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**AN EXAMINATION OF THE  
ISSUE OF BONE MARROW  
COMPENSATION**

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Johns Hopkins Institute for Applied Economics,  
Global Health, and the Study of Business  
Enterprise



# **An Examination of the Issue of Bone Marrow Compensation**

**By Valerie Vilariño**

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## **About the Series**

The Studies in Applied Economics series is under the general direction of Professor Steve H. Hanke, co-director of the Institute for Applied Economics, Global Health, and Study of the Business Enterprise (hanke@jhu.edu). The authors are mainly students at The Johns Hopkins University in Baltimore.

## **About the Author**

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## **Abstract**

The National Organ Transplant Act of 1984 banned compensation for organ donation. The ban was interpreted as applying also to bone marrow. An August 2017 decision by the U.S. Department of Health and Human Services made compensation legal for bone marrow. I review the situation regarding compensation for bone marrow donations from 1984 to 2017 and describe what has happened so far under legalized compensation.

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## Introduction

Bone marrow is a soft, spongy tissue located inside the center cavity of bones. It is the production site of blood stem cells. These blood stem cells can differentiate into white blood cells for immune function, red blood cells for the transport of oxygen, or platelets for the prevention of excessive bleeding.

Because bone marrow has such a varied range of functions within the body it has become an important tool in treating various blood cancers and bone marrow diseases, as well as immune and genetic diseases. To treat a patient with bone marrow, an analysis of the proteins in the patient's blood is done to find a donor who has very similar human leucocyte antigen (HLA). According to the National Cancer Institute (NCI), "Human leucocyte antigen is a type of molecule found on the surface of most cells in the body that plays an important part in the body's immune response to foreign substances. They make up a person's tissue type, which varies from person to person."<sup>1</sup> Once it is confirmed that the donor and the patient have almost identical HLAs, bone marrow is extracted from the donor and transfused into the patient.<sup>2</sup>

Bone marrow transplants can generally be classified into one of three categories: autologous transplants, allogenic transplants, or haploidentical transplants. An autologous transplant, the most common form of bone marrow transplant today, is one in which the patient's own bone marrow is reintroduced after having undergone treatment. An allogenic transplant is one in which the patient receives bone marrow from a donor who has a very similar HLA type to that of the patient.<sup>3</sup> The last form, a haploidentical transplant, is one in which the patient receives bone marrow from someone whose HLA matches 50 percent of that of the patient's. In most cases, haploidentical transplants occur between parents and children or between siblings.<sup>4</sup>

This paper focuses on the issue of bone marrow compensation. It analyzes the potential effect that compensation would have on the supply of bone marrow, as well as discussing why the United States currently does not have a system by which donors can be compensated for donations, even though compensation has been legal since August 2017. The paper focuses on allogenic transplants from unrelated donors – meaning situations where the donor and the receipt of the bone marrow are not genetically related, but they are a very close HLA match for one another – because they are the type of transplants for which abstract economic theory suggests that compensation would be the most effective in increasing supply.

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<sup>1</sup> NCI Dictionary of Cancer Terms. "Human Leukocyte Antigen." (n.d.),

<https://www.cancer.gov/publications/dictionaries/cancer-terms/def/human-leukocyte-antigen>.

<sup>2</sup> National Marrow Donor Program - Donate Today. "What Is a Bone Marrow Transplant." Be the Match, (n.d.), [bethematch.org/patients-and-families/about-transplant/what-is-a-bone-marrow-transplant/](http://bethematch.org/patients-and-families/about-transplant/what-is-a-bone-marrow-transplant/).

<sup>3</sup> National Marrow Donor Program - Donate Today. "Allogeneic Transplant." Be the Match, (n.d.), [bethematch.org/patients-and-families/about-transplant/what-is-a-bone-marrow-transplant/allogeneic-transplant/](http://bethematch.org/patients-and-families/about-transplant/what-is-a-bone-marrow-transplant/allogeneic-transplant/).

<sup>4</sup> National Marrow Donor Program – Donate Today. "Haploidentical Transplant." Be the Match, (n.d.), [bethematch.org/patients-and-families/about-transplant/what-is-a-bone-marrow-transplant/haploidentical-transplant/](http://bethematch.org/patients-and-families/about-transplant/what-is-a-bone-marrow-transplant/haploidentical-transplant/).

