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21
22 IN THE UNITED STATES DISTRICT COURT

23 CENTRAL DISTRICT OF CALIFORNIA

CV09 07772 VBF AWX
CASE NUMBER:

24 DOREEN FLYNN, JOHN WAGNER,
25 M.D., AKIIM DESHAY, MIKE HAMEL,)
26 MARK HACHEY, KUMUD MAJUMDER,)
27 and MOREMARROWDONORS.ORG)
28 Plaintiffs,)

To be supplied by Clerk
of The United States
District Court

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ORIGINAL

1 vs.

2

3 ERIC HOLDER, ATTORNEY GENERAL)
4 of the UNITED STATES, sued in his)
5 OFFICIAL CAPACITY)
6 Defendant.)
7)
8)

**COMPLAINT FOR
DECLARATORY AND
INJUNCTIVE RELIEF**

9

INTRODUCTION

10

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

16

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

23

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

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

7 **JURISDICTION**

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

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

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

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

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

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

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

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

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

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

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

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

1 *Plaintiff Kumud Majumder*

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

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

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

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

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

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

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

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

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

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

9 *Plaintiff Mark Hachey*

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

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

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

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

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

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

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

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

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

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

17 *Plaintiff Akiim DeShay*

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

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

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

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

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

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

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

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

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

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

4 *Plaintiff Mike Hamel*

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

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

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

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

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

16 61. The cancer returned aggressively in March 2009.

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

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

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

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

6 *Plaintiff MoreMarrowDonors.org*

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

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

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

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

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

18 70. Plaintiff MoreMarrowDonors.org’s incentive plan will be
19 explained in detail in paragraphs 146 through 160 below.

20

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).

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

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

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

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

11 *Bone-Marrow Failure*

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

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

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

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

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

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

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

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

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

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

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

6 88. Because marrow cells, as described above, are just immature
7 blood cells, a “bone marrow” donation is just a different kind of blood
8 donation and a “bone marrow” transplant is just a different kind of blood
9 transfusion.

10 *There Are Two Ways to Donate Marrow Cells*

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

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

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

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

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

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

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

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

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

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

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

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

10 *Donating Marrow Cells Is Safe*

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

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

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

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

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

3 *Transplanting Marrow Cells into a Patient*

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

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

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

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

16 **How Are Donors and Patients Matched?**

17 *Matching Is Extremely Important*

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

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

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

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

10 112. White blood cells identify foreign invaders by recognizing that
11 those entities lack the HLA “fingerprints” that every native cell in a person’s
12 body has.

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

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

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

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

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

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

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

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

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

9 *Finding a Matching Donor Is Extremely Difficult*

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

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

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

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

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

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

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

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

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

18 *The National Bone Marrow Registry*

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

5 **Plaintiff MoreMarrowDonors.org and Strategic Financial Incentives**

6
7 146. Plaintiff MoreMarrowDonors.org (MoreMarrowDonors.org) is
8 a California nonprofit corporation that wants to operate a pilot program
9 offering strategic financial incentives to marrow-cell donors. Specifically,
10 MoreMarrowDonors.org wants to provide a \$3,000 award to the donors
11 whose marrow cells are most needed.

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

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

- 17 a. More people with rare marrow-cell types such as
18 minorities will sign up for the national registry;
19 b. More people will stay in touch with the registry so they
20 can be found if they turn up as a match; and
21 c. More people will go through with the donation process.

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

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

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

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

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

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

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

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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.

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

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

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

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

12 **MoreMarrowDonors.org's Proposed Incentive Program Is Illegal**

13 161. MoreMarrowDonors.org's plan to offer strategic compensation
14 such as scholarships to minority marrow-cell donors is considered organ
15 selling under the National Organ Transplant Act (NOTA) of 1984, 42 U.S.C.
16 § 274e, and is a felony punishable by up to five years in prison.

17 162. 42 U.S.C. § 274e(a), reads in relevant part that it "shall be
18 unlawful for any person to knowingly acquire, receive, or otherwise transfer
19 any human organ for valuable consideration for use in human
20 transplantation[....]"

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

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

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

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

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

6 **Congress Included Bone Marrow in the NOTA by Mistake**

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

14 **INJURY TO PLAINTIFF DR. WAGNER**

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

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

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

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

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

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

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

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

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

5 199. Plaintiff Wagner's concerns are objectively reasonable.

