIKE HAMEL, MARK HACHEY, KUMUD MAJUMDER, and MOREMARROWDONORS.ORG Plaintiffs,	CASE NUMBER: To be supplied by Clerk of The United States District Court

vs.

ERIC HOLDER, ATTORNEY GENERAL of the UNITED STATES, sued in his OFFICIAL CAPACITY Defendant.	**COMPLAINT FOR DECLARATORY AND INJUNCTIVE RELIEF**

INTRODUCTION

This constitutional challenge is about an arbitrary law that criminalizes a promising effort to save lives. Every year, tens of thousands of Americans—many of whom are just children—learn they have a deadly blood disease such as leukemia. Often, their only hope is a bone marrow transplant from a stranger, but there is a desperate shortage of unrelated marrow donors, particularly for minorities.

Plaintiffs intend to change that by implementing a pilot program offering strategic compensation such as a modest scholarship to the most-needed marrow donors. But providing a $3,000 scholarship to a Hispanic college student for donating bone marrow is a major federal crime. Under the National Organ Transplant Act (NOTA), 42 U.S.C. § 274e, granting a scholarship or even making a charitable gift on a marrow donor's behalf is punishable by up to five years in prison.

This criminal prohibition violates the Due Process Clause of the Fifth Amendment to the U.S. Constitution in two respects. First, the bone-

marrow provision denies equal protection by arbitrarily and irrationally treating renewable bone-marrow cells like nonrenewable solid organs such as kidneys, instead of treating them like other renewable or inexhaustible cells such as blood cells, sperm cells, and egg cells for which compensated donation is legal. Second, the statute violates Plaintiffs' substantive-due-process right to participate in safe, accepted, lifesaving medical treatment.

JURISDICTION

1. Plaintiffs bring suit under the Fifth Amendment to the U.S. Constitution and the Declaratory Judgment Act, 28 U.S.C. § 2201.

2. Plaintiffs seek injunctive and declaratory relief against the Attorney General of the United States in his official capacity to enjoin enforcement of the National Organ Transplant Act, 42 U.S.C. § 274e, against them insofar as their program of strategic incentives for bone-marrow donation constitutes providing "valuable consideration" in exchange for a "human organ" or "any subpart thereof." Application of this statute to Plaintiffs arbitrarily and irrationally interferes with their rights to equal protection and substantive due process under the Due Process Clause of the Fifth Amendment to the U.S. Constitution.

3. This Court has jurisdiction under 28 U.S.C. §§ 1331 and 1367.

VENUE

4. Venue is proper in the Central District of California, Western Division, under 28 U.S.C. § 1391(e) and the Local Rules. Plaintiff MoreMarrowDonors.org is a California nonprofit corporation subject to personal jurisdiction in the Central District of California.

PARTIES

5. Plaintiff Doreen Flynn is a U.S. citizen and a resident of Maine.

6. Plaintiff John Wagner is a U.S. citizen and a resident of Minnesota.

7. Plaintiff Kumud Majumder is U.S. citizen and a resident of New Jersey.

8. Plaintiff Mark Hachey is a U.S. citizen and a resident of Washington State.

9. Plaintiff Akiim Deshay is a U.S. citizen and a resident of Texas.

10. Plaintiff Mike Hamel is a U.S. citizen and a resident of Colorado.

11. Plaintiff MoreMarrowDonors.org is a nonprofit corporation organized under the laws of California and subject to personal jurisdiction in the Central District of California.

12. Defendant Eric Holder is the Attorney General of the United States and is sued in his official capacity.

STATEMENT OF FACTS

The Plaintiffs

Doreen Flynn

13. Plaintiff Doreen Flynn is a working single mother of five children, three of whom are relevant to this action—an eleven-year-old girl and five-year-old twin girls.

14. All three girls have Fanconi anemia, a rare and deadly genetic disorder that causes, among other things, bone-marrow failure, usually in the teens.

15. Bone-marrow failure means that the girls will lose the ability to make healthy blood because that is the function of bone marrow.

16. All three girls will need a bone-marrow transplant to survive.

17. Plaintiff Flynn's oldest daughter's blood counts are already declining, meaning she will need her transplant soon.

Plaintiff John Wagner, M.D.

18. Plaintiff Wagner has a Bachelor of Arts degree in Biological Science and Psychology from the University of Delaware and a Medical Degree from Jefferson Medical College at Thomas Jefferson University.

19. Plaintiff Wagner is Professor of Pediatrics, Director of the Division of Hematology-Oncology and Blood and Marrow Transplantation, Director of the Center of Molecular and Cellular Therapeutics, and Medical Director of the Stem Cell Institute at the University of Minnesota. Plaintiff Wagner's research is focused on the development of novel strategies for preventing the immunologic complications of bone-marrow transplantation.

20. Plaintiff Wagner has authored more than 180 articles and book chapters on the subject of bone-marrow transplantation, is a member of a number of professional societies, and was elected into the American Society of Clinical Investigation in 2000 and Association of Physicians in 2006. He co-chairs the Committee on Alternative Stem Cell Sources of the International Bone Marrow Transplant Registry and serves on the Board of Directors of the National Marrow Donors Program. He has received numerous awards including the 2002 Pioneer Award for Therapeutic Advancement from the Fanconi Anemia Research Fund.

21. In addition to his academic work, Plaintiff Wagner continues to be actively involved in the treatment of patients.

22. In his career, Plaintiff Wagner has treated more than 2,000 patients who were in need of a bone-marrow transplant.

23. Of these past patients, at least 20 percent have died because they were unable to find a matching bone-marrow donor.

24. This understates the problem of finding a matching donor: Many potential patients are not even referred to Plaintiff Wagner because those patients' primary oncologists inform them that pursuing a transplant is not a viable option because there are not any matching donors available.

25. Plaintiff Wagner has also been forced at least hundreds of times to resort to using bone marrow from donors that are not well matched with his patients. These mismatched transplants routinely cause severe and even fatal medical complications for patients.

26. If the current shortage of donors continues, Plaintiff Wagner will in the future have patients with deadly blood diseases in need of a bone-marrow transplant who will not be able to find a matching donor and those patients will die as a result.