## Bone Marrow Background

In the last several years, bone marrow has become a topic of interest because there is controversy as to whether or not bone marrow donations to unrelated recipients should be monetarily compensated.<sup>4</sup> Those who argue in favor of compensation claim that bone marrow is no different from blood plasma, eggs, or sperm, the donations of which are legal to compensate. Furthermore, compensation has been proven to work to increase donations of blood and therefore could be an appropriate method to decrease the current scarcity of bone marrow matches. Those opposed to compensation argue that it will not only place those of lower socioeconomic status at a significant disadvantage if they were to need bone marrow, but it would also lead donors in need of money to lie about health problems that could potentially render their donation useless.<sup>5</sup>

For simplicity, my discussion will designate the patient to be a female and the donor to be a male. When a patient is in need of a bone marrow transplant her doctor will search the National Bone Marrow Donor Program (NMDP) registry called “Be the Match” for a close match to the patient’s HLA type. This registry contains the HLA typing information for all registered donors for a patient in the United States.<sup>6</sup>

The NMDP, which was called the National Bone Marrow Donor Registry when it started in July 1986, has grown tremendously since its inception. Originally, the National Bone Marrow Donor Registry was given a contract through the U.S. Navy with enough funds to employ just one full-time employee and to subcontract software from the University of Minnesota. The software system was given to hospitals for free to allow doctors to be able to search for matches for their patients. These beginnings are a far cry from today’s NMDP, which employs over 600 people and is financially supported by multiple federal contracts organized through the Health Resources and Services Administration, an agency of the U.S. Department of Health and Human Services.<sup>7</sup>

The registry works in the following way: an interested donor registers with the NMDP through the phone, online, or a third-party campaign. Once he is registered he can go to a donor center for a small blood sample or will receive a kit in the mail that contains the necessary instruments for a mouth swab. Either of these will be sent back to the NMPD, analyzed for the necessary HLA typing information, and placed in the database of potential donors. This is the database

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<sup>5</sup> Sibilla, Nick. “Without Matching Bone Marrow Donors, 3,000 Americans Die Each Year – Movie Wants to Change That.” *Forbes*, 31 August 2016, [www.forbes.com/sites/instituteforjustice/2016/08/31/without-matching-bone-marrow-donors-3000-americans-die-each-year-this-movie-wants-to-change-that/#1612cd155025](http://www.forbes.com/sites/instituteforjustice/2016/08/31/without-matching-bone-marrow-donors-3000-americans-die-each-year-this-movie-wants-to-change-that/#1612cd155025).

<sup>6</sup> American Society of Clinical Oncology. “Donating Bone Marrow Is Easy and Important: Here’s Why.” *Cancer.Net*, 5 January 2017, [www.cancer.net/blog/2017-01/donating-bone-marrow-easy-and-important-heres-why](http://www.cancer.net/blog/2017-01/donating-bone-marrow-easy-and-important-heres-why).

<sup>7</sup> Ballen, K. K., King, R.J., Chitphakdithai, P., Bolan, C. D., jr., Agura, E., Hartman, R. J., & Kernan, N.A. “The US National Marrow Donor Program 20 Years of Unrelated Donor Hematopoietic Cell Transplantation.” *Biology of Blood and Marrow Transplantation*, 14(9), 2-7. 2008, <https://www.sciencedirect.com/science/article/pii/S1083879108002309>.

used by physicians at bone marrow transplant centers to find donors when patients are in need. Once a patient is a match for a donor in the registry, the donor is contacted and asked for a second sample to confirm the accuracy of the match. If the patient's physician verifies the match, the donor is then contacted by a counselor from the NMPD. The counselor will discuss with the potential donor the type of procedure that the patient's doctor is recommending and what exactly that entails for the donor. This is when the donor decides whether or not he would like to donate his bone marrow.<sup>5</sup> Often, potential donors choose not to donate. Many economists as well as experts in bone marrow donation have suggested that the share of potential donors who match but then choose not to donate their bone marrow (about 39 percent) could be decreased significantly if they were compensated for their donation.<sup>8</sup>

Although everyone who chooses to register to be a potential bone marrow donor ends up in the Be the Match registry organized by the NMDP, not all donors initially make contact with the NMDP. Many donors register through third-party donation campaigns such as Delete Blood Cancers and the Asian American Donor Program (AADP).<sup>9</sup> All U.S. registries ultimately list their donors in Be the Match, but some recruit outside of Be the Match. Two that make large contributions to the NMDP are the Gift of Life Marrow Registry and DKMS. Gift of Life is a primarily Jewish registry started in 1991 to help find Jay Feinberg a match; to this day it continues to register potential donors.<sup>10</sup> DKMS is a registry started in Germany in the 1990s by Dr. Peter Harf, who lost his wife to leukemia; his aim is to end blood cancers by finding matches for all patients in need.<sup>11</sup> Although Be the Match is a registry that is run by the NMDP, a U.S. national program, 47 percent of transplants arranged through the NMDP have either a foreign donor or recipient. This is accomplished through partnerships with other cooperative registries that work similarly to Be the Match. By working with the registries of other countries, the NMDP is able to make a significantly greater number of matches for those in need in the United States and abroad.<sup>12</sup>