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

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

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

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

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

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

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

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

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

3 207. As described above in paragraphs 105 through 108, preparing a
4 patient for a marrow-cell transplant is extremely dangerous for the patient,
5 and, on average, half of adults who receive marrow-cell transplants die
6 within two years.

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

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

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

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

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

3 212. As a direct result of (1) his fear of enforcement by Defendant of
4 42 U.S.C. § 274e, and (2) the fact that a doctor of Plaintiff Wagner's
5 expertise and international notoriety must avoid even the appearance of
6 engaging in the practice of medicine in a way that violates federal criminal
7 law, Plaintiff Wagner is injured because 42 U.S.C. § 274e imposes economic
8 and noneconomic harms by preventing him and medical professionals under
9 his supervision from participating in the collection or transplantation of
10 marrow cells provided by a donor who receives financial incentives from
11 MoreMarrowDonors.org.

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

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

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

5 **INJURY TO PLAINTIFF MOREMARROWDONORS.ORG**

6 215. As a direct result of (1) its fear of enforcement by Defendant of
7 42 U.S.C. § 274e, and (2) the fact that a California nonprofit corporation is
8 bound by California law not to violate any laws, including 42 U.S.C. § 274e,
9 Plaintiff MoreMarrowDonors.org cannot award financial incentives such as
10 scholarships to marrow-cell donors because doing so violates the statutory
11 proscription in 42 U.S.C. § 274e against providing “valuable consideration”
12 for “any subpart” of “bone marrow.”

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

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

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

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

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

10 220. Absent its fear of prosecution under 42 U.S.C. § 274e, Plaintiff
11 MoreMarrowDonors.org would engage in conduct that is presently
12 statutorily forbidden, specifically including providing compensation to
13 marrow cell donors who met the requirements described in paragraphs 146
14 through 156.

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

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

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

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

18 **INJURY TO OTHER PLAINTIFFS**

19 225. As a direct result of his fear of prosecution under 42 U.S.C. §
20 274e, Plaintiff Akiim DeShay is harmed in his capacity as a member of the

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

12 226. As a direct result of her fear of prosecution under 42 U.S.C. §
13 274e, Plaintiff Doreen Flynn is harmed because she cannot take concrete
14 steps calculated to safeguard her three daughters against the possibility that
15 matched, available, and willing donors will not be found when it becomes
16 necessary for them to undergo marrow-cell transplants. These steps will
17 include raising money for and promoting MoreMarrowDonors.org's
18 financial-incentives pilot program. Because there is a very real possibility
19 that at least one of her daughters will need a second transplant from the same
20 matching donor if such a person is found, Plaintiff Flynn also wants the

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

5 227. As a direct result of his fear of prosecution under 42 U.S.C. §
6 274e, Plaintiff Mike Hamel is harmed in his capacity as a member of the
7 board of directors of MoreMarrowDonors.org because he cannot execute his
8 obligation to implement the organization's financial-incentives pilot
9 program. Plaintiff Hamel is further harmed in his personal capacity because
10 he cannot use the network he created through his blog, Open Mike, to raise
11 funds for, and then apply those funds to, a financial-incentive program for
12 marrow cell donors. Finally, Plaintiff Hamel is harmed in that he is a
13 lymphoma patient who may need a marrow-cell donation from an unrelated
14 donor and he wants a financial-incentive program available to maximize his
15 chances of finding a matching, available, and willing unrelated donor.

16 Absent his fear of prosecution under 42 U.S.C. § 274e, Plaintiff Hamel
17 would engage in conduct that is presently statutorily forbidden, specifically
18 including implementing the concrete objectives of MoreMarrowDonors.org,
19 raising money for MoreMarrowDonors.org, and causing that money to be
20 spent on providing financial incentives to marrow-cell donors.

1 228. As a direct result of his fear of prosecution under 42 U.S.C. §
2 274e, Plaintiff Mark Hachey is harmed because he cannot take concrete
3 steps calculated to safeguard his son against the possibility that a matched,
4 available, and willing donor will not be found if his mixed-race son, who
5 received a mismatched cord blood transplant, needs another transplant.
6 These steps will include raising money for and promoting
7 MoreMarrowDonors.org's financial incentives pilot program. Absent his
8 fear of prosecution under 42 U.S.C. § 274e, Plaintiff Hachey would engage
9 in conduct that is presently statutorily forbidden.