27. If the current shortage of donors continues, Plaintiff Wagner will also have patients in the future on whom he will perform a bone-marrow transplant with a partially mismatched donor and the patient will either die as a result or suffer severe medical complications.

Plaintiff Kumud Majumder

28. Plaintiff Majumder lives with his wife and son in Saddle River, New Jersey. He has a Ph.D. in biological sciences.

29. Plaintiff Majumder has an eleven-year-old son with acute lymphoblastic leukemia (ALL).

30. ALL is characterized by the runaway proliferation of cancerous white blood cells inside the bone marrow cavities of the large bones. These cells squeeze out all other activity in the bone marrow, which destroys the body's capacity to make blood, and these diseased cells spread to other parts of the body such as the brain and spine.

31. Plaintiff Majumder's son was diagnosed in the summer of 2006 after he became sick with fevers and other symptoms.

32. Plaintiff Majumder's son was immediately treated with chemotherapy to suppress the leukemia. He was off chemotherapy and his leukemia was in apparent remission by summer of 2008.

33. Plaintiff Majumder's son then relapsed in December of 2008 and his health rapidly declined. He began to lose his eyesight and the cancer invaded his brain and testicles.

34. Plaintiff Majumder's son needed an immediate bone-marrow transplant or he would die, but no one in his family was a match. His

doctors searched a national database of potential donors, but could not find one.

35. In the absence of a perfect match, Plaintiff Majumder's son had a bone-marrow transplant in April 2009 after a long search using marrow cells from an unrelated donor that were his son's next best match.

36. If Plaintiff Majumder's son needs a second transplant, a different donor will be needed because the recent donor, whose identity is unknown to the Majumder, is an undesirable match.

Plaintiff Mark Hachey

37. Plaintiff Mark Hachey lives in Puyallup, Washington, with his wife and their two sons. Plaintiff Hachey is retired from the military but continues to work at a military medical facility as a nurse-anesthetist. His wife also works at a military medical facility in a civilian capacity as a neonatal-intensive-care nurse.

38. Plaintiff Hachey is of Caucasian descent and his wife is of Filipino descent. Their two sons are of mixed race.

39. Plaintiff Hachey's youngest son is now sixteen. He was diagnosed with acute lymphoblastic leukemia (the same condition Plaintiff Majumder's son has) in May of 2000 when he was seven years old. He underwent low-dose chemotherapy for two-and-a-half years.

40. He then went into remission for 15 months, but relapsed.

41. Plaintiff Hachey's son needed a bone-marrow transplant but no one in his family was a match. His doctors searched the national registry for an unrelated donor but could not find a match.

42. Plaintiff Hachey's son then underwent two-and-a-half years of debilitating high-dose chemotherapy that had devastating side effects.

43. He then went into remission again for 15 months, but suffered another relapse.

44. Plaintiff Hachey's son's leukemia was so aggressive that his only option at this point was a bone-marrow transplant, but the Hachey family's doctors were not able to find a matching donor.

45. In May of 2008, Plaintiff Hachey's son underwent a transplant using bone-marrow cells from umbilical-cord blood, but those cells were not well matched to his body.

46. Plaintiff Hachey's son is now suffering potentially life-threatening complications due to the mismatched transplant.

Plaintiff Akiim DeShay

47. Plaintiff Akiim DeShay is an African-American who lives in Irving, Texas, with his wife and two young children. He is an information-

technology specialist but cannot work because of complications from his bone-marrow transplant.

48. Plaintiff DeShay was diagnosed with Acute Myeloid Leukemia (AML) in November 2003.

49. Like ALL, AML is characterized by the proliferation of cancerous white blood cells, though white blood cells of the myeloid line. AML kills by destroying the ability of bone marrow to make healthy blood.

50. Plaintiff DeShay received a bone-marrow transplant from his sister in April 2004 and he remains cancer-free.

51. Although his leukemia has not returned, Plaintiff DeShay suffers from medical complications associated with his transplant. He became very sick in February 2009 and was hospitalized.

52. His heart stopped beating on two separate occasions within twenty minutes in the operating room and intensive-care unit and each time he was resuscitated.

53. Plaintiff DeShay is not able to work because of complications associated with his transplant.

54. In March 2007, Plaintiff DeShay became an activist for bone-marrow issues facing the African-American community, which has an especially difficult time finding compatible bone-marrow donors.

55. In October 2007, he started the website www.BlackBoneMarrow.com. He has also participated in bone marrow drives and public talks about bone-marrow issues.

Plaintiff Mike Hamel

56. Plaintiff Mike Hamel lives in Colorado Springs, Colorado.

57. Plaintiff Hamel is a former pastor and now a professional writer. He has written 14 books and he has a blog called Open Mike (http://mikehamel.wordpress.com/).

58. In June of 2008, Plaintiff Hamel went to the doctor to have a mysterious lump in his abdomen examined.

59. In August of 2008, this lump was diagnosed as a symptom of lymphoma, a form of cancer in which cancerous white blood cells congeal into solid tumors in the lymph nodes.

60. He began six rounds of chemotherapy and he was cancer free by the winter of 2008.

61. The cancer returned aggressively in March 2009.

62. In June 2009, Plaintiff Hamel had some of his own remaining, healthy bone-marrow cells removed and frozen.

63. On June 15, after his compromised bone marrow was killed off by high-dose chemotherapy in order to destroy the lymphoma-causing cells,

Plaintiff Hamel had his own frozen bone-marrow cells transplanted back into his body.

64. He is now undergoing continuous medical observation to determine if this "autologous" technique will work or whether he will require a bone-marrow transplant from a donor.

Plaintiff MoreMarrowDonors.org

65. Plaintiff MoreMarrowDonors.org is a California nonprofit corporation that intends to use financial incentives to combat the shortage of bone-marrow donors and increase the number of bone-marrow transplants.

66. Plaintiff MoreMarrowDonors.org also intends to raise public awareness about the shortage of bone marrow donors.

67. Plaintiff MoreMarrowDonors.org is a membership organization open to anyone.

68. Plaintiffs Flynn, Wagner, Hachey, and Majumder are members of Plaintiff MoreMarrowDonors.org.

69. Plaintiffs DeShay and Hamel are on the board of Plaintiff MoreMarrowDonors.org.

70. Plaintiff MoreMarrowDonors.org's incentive plan will be explained in detail in paragraphs 146 through160 below.

The Basics of Bone Marrow Transplantation

What Is Bone Marrow?