Many patients and their families are disappointed when they learn that a potential donor has chosen not to donate after being confirmed as a match. In many cases these donors are the patient's best hope for survival, which is why the issue of compensation becomes personal for families. Research has shown that compensating donors helps to increase the number of donations. Knowing this, many families ask their doctors if they can compensate the donor out of pocket.<sup>13</sup>

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<sup>8</sup> Barakat, Matthew. "Money for Bone Marrow Donors? Company Says Yes; Fed Say No." AP News, Associated Press, 16 September 2016, [apnews.com/eb9cceb42fb4bae8a9e1fc5154872d1](http://apnews.com/eb9cceb42fb4bae8a9e1fc5154872d1).

<sup>9</sup> Marrow Drives. "Marrow and Stem Cell Donor Programs." (n.d.), [marrowdrives.org/bone\\_marrow\\_donor\\_programs.html](http://marrowdrives.org/bone_marrow_donor_programs.html).

<sup>10</sup> Gift of Life. "History." (n.d.), [www.giftoflife.org/page/content/history.h\h](http://www.giftoflife.org/page/content/history.h\h)

<sup>11</sup> DKMS. "About Us." About, (n.d.), [www.dkms.org/en/about](http://www.dkms.org/en/about).

<sup>12</sup> National Marrow Donor Program, Be the Match. "Cooperative Registries." (n.d.), [bethematch.org/about-us/global-transplant-network/cooperative-registries/](http://bethematch.org/about-us/global-transplant-network/cooperative-registries/).

<sup>13</sup> (Flynn v. Holder) Doreen Flynn, John Wagner, M.D., Akiim Deshay, Mike Hamel, Mark Hashey, Kumud Majumder, and MoremarrowDonors.org vs Eric Holder (U.S. District Court Central District of California, Los Angeles October 26, 2009) (Institute for Justice, Dist. file).

Up until August 2017, giving compensation was considered a felony punishable by up to a \$50,000 fine and five years of jail time. This was because the 1984 National Organ Transplant Act (NOTA) states, “It shall be unlawful for any person to knowingly acquire, receive, or otherwise transfer any human organ for valuable consideration for use in human transplantation if the transfer affects interstate commerce.” Here “organ” was interpreted to refer to bone marrow as well.<sup>14</sup> From 1984 to August 2017 regulation of bone marrow under the NOTA was at times contested because it was unclear whether bone marrow was correctly categorized as an organ, since the body can replenish bone marrow, unlike solid organs.<sup>15</sup> (The liver can regenerate, but liver transplants involve surgery. Other frequently transplanted organs such as kidneys, hearts, lungs, and corneas do not regenerate.)

### **Bone Marrow Transplant Process**

For people familiar with old-fashioned bone marrow donation, it conjures scary images of a large epidural-like needle being placed deep inside the hip bone. This procedure is called bone marrow harvesting, and although it used to be the primary procedure used for bone marrow transplants, today it is only used in about 30 percent of transplants. The other 70 percent of transplants use a method called peripheral blood stem cell donation (PBSC).<sup>16</sup> Below is a short description of each procedure, the pre-procedure preparation, and the post-procedure recovery for the donor as well as the patient. Prior to beginning either method, the patient and the donor must successfully complete extensive testing for both the patient and the donor to assure optimal health for a transplant and to confirm the match is strong. In addition, patients undergo weeks of drug therapy to help prepare the immune system for the transplant.<sup>17</sup>

Bone Marrow Harvesting: Once the patient is ready for the transplant, the donor arrives at the hospital the day of the transplant and receives anesthesia. Doctors then remove liquid bone marrow from the back of the donor’s pelvis using a hollow needle. At this point the donor may receive a blood transfusion from blood that he previously donated. Once the donor has recovered from anesthesia, he can go home later the same day. After the donation, donors often experience soreness in the retrieval spot lasting anywhere from a few days to upwards of a week.<sup>18</sup> Complications from this procedure are rare: 98.5 percent of donors fully recover within a few weeks of the procedure. However, 2.4 percent of donors experience more serious

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<sup>14</sup> U.S. Code, Title 42, Chapter 6A, Subchapter II, Part H, Section 274e.

<sup>15</sup> Fund. Johns. “What Would You Do to Save Your Child’s Life?” National Review, National Review, 9 September 2016, [www.nationalreview.com/2016/09/bone-marrow-transplants-federal-donation-rules-kill-thousands/](http://www.nationalreview.com/2016/09/bone-marrow-transplants-federal-donation-rules-kill-thousands/).