10 229. As a direct result of his fear of prosecution under 42 U.S.C. §
11 274e, Plaintiff Kumud Majumder is harmed because he cannot take concrete
12 steps calculated to safeguard his son against the possibility that a matched,
13 available, and willing donor will not be found if his son, who received a
14 marrow-cell transplant in April 2009, needs another transplant. There is no
15 person who is a perfect match for Plaintiff Majumder's son. These steps
16 will include raising money for and promoting MoreMarrowDonors.org's
17 financial-incentives pilot program. Absent his fear of prosecution under 42
18 U.S.C. § 274e, Plaintiff Majumder would engage in conduct that is presently
19 statutorily forbidden.
20

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

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

10 **Count Two: Due Process**

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

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

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

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

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

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

16 **PRAYER FOR RELIEF**

17 WHEREFORE, Plaintiffs respectfully request relief as follows:

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

- 1 B. A permanent injunction forbidding further enforcement of 42
- 2 U.S.C. § 274e against Plaintiffs;
- 3 C. An award of attorneys' fees, costs, and expenses; and
- 4 D. For such further and equitable relief as the Court deems just and
- 5 proper.

6
7

Dated: October 26, 2009

8 THE LAW OFFICES OF
9 JUSTIN SOBODASH

10
11 By: Justin Sobodash
12 Justin Sobodash

INSTITUTE FOR JUSTICE
Jeff Rowes*
Robert McNamara*
William Mellor*
*Pro hac vice pending

13
14 Attorneys for Plaintiffs
15 Doreen Flynn, John Wagner,
16 M.D., Akiim DeShay, Mike
17 Hamel, Mark Hachey,
18 Kumud Majumder, and
19 MoreMarrowDonors.org
20

UNITED STATES DISTRICT COURT, CENTRAL DISTRICT OF CALIFORNIA CIVIL COVER SHEET

I (a) PLAINTIFFS (Check box if you are representing yourself) DOREEN FLYNN, JOHN WAGNER, M.D., AKIIM DESHAY, MIKE HAMEL, MARK HACHEY, KUMUD MAJUMDER, and MOREMARROWDONORS.ORG DEFENDANTS ERIC HOLDER, ATTORNEY GENERAL of the UNITED STATES, sued in his OFFICIAL CAPACITY (b) Attorneys (Firm Name, Address and Telephone Number. If you are representing yourself, provide same.) Justin Sobodash (State Bar #217450), The Law Offices of Justin Sobodash 9107 Wilshire Blvd., Suite 450, Beverly Hills, CA 90210, Tel: 310.461.3577 Attorney of Record (See Attached for additional attorneys) Attorneys (If Known) U.S. Department of Justice

II. BASIS OF JURISDICTION (Place an X in one box only.) 1 U.S. Government Plaintiff 3 Federal Question (U.S. Government Not a Party) 2 U.S. Government Defendant 4 Diversity (Indicate Citizenship of Parties in Item III) III. CITIZENSHIP OF PRINCIPAL PARTIES - For Diversity Cases Only (Place an X in one box for plaintiff and one for defendant.) Citizen of This State Citizen of Another State Citizen or Subject of a Foreign Country PTF DEF 1 1 2 2 3 3 Incorporated or Principal Place of Business in this State Incorporated and Principal Place of Business in Another State Foreign Nation PTF DEF 4 4 5 5 6 6

IV. ORIGIN (Place an X in one box only.) 1 Original Proceeding 2 Removed from State Court 3 Remanded from Appellate Court 4 Reinstated or Reopened 5 Transferred from another district (specify): 6 Multi-District Litigation 7 Appeal to District Judge from Magistrate Judge

V. REQUESTED IN COMPLAINT: JURY DEMAND: Yes No (Check 'Yes' only if demanded in complaint.) CLASS ACTION under F.R.C.P. 23: Yes No MONEY DEMANDED IN COMPLAINT: \$