71. Bone marrow is a spongy, fluid-filled tissue in the cavities of the large bones. The spaces inside bone marrow are home to special cells ("marrow cells") that produce the cellular components of blood.

72. The technical term for marrow cells is "hematopoietic stem cells." Hematopoiesis is the process by which blood-producing stem cells continuously divide and mature into the cellular components of blood. "Hematopoietic stem cells" are also called "blood stem cells."

73. A "stem cell" is just a cell that has the capacity to differentiate into other cell types. A blood stem cell, for example, has the capacity to mature into any type of blood cell. The term "stem cell" as used in this Complaint and throughout this case has nothing to do with "embryonic stem cells." Embryonic stem cells are completely different from blood stem cells and have no relevance to this case.

74. Marrow cells mature into three different types of blood cells: red blood cells (which carry oxygen throughout the body), white blood cells (which defend the body against infections and foreign matter), and platelets (which stabilize blood volume by clotting when there is bleeding).

75. Once a marrow cell has matured into a specific type of blood cell such as a red blood cell, it leaves the spongy bone marrow tissue and enters the bloodstream.

76. Not all marrow cells transform into blood cells. If they did, then there would not be any marrow cells left inside the bone marrow to make more blood.

77. Some marrow cells divide into two marrow cells instead of maturing into ordinary blood cells.

78. As a result, a healthy person has a stable population of marrow cells and a continuous supply of fresh blood cells.

Bone-Marrow Failure

79. Healthy blood cells are necessary for human life because they perform jobs that directly support human life such as transporting oxygen, fighting infections, and preventing blood loss in the event of an injury.

80. If marrow cells in a person's bone marrow fail to produce a steady supply of healthy blood cells, the person will die.

81. There are many diseases characterized by the failure of marrow cells to produce healthy blood cells. Broadly speaking, these diseases fall into two categories: (1) hematological neoplasms, which cause the

proliferation of abnormal blood cells; and (2) anemias, which are characterized by a failure to produce enough blood cells.

82. The most-well-known hematological neoplasms are the many kinds of leukemia and lymphoma.

83. One type of leukemia is acute lymphoblastic leukemia (ALL)—a common childhood cancer that causes runaway growth of cancerous white blood cells in the bone marrow, cells which crowd out normal blood cells. These malignant white blood cells can pass out of the bone marrow and continue metastasizing in other parts of the body such as the brain or spine. If left untreated, ALL is fatal, often within weeks.

84. In anemia, by contrast, marrow cells fail to produce enough blood cells to replenish the blood. In Fanconi anemia, for example, which usually manifests in childhood, patients suffer a variety of hematological abnormalities, including an inability to produce healthy blood. Fanconi anemia can also cause leukemia.

A "Bone Marrow" Transplant Is Actually a "Marrow Cell" Transplant

85. The term "bone-marrow transplant," while commonly used, is a misnomer.

86. Patients do not need, and doctors do not transplant, actual "bone marrow," meaning that doctors do not remove the spongy, fluid-filled tissue inside the bones and then put that tissue into the bones of patients.

87. What patients need, and what doctors transplant, are marrow cells.

88. Because marrow cells, as described above, are just immature blood cells, a "bone marrow" donation is just a different kind of blood donation and a "bone marrow" transplant is just a different kind of blood transfusion.

There Are Two Ways to Donate Marrow Cells

89. There are two different methods by which marrow cells can be donated.

90. The most common of these—used in about 70 percent of marrow donations—is a technique called peripheral blood stem cell (PBSC) apheresis.

91. In apheresis, a donor is given an injection of a granulocyte colony-stimulating factor (GCSF) every day for five days. A GCSF medication causes marrow cells to proliferate so rapidly that many are pushed into the circulating bloodstream.

92. An apheresis donor sits in a comfortable chair such as a recliner and has a needle inserted into her arm. As the donor's blood is drawn out through the needle, an apheresis machine filters out the marrow cells and returns the plasma and other cellular components of the blood back to the donor's bloodstream.

93. As in ordinary blood donation, apheresis donors do not require sedatives or anesthesia because, other than the needle prick, donation is essentially painless. Apheresis donors can read, watch television, listen to music, or engage in many other activities as long as they sit still.

94. The result of apheresis donation is a bag of liquid marrow cells.

95. Blood banks use exactly the same apheresis technique to collect other specific components of the bloodstream such as plasma or platelets.

96. Medical science applied the apheresis method to marrow-cell donation in the 1990s and, in the 2000s, the use of this technology became the most common method for gathering marrow cells.

97. About 30 percent of marrow donations use the original technique in which the donor is given anesthesia and marrow cells are drawn directly out of the marrow tissue using a long needle. Extracting marrow cells directly from the marrow tissue is called "aspiration."

98. As with apheresis, the end product of aspiration is a bag of liquid marrow cells.

99. Doctors often prefer donors to donate via the aspiration method because marrow cells procured this way tend to have fewer of the donor's white blood cells mixed in. These stray white blood cells can cause complications for certain patients.

100. Many donors will not consent to the aspiration procedure because it is more painful and less pleasant than donating using the PBSC apheresis method.

Donating Marrow Cells Is Safe

101. Donated marrow cells regenerate in three to six weeks.

102. Donating marrow cells does not impair the ability of a donor to produce normal blood.

103. Over the last 25 years, more than 35,000 marrow-cell donations have taken place in the United States between strangers without a single donor death.

104. Less than one percent of marrow-cell donors report a notable adverse event such as serious nausea. The overwhelming majority of these clear up within hours or a few days. Donors who have marrow drawn

directly from their hip bones may report bruising and soreness that lasts a few weeks.

Transplanting Marrow Cells into a Patient

105. Once marrow cells are collected, transplantation is simple and noninvasive: the liquid marrow cells flow into the patient's arm through a normal intravenous line as though it were a simple blood transfusion. The donated marrow cells "know" to travel to the recipient's bones and, if the transplant works, start producing blood for a lifetime.

106. Before a patient receives a donor's marrow cells, doctors must first destroy the patient's own diseased marrow cells with radiation and chemotherapy.