<sup>16</sup> Institute for Justice. “Bone Marrow Statistics.” (n.d.), [ij.org/bonemarrowstatistics/](http://ij.org/bonemarrowstatistics/).

<sup>17</sup> Johns Hopkins Medicine. “Bone Marrow Transplantation.” Johns Hopkins Medicine Health Library, (n.d.), [www.hopkinsmedicine.org/healthlibrary/conditions/hematology\\_and\\_blood\\_disorders/bone\\_marrow\\_transplantation\\_85,P00086](http://www.hopkinsmedicine.org/healthlibrary/conditions/hematology_and_blood_disorders/bone_marrow_transplantation_85,P00086).

<sup>18</sup> Health Resources & Services Administration. “Donating Marrow.” U.S. Department of Health and Human Services, (n.d.), [bloodcell.transplant.hrsa.gov/donor/donating/index.html#DonationProcess](http://bloodcell.transplant.hrsa.gov/donor/donating/index.html#DonationProcess).

side effects from the general anesthesia, or damage to the bone, nerve, or muscle in the hip region.<sup>19</sup>

Peripheral Blood Stem Cells (PRSC): Once the patient is about 5 days away from optimal bone marrow introduction, the donor begins to receive daily injections of filgrastim\*. This is a protein that simulates one naturally produced by the body that transports blood stem cells out of the bone marrow and into the blood stream so that there are enough blood stem cells in the bloodstream for a transplant. The injections can be given at any local clinic. Donors may experience varied side effects from the injections, such as nausea, headaches, bone and muscle pain, tiredness, and trouble sleeping. However, fewer than 1 percent of donors experience severe side effects from the filgrastim shots. Once the number of blood stem cells in the bloodstream has reached optimal transplant levels, the donor visits an “apheresis center” where one needle is placed in each arm. One needle removes blood, circulates it through a machine that filters the blood stem cells out of the blood, and then the second needle returns the blood to the donor. Donation sessions may last anywhere from three to eight hours, and in about 96 percent of cases enough blood stem cells to meet the recipient’s needs are collected in one session. The remaining 4 percent of donations require two to four apheresis sessions that may last between four and six hours each.

Complications associated with the extraction of blood stem cells using this method are rare: fewer less than 1 percent of donors experience them. This figure is similar to that for donating blood plasma. Complications are mainly associated with having to place a central line in donors who lack suitable arm veins.

Before a patient can receive the donor’s bone marrow, she has to undergo necessary drug therapies to remove the malignancy, make space in the bone marrow for healthy bone marrow, and prepare the immune system to receive foreign bone marrow. Most of the medications involved have strong side effects resembling those of chemotherapy. Regardless of how the donor donated the bone marrow, the process of giving it to the patient, called infusion, is the same. A catheter that had previously been placed to administer drug therapies is now used to infuse the donor’s bone marrow into the patient’s bloodstream. Bone marrow infusion closely resembles a blood transfusion. During infusion patients may experience pain, chills, fever, and hives. After the transplant, patients are given drug therapy to limit complications such as infection and rejection. Patients may for a time experience lowered immune function, excessive bleeding, nausea, vomiting, diarrhea, and mouth sores. After infusion, patients are normally placed on a regimen of antibiotics and graft-versus-host disease preventing medications, which each have side effects of their own.

Although preparing for a bone marrow infusion, the actual process of the infusion, and the aftermath may have serious side effects, for most patients it is their best chance at survival. According to Milliman, a long-established actuarial consulting firm, the five-year survival rate

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<sup>19</sup> Health Resources & Services Administration. “Donation Frequently Asked Questions.” U.S. Department of Health and Human Services, (n.d.), [bloodcell.transplant.hrsa.gov/donor/Donating/Donation\\_FAQs/index.html](http://bloodcell.transplant.hrsa.gov/donor/Donating/Donation_FAQs/index.html).

for patients who received allogenic bone marrow transplants between 2003 and 2010 was 46 percent to 50 percent.<sup>20</sup> This estimate is a recalculated composite statistic based on the survival rates for acute myelogenous leukemia, acute lymphoblastic leukemia, myelodysplasia, non-Hodgkin's lymphoma, aplastic anemia, chronic myelogenous leukemia, multiple myeloma, and Hodgkin's disease, which together made up 89 percent of the allogenic bone marrow transplants in the United States. Because five-year survival rates are typically calculated based on a specific disease, not a treatment, a five-year survival rate for patients who needed allogenic bone marrow transplants but were unable to get them is not available.