VI. CAUSE OF ACTION (Cite the U.S. Civil Statute under which you are filing and write a brief statement of cause. Do not cite jurisdictional statutes unless diversity.) *28 U.S.C. § 2201 (See Attached for statement of cause)

VII. NATURE OF SUIT (Place an X in one box only.) OTHER STATUTES 400 State Reapportionment 410 Antitrust 430 Banks and Banking 450 Commerce/ICC Rates/etc. 460 Deportation 470 Racketeer Influenced and Corrupt Organizations 480 Consumer Credit 490 Cable/Sat TV 810 Selective Service 850 Securities/Commodities/Exchange 875 Customer Challenge 12 USC 3410 890 Other Statutory Actions 891 Agricultural Act 892 Economic Stabilization Act 893 Environmental Matters 894 Energy Allocation Act 895 Freedom of Info. Act 900 Appeal of Fee Determination Under Equal Access to Justice 950 Constitutionality of State Statutes CONTRACT 110 Insurance 120 Marine 130 Miller Act 140 Negotiable Instrument 150 Recovery of Overpayment & Enforcement of Judgment 151 Medicare Act 152 Recovery of Defaulted Student Loan (Excl. Veterans) 153 Recovery of Overpayment of Veteran's Benefits 160 Stockholders' Suits 190 Other Contract 195 Contract Product Liability 196 Franchise REAL PROPERTY 210 Land Condemnation 220 Foreclosure 230 Rent Lease & Ejectment 240 Torts to Land 245 Tort Product Liability 290 All Other Real Property TORTS PERSONAL INJURY 310 Airplane 315 Airplane Product Liability 320 Assault, Libel & Slander 330 Fed. Employers' Liability 340 Marine 345 Marine Product Liability 350 Motor Vehicle 355 Motor Vehicle Product Liability 360 Other Personal Injury 362 Personal Injury-Med Malpractice 365 Personal Injury-Product Liability 368 Asbestos Personal Injury Product Liability IMMIGRATION 462 Naturalization Application 463 Habeas Corpus-Alien Detainee 465 Other Immigration Actions TORTS PERSONAL PROPERTY 370 Other Fraud 371 Truth in Lending 380 Other Personal Property Damage 385 Property Damage Product Liability BANKRUPTCY 422 Appeal 28 USC 158 423 Withdrawal 28 USC 157 CIVIL RIGHTS 441 Voting 442 Employment 443 Housing/Accommodations 444 Welfare 445 American with Disabilities - Employment 446 American with Disabilities - Other 440 Other Civil Rights PRISONER PETITIONS 510 Motions to Vacate Sentence Habeas Corpus 530 General 535 Death Penalty 540 Mandamus/Other 550 Civil Rights 555 Prison Condition FORFEITURE/PENALTY 610 Agriculture 620 Other Food & Drug 625 Drug Related Seizure of Property 21 USC 881 630 Liquor Laws 640 R.R. & Truck 650 Airline Regs 660 Occupational Safety /Health 690 Other LABOR 710 Fair Labor Standards Act 720 Labor/Mgmt. Relations 730 Labor/Mgmt. Reporting & Disclosure Act 740 Railway Labor Act 790 Other Labor Litigation 791 Empl. Ret. Inc. Security Act PROPERTY RIGHTS 820 Copyrights 830 Patent 840 Trademark SOCIAL SECURITY 861 HIA (1395ff) 862 Black Lung (923) 863 DIWC/DIWW (405(g)) 864 SSID Title XVI 865 RSI (405(g)) FEDERAL TAX SUITS 870 Taxes (U.S. Plaintiff or Defendant) 871 IRS-Third Party 26 USC 7609

CV09 07772

FOR OFFICE USE ONLY: Case Number: AFTER COMPLETING THE FRONT SIDE OF FORM CV-71, COMPLETE THE INFORMATION REQUESTED BELOW.

**UNITED STATES DISTRICT COURT, CENTRAL DISTRICT OF CALIFORNIA
CIVIL COVER SHEET**

VIII(a). IDENTICAL CASES: Has this action been previously filed in this court and dismissed, remanded or closed? No Yes
If yes, list case number(s): _____

VIII(b). RELATED CASES: Have any cases been previously filed in this court that are related to the present case? No Yes
If yes, list case number(s): _____

Civil cases are deemed related if a previously filed case and the present case:

- (Check all boxes that apply) A. Arise from the same or closely related transactions, happenings, or events; or
 B. Call for determination of the same or substantially related or similar questions of law and fact; or
 C. For other reasons would entail substantial duplication of labor if heard by different judges; or
 D. Involve the same patent, trademark or copyright, and one of the factors identified above in a, b or c also is present.