107. If a patient does not receive a marrow-cell transplant after this process, the patient will die.

108. Doctors do not perform marrow-cell transplants unless the patient will die without one.

How Are Donors and Patients Matched?

Matching Is Extremely Important

109. For a marrow-cell transplant to be successful, marrow-cell donors and marrow-cell recipients must match very closely at the deepest genetic level. One way to determine compatibility is by examining human

leukocyte antigen (HLA) markers. HLA markers combine so that each person has a distinct "fingerprint" on the surface of each cell. The other way is to look at the specific gene-fragments (called "alleles") on chromosome six that determine the HLA structure on each cell.

110. Deep genetic compatibility is necessary because transplanted marrow cells will mature into blood cells, including the white blood cells that play a key role in a person's immune system.

111. White blood cells fight disease by circulating around the body looking for foreign invaders such as viruses and then destroying them.

112. White blood cells identify foreign invaders by recognizing that those entities lack the HLA "fingerprints" that every native cell in a person's body has.

113. If there is not a near-perfect genetic match between the donor and recipient, the white blood cells produced by the transplanted marrow cells will attack the native cells of the patient's body.

114. This is basically a mirror image of the organ-rejection problem in the solid-organ context. When a patient receives a kidney, the patient's body tries to reject the kidney as a foreign object because the patient's white blood cells do not recognize the HLA "fingerprints" on the cells of the donated kidney.

115. In the marrow context, on the other hand, the patient receives marrow cells from a donor, which then begin to produce white blood cells inside the patient's body that are genetically related to the donor, not the patient. These new white blood cells do not realize that they are the result of a bone-marrow transplant. As they circulate through the patient's body, these new white blood cells do not recognize the HLA "fingerprints" on any of the patient's own cells. As a result, these new white blood cells mistakenly treat the patient's whole body as a foreign entity such as a bacterium that must be destroyed.

116. The process by which the white blood cells produced by a marrow cell transplant mistakenly attack a patient's body is called graft-versus-host (GVH) disease.

117. GVH disease can be fatal or result in serious, lifelong medical complications.

118. Other than patients who receive their own frozen marrow cells (autologous transplant) or marrow cells from an identical twin (syngenic transplant), virtually every marrow-cell recipient will experience GVH disease to some degree.

119. The intensity of GVH disease increases in direct proportion to the dissimilarity between donor and recipient.

120. GVH disease is typically characterized by progressive damage to the liver, skin, mucosal membranes, and gastrointestinal tract.

121. Marrow-cell donors and patients often must also be matched for viral antibodies such as those associated with Cytomegalovirus (CMV) infection. An antibody mismatch for CMV can make an otherwise tolerable or even perfect HLA matching donor ineligible because the recipient will not be able to survive both GVH disease and the complications associated with CMV antibody mismatch.

Finding a Matching Donor Is Extremely Difficult

122. Only 30 percent of patients in need of a marrow-cell transplant will find a donor among their blood relatives.

123. For the 70 percent without a matching blood relative, an unrelated marrow-cell donor is necessary to survive.

124. Although marrow cells are just immature blood cells and regenerate after donation just like donated blood cells, matching marrow-cell donors with recipients is much more complex than matching ordinary blood donors with recipients.

125. In the blood context, there are only four blood types and literally hundreds of millions or even billions of people with each blood

type. For example, there are roughly three billion people on earth with the most common blood type: O-positive.

126. In the marrow context, there are literally millions of marrow-cell types and often only a handful of people or even just one person who will be compatible with any given patient. It is also possible for a patient to have a literally unique marrow-cell type for which no donor exists.

127. The more diverse a patient's genetic heritage, the rarer the patient's marrow-cell type will be and the more difficult it will be to find a compatible donor.

128. The average African-American, for example, has a comparatively high degree of genetic heterogeneity because African-American genes tend to be a diverse mixture of African, Caucasian, and Native-American genes. Of all American racial categories (Caucasian, African-American, Hispanic, Asian, and Native American), African-Americans have the greatest difficulty finding a compatible unrelated donor.

129. Mixed-race patients such as Plaintiff Hachey's son face the longest odds because they typically have the rarest marrow-cell types.

The National Bone Marrow Registry

130. It is all-but-impossible for a patient to find a compatible unrelated donor on her own.

131. The only practical way to match patients with unrelated donors is to create an enormous database cataloguing the marrow-cell types of people who have agreed to serve as marrow-cell donors if a need ever arises for their specific marrow-cell type.

132. The federal government funds a national registry, which evolved in the mid-1980s out of a registry of military personnel developed by the Navy.

133. This federal funding, and regulations and mandates associated with it, fall under the aegis of what is now called the "C.W. Bill Young Cell Transplantation Program" codified at 42 U.S.C. §§ 274k-m.

134. This federal program originated in 1986 when the Office of Naval Research, which had extensive experience with bone-marrow research related to radiation-induced forms of leukemia and other diseases, awarded a contract to the Minneapolis-based nonprofit corporation National Marrow Donor Program (NMDP) to operate a national civilian registry for the purpose of matching unrelated marrow-cell donors with patients in need of transplants.

135. The NMDP began in September 1987 as a cooperative venture of the American Association of Blood Banks, the American Red Cross, and the Council of Community Blood Centers.

136. At its inception, the NMDP had a registry of 8,000 potential donors

137. The NMDP now has over seven million potential donors in its database.

138. The size of the registry overstates the number of potential donors because a sizeable fraction of donors on the registry cannot be located if their name turns up as a possible match for a dying patient, and some fraction of potential donors who can be located are not willing to donate.

139. Caucasian potential donors are available and willing to donate about 65 percent of the time.

140. Hispanic and Asian potential donors are available and willing to donate about 50 percent of the time.

141. African-American potential donors are available and willing to donate about 34 percent of the time.

142. Caucasian patients can find a matching, available, and willing donor about 75 percent of the time.

143. Hispanic patients find a matching, available, and willing donor about 45 percent of the time.

144. Asian-American patients find a matching, available, and willing donor about 40 percent of the time.

145. African-American patients find a matching, available, and willing donor about 25 percent of the time.

Plaintiff MoreMarrowDonors.org and Strategic Financial Incentives

146. Plaintiff MoreMarrowDonors.org (MoreMarrowDonors.org) is a California nonprofit corporation that wants to operate a pilot program offering strategic financial incentives to marrow-cell donors. Specifically, MoreMarrowDonors.org wants to provide a $3,000 award to the donors whose marrow cells are most needed.