As mentioned before, there are various types of bone marrow transplants, so not all patients in need of a bone marrow transplant are dependent on an unrelated allogenic transplant. However, 25 percent of all bone marrow transplants that occurred in the United States from 2010 to 2014 were from donors who were unrelated to the patient.<sup>21</sup> When patients cannot find a suitable match on Be the Match, there are two relatively new alternatives: the first is the previously mentioned haploidentical transplant, while the second is a cord blood transplant.

A haploidentical transplant is not ideal because much stronger medications, as compared to those given to the patient if the unrelated donor is a better match, must be given to the already weakened patient in order to prevent graft-versus-host-disease. Nonetheless, this option provides patients without a match the chance at a lifesaving transplant.

In the case of cord blood transplants, the blood-forming stem cells from the placenta and umbilical cord of a newborn (or two newborns if the recipient is an adult) are taken—posing no threat to the newborn or the mother—and infused into a patient in need. These cells are more “naïve” than stem cells collected from older donors, meaning they will not attack the tissues of the recipient as readily as would stem cells from older donors. Accordingly, there is a lower probability of graft-versus-host-disease, which means the newborn donor(s) and the patient do not have to be as close a match as they would in a traditional unrelated allogenic transplant. This circumstance greatly increases the number of patients who can benefit from cord blood transplants. Cord blood transplants work for all patients in need of bone marrow transplants. However, they also involve additional risks because the restoration of blood counts for patients with cord blood transplants takes longer than it does with both bone marrow transplants and PBSC transplants.<sup>22</sup>

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<sup>20</sup> Bentley, Scott. T., & Phillips, Steven. J. “2017 U.S. Organ and Tissue Transplant Cost Estimates and Discussion.” Milliman Research Report, (n.d.), <http://www.milliman.com/uploadedFiles/insight/2017/2017-Transplant-Report.pdf>

<sup>21</sup> Health Resources & Services Administration. “Center for International Blood and Marrow Transplant Research Transplant Activity Report Covering 2010-2014.” U.S. Department of Health and Human Services, 10 March 2017.

<sup>22</sup> Seattle Cancer Care Alliance. “New Transplant Options for People Seeking a Donor Match.” (n.d.), [www.seattlecca.org/treatments/bone-marrow-transplant/mismatched-haploidentical-cord-blood](http://www.seattlecca.org/treatments/bone-marrow-transplant/mismatched-haploidentical-cord-blood).

## Bone Marrow Case Law

The National Organ Transplant Act of 1984 (NOTA) was apparently enacted to prevent poor Americans or foreigners in poor countries from selling their kidneys for a pittance.<sup>23</sup> The NOTA specified a list of organs covered but permitted regulation to extend to others:

The term “human organ” means the human (including fetal) kidney, liver, heart, lung, pancreas, bone marrow, cornea, eye, bone, and skin or any subpart thereof and any other human organ (or any subpart thereof, including that derived from a fetus) specified by the Secretary of Health and Human services by regulation.

The NOTA therefore implicitly regulated the compensation of bone marrow. Since 1984, when the NOTA was interpreted as declaring that compensating bone marrow donors was illegal, there has been plenty of activity in the legal system over whether compensation should be allowed. One of the strongest arguments is that at the time the NOTA was enacted, PBSC was not yet available as a method for collecting bone marrow for transplants. Because bone marrow harvesting was the only method for obtaining bone marrow from a donor, bone marrow donations resembled organ donations more than they did blood or plasma donations. However, in 1999 PBSC became a widely accepted transplant method, with post-transplant success rates equal to those of bone marrow harvesting. Years later, advocates of compensation began to argue that donating bone marrow through PBSC was not much different than donating blood or plasma, for both of which it was legal to compensate donors. Moreover, bone marrow transplants consist of infusing patients with blood stem cells, not the actual bone marrow, so no solid tissue is being taken from one person to another. Furthermore, a donor’s body replenishes the donated blood stem cells within four to six weeks of the donation date, unlike a solid organ which the donor’s body cannot regenerate. Using these arguments, it seemed logical to amend the NOTA or its ancillary regulations to exclude bone marrow so that compensation for bone marrow donations would be legal.<sup>24</sup>

The first notable case to bring up the issue of compensation regarding bone marrow was a constitutional challenge filed on October 26, 2009 by the Law Offices of Justin Sobodash and the Institute for Justice on behalf of several plaintiffs, including various parents of children in need of bone marrow donations; patients; doctors; and an organization with a proposed business plan for compensation. The defendant named in the court documents was Eric Holder, the Attorney General of the United States at the time. The case was filed in the U.S. District

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<sup>23</sup> Sullivan, Walter. “Buying of Kidneys of Poor Attacked.” 24 September 1983, <https://www.nytimes.com/1983/09/24/us/buying-of-kidneys-of-poor-attacked.html>

<sup>24</sup> Park, Alice. “A Court Allows Payment for Bone Marrow. Should People Be Able to Sell Their Parts?” Time, Time, 2 July 2012, [healthland.time.com/2012/07/02/a-court-allows-payment-for-bone-marrow-should-people-be-able-to-sell-their-parts/](http://healthland.time.com/2012/07/02/a-court-allows-payment-for-bone-marrow-should-people-be-able-to-sell-their-parts/).