IX. VENUE: (When completing the following information, use an additional sheet if necessary.)

- (a) List the County in this District; California County outside of this District; State if other than California; or Foreign Country, in which EACH named plaintiff resides.
 Check here if the government, its agencies or employees is a named plaintiff. If this box is checked, go to item (b).

County in this District:*	California County outside of this District; State, if other than California; or Foreign Country
Los Angeles County	Maine, Minnesota, Texas, Colorado, Washington, and New Jersey

- (b) List the County in this District; California County outside of this District; State if other than California; or Foreign Country, in which EACH named defendant resides.
 Check here if the government, its agencies or employees is a named defendant. If this box is checked, go to item (c).

County in this District:*	California County outside of this District; State, if other than California; or Foreign Country

- (c) List the County in this District; California County outside of this District; State if other than California; or Foreign Country, in which EACH claim arose.
Note: In land condemnation cases, use the location of the tract of land involved.

County in this District:*	California County outside of this District; State, if other than California; or Foreign Country
Los Angeles County	Maine, Minnesota, Texas, Colorado, Washington, and New Jersey

* Los Angeles, Orange, San Bernardino, Riverside, Ventura, Santa Barbara, or San Luis Obispo Counties

Note: In land condemnation cases, use the location of the tract of land involved

X. SIGNATURE OF ATTORNEY (OR PRO PER): Justin Substant Date 10.26.09

Notice to Counsel/Parties: The CV-71 (JS-44) Civil Cover Sheet and the information contained herein neither replace nor supplement the filing and service of pleadings or other papers as required by law. This form, approved by the Judicial Conference of the United States in September 1974, is required pursuant to Local Rule 3-1 is not filed but is used by the Clerk of the Court for the purpose of statistics, venue and initiating the civil docket sheet. (For more detailed instructions, see separate instructions sheet.)

Key to Statistical codes relating to Social Security Cases:

Nature of Suit Code	Abbreviation	Substantive Statement of Cause of Action
861	HIA	All claims for health insurance benefits (Medicare) under Title 18, Part A, of the Social Security Act, as amended. Also, include claims by hospitals, skilled nursing facilities, etc., for certification as providers of services under the program. (42 U.S.C. 1935FF(b))
862	BL	All claims for "Black Lung" benefits under Title 4, Part B, of the Federal Coal Mine Health and Safety Act of 1969. (30 U.S.C. 923)
863	DIWC	All claims filed by insured workers for disability insurance benefits under Title 2 of the Social Security Act, as amended; plus all claims filed for child's insurance benefits based on disability. (42 U.S.C. 405(g))
863	DIWW	All claims filed for widows or widowers insurance benefits based on disability under Title 2 of the Social Security Act, as amended. (42 U.S.C. 405(g))
864	SSID	All claims for supplemental security income payments based upon disability filed under Title 16 of the Social Security Act, as amended.
865	RSI	All claims for retirement (old age) and survivors benefits under Title 2 of the Social Security Act, as amended. (42 U.S.C. (g))

**UNITED STATES DISTRICT COURT, CENTRAL DISTRICT OF
CALIFORNIA
CIVIL COVER SHEET
Attachment**

(b) Attorneys (Firm Name, Address and Telephone Number. If you are representing yourself, provide same.)

Jeff Rowes*
Robert McNamara*
William H. Mellor*
Institute for Justice
901 N. Glebe Rd., Suite 900
Arlington, VA 22203
Tel: 703.682.9320
**Pro hac vice application pending*

VI. CAUSE OF ACTION (Cite the U.S. Civil Statute under which you are filing and write a brief statement of cause. Do not cite jurisdictional statutes unless diversity.)

28 U.S.C. § 2201: Plaintiffs seek a declaration that the bone marrow provision of 42 U.S.C. § 274e violates their rights to due process and equal protection under the Fifth Amendment to the U.S. Constitution.