147. MoreMarrowDonors.org will offer compensation in three forms only: (1) a scholarship; (2) a housing allowance; or (3) a gift to a charity of the donor's choice.

148. MoreMarrowDonors.org expects compensation to affect potential donors in three critical ways:

a. More people with rare marrow-cell types such as minorities will sign up for the national registry;

b. More people will stay in touch with the registry so they can be found if they turn up as a match; and

c. More people will go through with the donation process.

149. Plaintiff MoreMarrowDonors.org will provide the awards using funds raised from third-party philanthropists.

150. MoreMarrowDonors.org will have absolutely no involvement in the transplant process, which is strictly the purview of medical professionals.

151. MoreMarrowDonors.org will not attempt to determine the identity of patients or put donors in touch with patients. By law, donors and patients are matched anonymously and must remain unknown to each other for a year after any transplant.

152. MoreMarrowDonors.org will also not attempt to obtain donors for specific, identified patients.

153. The compensation offered by MoreMarrowDonors.org will be fixed at $3,000 and MoreMarrowDonors.org will not engage in any negotiation with any donor.

154. MoreMarrowDonors.org will require the following of a donor in order for the donor to obtain a reward for donating:

a. Potential donors must register with MoreMarrowDonors.org and sign up to the national registry if they have not already done so;

b. Once registered, in order to obtain the reward, the donor must provide MoreMarrowDonors.org with a disclosure signed by the presiding transplant doctor indicating that the MoreMarrowDonors.org member has informed the doctor of the member's intention to collect compensation after donating. This disclosure will also require the donor to be completely honest about her own medical history; and

c. Finally, to collect the award, the donor must provide signed proof from a medical professional that the donation occurred.

155. In its initial phase, MoreMarrowDonors.org will offer compensation only to minorities and people of mixed race since they are the most likely to have the rarest marrow-cell types.

156. Because MoreMarrowDonors.org's goal is to increase the supply of marrow-cell donors whose marrow cells are rare, MoreMarrowDonors.org will also develop a method for identifying rare marrow-cell types using proxies that are even more accurate than race, and offer compensation to people with those marrow-cell types.

157. MoreMarrowDonors.org has received a $25,000 pledge from a private charitable foundation. By the terms of the gift, most of these pledged funds are restricted to being spent on implementing MoreMarrowDonors.org's above-described donor-incentive program.

158. MoreMarrowDonors.org intends to raise further funds to support its pilot program, including medical-research grants.

159. MoreMarrowDonors.org will be able to raise ample funds to support its pilot program if it is legally possible to implement it.

160. The chair of MoreMarrowDonors.org's board, Shaka Mitchell, has experience operating and growing nonprofit organizations to fulfill their missions.

MoreMarrowDonors.org's Proposed Incentive Program Is Illegal

161. MoreMarrowDonors.org's plan to offer strategic compensation such as scholarships to minority marrow-cell donors is considered organ selling under the National Organ Transplant Act (NOTA) of 1984, 42 U.S.C. § 274e, and is a felony punishable by up to five years in prison.

162. 42 U.S.C. § 274e(a), reads in relevant part that it "shall be unlawful for any person to knowingly acquire, receive, or otherwise transfer any human organ for valuable consideration for use in human transplantation[....]"

163. Section 274e(c) defines "human organ" as, among other things, "any subpart" of human "bone marrow," which necessarily includes loose marrow cells because, as explained in paragraphs 85 through 88, marrow cells are what doctors actually remove from a donor's bone marrow and transplant into a patient.

164. Section 274e(c)(2) provides that "valuable consideration" does not include "the reasonable payments associated with the removal, transportation, implantation, processing, preservation, quality control, and storage of a human organ or the expenses of travel, housing, and lost wages incurred by the donor of a human organ in connection with the donation of the organ."

165. The specific incentives in MoreMarrowDonors.org's pilot program—a $3,000 scholarship, a $3,000 housing allowance for rent or a mortgage, or a $3,000 gift to the charity of a marrow-cell donor's choice—do not fall under any of the statutory exceptions to the term "valuable consideration." Therefore, the program for strategic incentives that MoreMarrowDonors.org and the other Plaintiffs want to implement is proscribed by 42 U.S.C. § 274e.

166. Defendant U.S. Attorney General and his agents investigate violations of, and enforce through arrest and prosecution, the criminal

provisions of NOTA. Defendant U.S. Attorney General will enforce the National Organ Transplant Act through investigation, arrest, and prosecution if Plaintiffs implement a high-profile, nationwide pilot program—involving literally thousands of potential marrow-cell donors and dozens or hundreds of actual donors—that plainly violates 42 U.S.C. § 274e.

Congress Included Bone Marrow in the NOTA by Mistake

167. Congress included a prohibition on providing valuable consideration for organs in the National Organ Transplant Act to outlaw markets in solid organs such as kidneys.

168. In more than 1,500 pages of legislative history associated with the National Organ Transplant Act, virtually every page is devoted to the problem of too few kidney and liver donors, and primarily the failure of people to agree to donate their organs after death.

169. There is barely a mention of bone marrow in the legislative history and absolutely no substantive discussion of any issue related to bone marrow, much less any substantive discussion of why bone marrow was included in the statutory definition of "human organ."

170. None of the governmental interests that underlie Congress's desire to prohibit markets in solid organs applies to marrow cells.

171. One of the interests motivating Congress's prohibition on the sale of solid organs was Congress's concern that a market for organs would result in the flow of organs from poor people to rich people.

172. This concern has no application to marrow cells because there can be no "market" in marrow cells. While a solid organ (like a kidney) can be sold to the highest bidder among many potential recipients, the close genetic match required for a marrow-cell transplant makes an open market of that kind impossible.

173. This concern also has no application to incentives that take the form of a fixed financial incentive from a third party like MoreMarrowDonors.org.