Court for the Central District of California, which covers Los Angeles and neighboring jurisdictions.<sup>25</sup>

The plaintiffs argued that the ban against compensation for bone marrow donors was unconstitutional because it violated the Due Process Clause of the Fifth Amendment of the U.S. Constitution, which states that the federal government does not have the power to limit a person's life, liberty, or property without due process. Here "due process" describes a legal obligation on behalf of the federal government and the states to adhere to the law and to use fair procedures when applying the law to its citizens.<sup>26</sup> The plaintiffs argued that the NOTA violates due process in two ways: (1) It does not give citizens equal protection under the law. (2) It violates a citizen's right to scientifically accepted, lifesaving treatment. The plaintiffs supported their first argument by observing that the NOTA includes bone marrow but does not include other cell components found in blood. They claimed that this was an inequitable protection under the law because patients who needed other components found in blood could compensate their donors, thus gaining access to more donors, but patients in need of bone marrow could not, thereby limiting their ability to obtain the lifesaving treatments. The plaintiffs supported their second argument by saying that the doctor listed in the case had a right to engage in "safe, non-experimental, lifesaving medical treatment" and the NOTA was not allowing him or his patients to exercise that right.

The plaintiffs asked for the court to allow a proposed pilot study by MoreMarrowDonors.Org that would have entailed giving an equivalent compensation of \$3,000 to donors whose bone marrow was most needed. The compensation would not have been direct monetary compensation, but instead would have taken the form of scholarships, housing allowances, or a donation to a charity of the donor's choosing. The funds were to come from third-party philanthropists who had donated to MoreMarrowDonors.Org.

The plaintiffs added that one of the most prominent arguments against compensating donors was the fact that a market could emerge where there would be a flow of organs from the poor to the rich. However, that could not be the case for bone marrow because the required HLA specificity for bone marrow is much higher than that for kidneys and other organs. This is partly what makes finding a bone marrow donor so difficult. The high HLA specificity makes it so that there is a low probability that donors looking to make fast cash will be a match for a patient currently in need. Out of all the donors registered on Be the Match, only 1 in 40 will be called for additional testing to confirm a match and only 1 in 360 will go on to donate. Furthermore, the plaintiffs argued the previously mentioned point that unlike organ donations, bone marrow

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<sup>25</sup> (Flynn v. Holder) Doreen Flynn, John Wagner, M.D., Akiim Deshay, Mike Hamel, Mark Hashey, Kumud Majumder, and MoremarrowDonors.org vs Eric Holder (U.S. District Court Central District of California, Los Angeles October 26, 2009) (Institute for Justice, Dist. file).

<sup>26</sup> Cornell Law School. "Fifth Amendment." LII Legal Information Institute, 10 October 2017, [www.law.cornell.edu/constitution/fifth\\_amendment](http://www.law.cornell.edu/constitution/fifth_amendment).

donations do not have to occur through invasive means like surgery, further removing bone marrow donations from the initial protective intent of the NOTA.<sup>27</sup>

On December 1, 2011 the Ninth Circuit Court decided that the proposed pilot program was legal so long as the blood stem cells were retrieved through PBSC and not bone marrow harvesting. This not only allows for the proposed pilot program but expands the definition of compensation to any form of compensation so long as it occurs within the jurisdiction of the Ninth Circuit Court, which includes all of the following nine states: California, Alaska, Hawaii, Idaho, Montana, Nevada, Oregon, Washington, and some U.S. territories.<sup>28</sup>

In response to the decision by the Ninth Circuit Court, Holder decided to ask the court for an en banc review, in which all of the judges that sit on a court are asked to hear a case instead of just a select few judges. This is usually done in either very complex cases or in cases expected to set a precedent for future cases.<sup>29</sup> The Ninth Circuit Court as a whole did not grant the en banc review, so it upheld the decision made by the three-judge panel declaring that compensation was not illegal. After this decision the Supreme Court of the United States offered to hear Holder's case, but he declined to pursue the case up the judicial ladder in late June of 2012.<sup>30</sup> At the time it seemed like this was the end and that MoreMarrowDonors.org would be able to begin their registry that would allow for compensation of the rarest donors. Here rarest describes donors from minority backgrounds that are most often not on the NMDP registry.