174. One of the interests motivating Congress's prohibition on the sale of solid organs was Congress's concern that solid-organ donors who were enticed to sell an organ would be left with a permanent deficit, such as going through the rest of their lives with only one kidney.

175. This concern has no application to marrow cells because marrow cells regenerate completely, and a marrow-cell donor will go through the rest of her life with the same amount of marrow cells she would otherwise have had.

176. One of the interests motivating Congress's prohibition on the sale of solid organs was Congress's concern that transplants of solid organs like kidneys require invasive surgery.

177. This concern has no application to marrow cells because marrow-cell donation is not invasive and is no more dangerous than getting one's wisdom teeth removed.

178. In more than 1,500 pages of legislative history associated with the National Organ Transplant Act, there is no explanation for why marrow cells should not be treated like other renewable or inexhaustible cells such as blood cells, sperm cells, and egg cells.

179. The report of the Senate Committee on Labor and Human Resources, which was issued three days before Senate Bill 2048 (a late draft of NOTA) was published in the Congressional Record, expressly stated that the prohibition on organ sales was not "meant to include blood and blood derivatives, which can be replenished and whose donation does not compromise the health of the donor." S. Rep. No. 98-382 (April 6, 1984).

180. The House of Representatives and the Senate issued a Conference Report on the meaning of the final bill they sent to President Reagan. This Report stated that the "term 'human organ' is not intended to

include replenishable tissues such as blood or sperm." Conf. Rep. No. 98-1127 (Oct. 2, 1984).

181. On October 19, 1984, President Reagan signed into law the bill accompanying Conference Report 98-1127. Weekly Compilation of Presidential Documents, Vol. 20, No. 42 (1984): Oct. 19, Presidential Statement.

182. When NOTA was enacted, it was not the intent of Congress to criminalize compensation for renewable or inexhaustible cells such as blood cells, sperms cells, and egg cells.

183. The plain language of NOTA does not cover renewable or inexhaustible cells such as blood cells, sperm cells, and egg cells.

184. Blood cells, sperm cells, and egg cells are routinely acquired for compensation.

185. Bloodstream components, like platelets, are routinely harvested using exactly the same type of apheresis machine that doctors use to harvest marrow cells. The application of apheresis technology to marrow-cell donation had not yet been developed when NOTA was passed.

186. Tissues are biological matter organized into a definite structural material that has a definite structural function. Tendons, for example, are

classified as connective tissue and formed by parallel arrays of closely packed collagen fibers.

187. Marrow cells are not tissues because they lack any degree of structural organization. Marrow cells are undifferentiated loose cells.

188. Organs are composed of specific tissues that, due to their high degree of organizational complexity, perform a function necessary to sustain life. The heart, for example, is an organ composed mainly of myocardial tissue and composed sporadically of nerve and connective tissues.

189. Because marrow cells are not tissues, they cannot be organs by definition.

190. Marrow cells are like other loose cells found in the human body that lack the structural organization of even tissues, such as red blood cells, white blood cells, platelets, sperm cells, or egg cells.

INJURY TO PLAINTIFF DR. WAGNER

191. Plaintiff Wagner believes that providing marrow-cell donors with financial incentives could make a serious impact on the persistent shortage of marrow-cell donors, especially for minorities and other patients with rare marrow-cell types.

192. The idea of providing incentives to marrow-cell donors first occurred to Plaintiff Wagner during a medical conference several years ago

in which medical professionals described how women or couples with fertility problems routinely compensate a woman who donates her eggs, which are just individual cells.

193. Although eggs are not renewable per se, a healthy woman has tens of thousands more than she will use in a lifetime so eggs are for all practical purposes inexhaustible.

194. Plaintiff Wagner realized on the basis of his medical expertise that marrow-cell donation is actually much less invasive and much less risky than egg donation.

195. Plaintiff Wagner realized that this model could be adapted to the marrow-cell context and be used to produce more and better marrow-cell transplants to save countless lives.

196. Plaintiff Wagner has never offered financial incentives to potential marrow-cell donors because he is aware that such incentives violate the federal criminal law codified in the National Organ Transplant Act (NOTA).

197. It is generally understood by medical professionals in the marrow-cell transplant field that providing incentives to marrow-cell donors is a crime.

198. Plaintiff Wagner is unwilling to commit a federal crime both because he is concerned about prosecution and because committing a federal crime would adversely affect his standing in the medical community, potentially resulting in the loss of his license to practice medicine.

199. Plaintiff Wagner's concerns are objectively reasonable.

200. In the past, Plaintiff Wagner has not worked with outside groups offering financial incentives to potential marrow-cell donors because he is unwilling to commit a federal crime.

201. But for the fact that doing so is prohibited by federal statute, Plaintiff Wagner would offer financial incentives to potential marrow-cell donors under appropriate ethical and medical strictures, work with outside groups offering financial incentives to potential marrow-cell donors, or both.

202. In Plaintiff Wagner's professional judgment, but for the prohibition on providing financial incentives to potential marrow-cell donors, he would have been able to save the lives of more of his past patients by transplanting marrow cells from a matched donor who received financial incentives.

203. In Plaintiff Wagner's professional judgment, but for the prohibition on providing financial incentives to potential marrow-cell donors, he would be able to save the lives of more of his current and future

patients by transplanting marrow cells from matched donors who received financial incentives.

204. Plaintiff Wagner specifically intends to work with MoreMarrowDonors.org and to transplant marrow cells from donors who will receive incentive payments from MoreMarrowDonors.org, but is currently prohibited from doing so by law.

205. If compensation for marrow-cell donation were legal, Plaintiff Wagner would immediately work with Plaintiff MoreMarrowDonors.org to establish medical and ethical criteria for donor eligibility for compensation, advise MoreMarrowDonors.org on scientific issues concerning donor-patient matching, and devise parameters for a pilot program to track the empirical results of strategic compensation to ascertain the extent to which they alleviate the shortage of unrelated marrow donors. Plaintiff Wagner is not currently taking any of these steps because they would be futile because neither he nor MoreMarrowDonors.org are willing to violate federal law (and risk prosecution) by actually providing incentives to marrow-cell donors.

206. Like all or nearly all marrow-cell-transplant doctors, Plaintiff Wagner performs marrow-cell transplants as a last-resort treatment for

patients with advanced stages of cancer or other deadly diseases for which there is no realistic hope for survival without the transplant.