However, in October 2013 the Department of Health and Human Services (HHS), urged by the Obama Administration and the Attorney General, proposed a new rule that would define "organ" to include bone marrow cells regardless of the form in which they were donated.<sup>31</sup>

The timing of the proposed rule lined up with the emergence of a new start-up company named Hemeos. Started by students at Georgetown Business School, the idea behind Hemeos was to directly compensate bone marrow donors in order to boost the likelihood of potential donors both registering to be donors and following through with their donation. This business plan was different from that of MoreMarrowDonors.Org because Hemeos was designed to directly compensate donors with monetary payment, not just alternative forms of compensation. Had the regulation proposed by the Department of Health and Human Services been enacted, Hemeos' business would have been rendered illegal. In an interview with me, Doug Grant, the co-founder of Hemeos, claimed that the proposed change in the definition of

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<sup>27</sup> Institute for Justice. "Cancer Patients Win Bone Marrow Legal Fight Against U.S. Attorney General." 1 December 2011, [ij.org/press-release/bone-marrow-release-12-1-2011/](http://ij.org/press-release/bone-marrow-release-12-1-2011/).

<sup>28</sup> Kramer, John. "Cancer Patients Win Bone Marrow Legal Fight Against U.S. Attorney General." Institute for Justice, 1 December 2012, [ij.org/press-release/bone-marrow-release-12-1-2011/](http://ij.org/press-release/bone-marrow-release-12-1-2011/).

<sup>29</sup> Rottenstein Law Group LLP. "What Does 'En Banc' Mean?" (n.d.), [www.rotlaw.com/legal-library/what-does-en-banc-mean/](http://www.rotlaw.com/legal-library/what-does-en-banc-mean/).

<sup>30</sup> Kramer, John. "Final Victory for Cancer Patients in Bone Marrow Donor Case." Institute for Justice, 25 June 2012, [ij.org/press-release/bone-marrow-release-6-25-2012/](http://ij.org/press-release/bone-marrow-release-6-25-2012/).

<sup>31</sup> Bailey, Ronald. "Trump Administration Withdraws Proposed Ban on Compensation for Bone Marrow." Reasons.com, Reason Magazine, 7 August 2017, [reason.com/blog/2017/08/07/trump-administration-withdraws-proposed](http://reason.com/blog/2017/08/07/trump-administration-withdraws-proposed).

“organ” came at the urging of Be the Match in response to Hemeos picking up steam. At the time, Hemeos’ software was already being used at a couple of hospitals, which threatened Be the Match’s monopoly over the bone marrow market.<sup>32</sup> The department opened the proposed rule to public comment until December 2013. The proposal to redefine organ occurred right when the first research regarding compensation was about to be published, halting the research. This rule was not decided upon until late 2016, when HHS approved the change in the definition of “organ” and passed the rule on to the Office of Budget and Management. The Office of Budget and Management never approved the rule, meaning that the final rule by the Ninth Circuit Court held and the new HHS definition was not valid. Nonetheless, would-be givers and recipients of compensation were reluctant to act in the absence of clear guidance. The legal limbo continued until August of 2017, when the Trump Administration chose to officially rescind the rule, thus effectively confirming the legality of compensation.<sup>33</sup>

The Trump Administration provided no statement offering a rationale for its action. President Trump and other members of the administration had stressed their interest in reducing regulations, so possibly the bone marrow regulation was an application of that policy. The idea of removing the regulation was proposed by at least one federal employee, Kurt Schuler, in May 2017, in response to a Trump Administration solicitation the previous month for reform suggestions by federal employees and by the public.<sup>34</sup>

Another reason the bone marrow component of the NOTA has been controversial is that the NOTA is a federal law, so it may not apply to instances where the donor and the recipient are within the same state, in which case state law would take precedence. Twelve states (Colorado, Delaware, Georgia, Illinois, Indiana, Michigan, New York, Tennessee, Texas, Virginia, West Virginia, and Wisconsin) have legislation that does not allow the compensation of bone marrow donations through PBSC. The only state that limits the compensation of bone marrow donation, as well as cord blood donation, is Delaware.<sup>35</sup>

## Today’s Reality

Although compensation for bone marrow is no longer regulated by the federal government, there are many obstacles it must overcome before it becomes commonplace. Citizens who live

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<sup>32</sup> HHS/HRSA, Definition of Human Organ Under Section 301 of the National Organ Transplant Act of 1984, Office of Information and Regulatory Affairs (Update 2017).