207. As described above in paragraphs 105 through108, preparing a patient for a marrow-cell transplant is extremely dangerous for the patient, and, on average, half of adults who receive marrow-cell transplants die within two years.

208. Despite the extreme risks associated with marrow-cell transplantation, adult patients and their doctors are presumed by the medical profession and the law as capable of making an informed decision to undertake those risks.

209. Because of their advanced illnesses, it is generally not practicable for Plaintiff Wagner's current or future patients to assert their own rights in court to obtain marrow cells from a compensated donor.

210. In his capacity as a physician, Plaintiff Wagner asserts in this action the rights of his current, future, and (where applicable) past patients who wish to obtain marrow cells from a compensated donor, in addition to asserting his own rights.

211. As an expert in marrow-cell transplantation who has been and continues to be in direct communication with the critically ill patients whose

rights are being asserted, Plaintiff Wagner can adequately represent the interests of these absent patients.

212. As a direct result of (1) his fear of enforcement by Defendant of 42 U.S.C. § 274e, and (2) the fact that a doctor of Plaintiff Wagner's expertise and international notoriety must avoid even the appearance of engaging in the practice of medicine in a way that violates federal criminal law, Plaintiff Wagner is injured because 42 U.S.C. § 274e imposes economic and noneconomic harms by preventing him and medical professionals under his supervision from participating in the collection or transplantation of marrow cells provided by a donor who receives financial incentives from MoreMarrowDonors.org.

213. Plaintiff Wagner is further injured in his capacity as the representative of past, present, and future patients who would benefit from financial incentives like those that MoreMarrowDonors.org intends to implement. Plaintiff Wagner has in the past had, currently has, and will in the future have patients dying of fatal blood diseases for whom there is no match on the national registry or for whom there is a match but that matched donor is unavailable or unwilling to provide marrow cells.

214. Absent his fear of prosecution under 42 U.S.C. § 274e and of the reputational and professional harms that would be caused by his

violation of federal law, Plaintiff Wagner would engage in conduct that is presently statutorily forbidden and has concrete plans to do so. Specifically, Plaintiff Wagner would begin transplanting marrow cells from compensated donors as soon as reasonably possible.

INJURY TO PLAINTIFF MOREMARROWDONORS.ORG

215. As a direct result of (1) its fear of enforcement by Defendant of 42 U.S.C. § 274e, and (2) the fact that a California nonprofit corporation is bound by California law not to violate any laws, including 42 U.S.C. § 274e, Plaintiff MoreMarrowDonors.org cannot award financial incentives such as scholarships to marrow-cell donors because doing so violates the statutory proscription in 42 U.S.C. § 274e against providing "valuable consideration" for "any subpart" of "bone marrow."

216. Plaintiff MoreMarrowDonors.org is further injured because it does not know whether 42 U.S.C. § 274e can be constitutionally applied to MoreMarrowDonors.org's financial incentives program for marrow donors.

217. MoreMarrowDonors.org has received a substantial grant of charitable funds, the overwhelming majority of which may be spent only on providing financial incentives to marrow-cell donors.

218. If 42 U.S.C. § 274e can be constitutionally applied to MoreMarrowDonors.org's financial incentives program for marrow-cell

donors, then MoreMarrowDonors.org cannot spend its restricted funds and will be forced to forfeit those funds to another charitable organization yet to be determined. If, on the other hand, § 274e cannot be constitutionally applied to the financial incentives program, then MoreMarrowDonors.org will use those restricted funds for their intended purpose.

219. Absent a declaration from this Court, MoreMarrowDonors.org does not know if it can spend the restricted funds that it currently possesses without suffering adverse legal consequences under federal and California law.

220. Absent its fear of prosecution under 42 U.S.C. § 274e, Plaintiff MoreMarrowDonors.org would engage in conduct that is presently statutorily forbidden, specifically including providing compensation to marrow cell donors who met the requirements described in paragraphs 146 through156.

221. Specifically, if not for the prohibition on providing valuable consideration to marrow-cell donors in 42 U.S.C. § 274e, Plaintiff would immediately begin registering potential donors to eventually receive incentives, would advertise the availability of incentives for marrow-cell donation, and would actively solicit additional funds to be applied to its grant program.

222. MoreMarrowDonors.org also has concrete plans to collaborate with medical experts, specifically including Plaintiff Wagner, to devise medical criteria for determining the eligibility of potential donors for compensation, work with experts in ethics to ensure that the compensation program satisfies principles of informed consent, and work with economic and medical experts to establish a method of tracking the effectiveness of the compensation program.

223. MoreMarrowDonors.org will as rapidly as possible create a nationwide network of tens of thousands or even hundreds of thousands of potential marrow-cell donors in order to implement its compensation plan.

224. MoreMarrowDonors.org cannot offer incentives for marrow-cell donation, advertise the availability of incentives for marrow-cell donation, or solicit funds to be used providing incentives for marrow-cell donation without risking serious legal consequences, including criminal prosecution, for itself, its staff, its marrow-cell donors, its philanthropic supporters, and any outside personnel (including medical professionals) with whom it works.

INJURY TO OTHER PLAINTIFFS

225. As a direct result of his fear of prosecution under 42 U.S.C. § 274e, Plaintiff Akiim DeShay is harmed in his capacity as a member of the

board of directors of MoreMarrowDonors.org because he cannot execute his obligation to implement the organization's financial-incentives pilot program. Plaintiff DeShay is further harmed in his personal capacity because he cannot use the activist network he created through www.BlackBoneMarrow.com to raise funds for, and then apply those funds to, a financial incentive program for marrow-cell donors. Absent his fear of prosecution under 42 U.S.C. § 274e, Plaintiff DeShay would engage in conduct that is presently statutorily forbidden, specifically including implementing the concrete objectives of MoreMarrowDonors.org, raising money for MoreMarrowDonors.org, and causing that money to be spent on providing financial incentives to marrow-cell donors.

226. As a direct result of her fear of prosecution under 42 U.S.C. § 274e, Plaintiff Doreen Flynn is harmed because she cannot take concrete steps calculated to safeguard her three daughters against the possibility that matched, available, and willing donors will not be found when it becomes necessary for them to undergo marrow-cell transplants. These steps will include raising money for and promoting MoreMarrowDonors.org's financial-incentives pilot program. Because there is a very real possibility that at least one of her daughters will need a second transplant from the same matching donor if such a person is found, Plaintiff Flynn also wants the

option of compensation available to ensure that a matched donor remains available and willing for a second donation. Absent her fear of prosecution under 42 U.S.C. § 274e, Plaintiff Flynn would engage in conduct that is presently statutorily forbidden.

227. As a direct result of his fear of prosecution under 42 U.S.C. § 274e, Plaintiff Mike Hamel is harmed in his capacity as a member of the board of directors of MoreMarrowDonors.org because he cannot execute his obligation to implement the organization's financial-incentives pilot program. Plaintiff Hamel is further harmed in his personal capacity because he cannot use the network he created through his blog, Open Mike, to raise funds for, and then apply those funds to, a financial-incentive program for marrow cell donors. Finally, Plaintiff Hamel is harmed in that he is a lymphoma patient who may need a marrow-cell donation from an unrelated donor and he wants a financial-incentive program available to maximize his chances of finding a matching, available, and willing unrelated donor. Absent his fear of prosecution under 42 U.S.C. § 274e, Plaintiff Hamel would engage in conduct that is presently statutorily forbidden, specifically including implementing the concrete objectives of MoreMarrowDonors.org, raising money for MoreMarrowDonors.org, and causing that money to be spent on providing financial incentives to marrow-cell donors.

228. As a direct result of his fear of prosecution under 42 U.S.C. § 274e, Plaintiff Mark Hachey is harmed because he cannot take concrete steps calculated to safeguard his son against the possibility that a matched, available, and willing donor will not be found if his mixed-race son, who received a mismatched cord blood transplant, needs another transplant. These steps will include raising money for and promoting MoreMarrowDonors.org's financial incentives pilot program. Absent his fear of prosecution under 42 U.S.C. § 274e, Plaintiff Hachey would engage in conduct that is presently statutorily forbidden.

229. As a direct result of his fear of prosecution under 42 U.S.C. § 274e, Plaintiff Kumud Majumder is harmed because he cannot take concrete steps calculated to safeguard his son against the possibility that a matched, available, and willing donor will not be found if his son, who received a marrow-cell transplant in April 2009, needs another transplant. There is no person who is a perfect match for Plaintiff Majumder's son. These steps will include raising money for and promoting MoreMarrowDonors.org's financial-incentives pilot program. Absent his fear of prosecution under 42 U.S.C. § 274e, Plaintiff Majumder would engage in conduct that is presently statutorily forbidden.

CLAIMS

Count One: Equal Protection

230. Plaintiffs incorporate and re-allege each and every allegation in paragraphs 1 through 229 as though fully set forth herein.

231. The unconditional ban in the National Organ Transplant Act on providing "valuable consideration" for donation of "any subpart" of "bone marrow" violates the right of the Plaintiffs—and, where applicable, the right of Plaintiff Wagner's patients—to equal protection under the Fifth Amendment to the U.S. Constitution.

232. The National Organ Transplant Act arbitrarily and irrationally treats dissimilar things similarly by defining "any subpart" of "bone marrow," which includes marrow cells, as a "human organ." Because of this prohibition, it is illegal to offer any "valuable consideration" for marrow cells—even though marrow cells are neither organs nor tissues, and are instead completely renewable loose cells.

233. The National Organ Transplant Act also arbitrarily and irrationally treats similar things dissimilarly by prohibiting the payment of "valuable consideration" for marrow cells, but not prohibiting the payment of "valuable consideration" for any other renewable or inexhaustible loose-

cell types that are commonly donated such as the various types of blood cells, sperms cells, and egg cells.

234. Plaintiffs, and Plaintiff Wagner's patients, are irreparably harmed and continue to be irreparably harmed by an objectively reasonable fear that Defendant will enforce 42 U.S.C. § 274e against Plaintiffs for their participation in a high-profile, nationwide pilot program involving tens or even hundreds of thousands of potential marrow-cell donors that offers strategic incentives to those potential marrow-cell donors in order to make more marrow-cell donations happen overall.

Count Two: Due Process

235. Plaintiffs incorporate and re-allege each and every allegation in paragraphs 1 through 234 as though fully set forth herein.

236. The unconditional ban in the National Organ Transplant Act on providing "valuable consideration" for donation of "any subpart" of "bone marrow" violates the right of the Plaintiffs—and, where applicable, the right of Plaintiff Wagner's patients—to substantive due process under the Fifth Amendment to the U.S. Constitution.

237. Plaintiffs and Plaintiff Wagner's patients have a liberty interest in being able to participate in safe, non-experimental, lifesaving medical treatment. The Plaintiffs, and Plaintiff Wagner's patients, want to exercise

this liberty interest by offering strategic financial incentives to marrow-cell donors, but cannot because the National Organ Transplant Act arbitrarily and irrationally defines marrow cells as "human organs" and thus criminalizes the proposed pilot program as an act of organ selling.

238. Forbidding Plaintiffs and Plaintiff Wagner's patients from participating in a pilot program designed to ascertain if strategic financial incentives to marrow-cell donors can save lives does not rationally advance any legitimate government interest.

239. Plaintiffs, and Plaintiff Wagner's patients, are irreparably harmed and continue to be irreparably harmed by an objectively reasonable fear that Defendant will enforce 42 U.S.C. § 274e against Plaintiffs for their participation in a high-profile, nationwide pilot program involving tens or even hundreds of thousands of potential marrow-cell donors that offers strategic incentives to those potential marrow-cell donors in order to make more marrow-cell donations happen overall.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs respectfully request relief as follows:

A. Entry of final judgment against Defendant declaring that 42 U.S.C. § 274e violates the Due Process Clause of the Fifth Amendment to the U.S. Constitution as applied to Plaintiffs;

B. A permanent injunction forbidding further enforcement of 42 U.S.C. § 274e against Plaintiffs;

C. An award of attorneys' fees, costs, and expenses; and

D. For such further and equitable relief as the Court deems just and proper.

Dated: October 26, 2009

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