<sup>33</sup> Kramer, John. “In Victory for Cancer Patients & Their Families, HHS Withdraws Controversial Rule That Would Have Banned Compensating Bone Marrow Donors.” Institute for Justice, 7 August 2017, [ij.org/press-release/victory-cancer-patients-families-hhs-withdraws-controversial-rule-banned-compensating-bone-marrow-donors/](https://www.ij.org/press-release/victory-cancer-patients-families-hhs-withdraws-controversial-rule-banned-compensating-bone-marrow-donors/).

<sup>34</sup> Personal communication from Kurt Schuler. The Office of Management and Budget requested the public’s ideas on government reform on April 12, 2017 here: <https://www.whitehouse.gov/briefings-statements/president-trump-creating-efficient-effective-accountable-federal-government/>. Federal agencies also sent e-mails to their employees requesting ideas.

<sup>35</sup> Williams, Kristy. “The Hidden Economy of HSC Transplantation Is Inconsistent with Prohibiting the Compensation of HSC Donors.” *Minnesota Journal of Law, Science & Technology*, vol. 16, no.1, ser. 6, 2015, pp. 243-245.6, [scholarship.law.umn.edu/cgi/viewcontent.cgi?article=1353&context=mjlst](http://scholarship.law.umn.edu/cgi/viewcontent.cgi?article=1353&context=mjlst).

in states that ban it may not be able to participate in either end of compensation. This is due to grey areas between the laws of the state governments and the Commerce Clause of the U.S. Constitution. For example, a patient living in a state that bans compensation may not be able to receive bone marrow from a donor who was compensated, even if the donor lives in a state where compensation is allowed, because it breaches the law of the state in which the patient lives. However, this exchange constitutes interstate commerce since the donor and the patient are not in the same state. These types of legal uncertainties often result in cases being heard before the Supreme Court to determine precedents for similar scenarios in the future.<sup>36</sup>

Then there are the practical difficulties. At the moment, no compensatory bone marrow registries exist. According to Doug Grant of Hemeos, the main reason for that is that the NMDP opposes the compensation of bone marrow. Both MoreMarrowDonors.Org and Hemeos, despite having had different business plans in the way they were planning on going about compensating donors, were forced to close because of procedures indirectly imposed on them by Be the Match. Grant told me in an interview that he closed Hemeos in February 2017 because as a startup, the fight against regulation was too much for Hemeos to overcome. By the time that compensation became unquestionably legal, the startup had run out of capital. For compensation to become a reality, there must be registries that are willing to compensate. Because the NMDP so strongly opposes compensation, the experts I talked to agreed that the only option for a compensatory bone marrow registry to exist is for it to be a competitive, parallel registry to that of Be the Match.

This presents other logistical difficulties because currently Be the Match is the registry that most, if not all, physicians use when looking for a match for their patient. For a new registry to compete with Be the Match, not only would it, like Hemeos, have to develop its own software to provide transplant centers with, but it would also need to make connections with individual hospitals so that they begin to search the registry. Growing a registry to fully compete with Be the Match's could take years given that there is no centralized process by which hospitals partner with bone marrow registries. Each hospital would have to make an individual partnership with the compensatory registry. Furthermore, there is currently little incentive for entrepreneurs to tackle this seemingly daunting startup possibility since the entire bone marrow market accounts for only \$3 million to \$4 million a year.

In Grant's opinion, the only way for his vision to become a reality would be for a large medical center such as Johns Hopkins Medicine or Medstar at Georgetown University to undertake the project. It would have to take it upon itself to create the necessary software and partner with other similarly large centers. With the medical knowledge and household name that these centers could bring to the table, their registry could stand a chance against the power that Be the Match currently possesses.

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<sup>36</sup> Monk, Linda R. "State Powers." *PBS*, Public Broadcasting Service, (n.d.), [www.pbs.org/tpt/constitution-usa-peter-sagal/federalism/state-powers/](http://www.pbs.org/tpt/constitution-usa-peter-sagal/federalism/state-powers/).

Lastly, as previously mentioned, 47 percent of the matches made by Be the Match include either a foreign donor or recipient. Compensation poses a problem in those cases because many of the cooperative registries that partner with Be the Match are national registries of countries where compensation is not legal. By making compensation legal in the United States, some of these partnerships could be strained, potentially leading to a significant loss of international matches. All of these are barriers that would need to be somehow overcome in order for compensation not only to be realistic but also for it to accomplish its goal of helping to relieve the scarcity of bone marrow matches.

### **Evidence That Compensation Increases Donation**

Various research initiatives have shown that for bone marrow donation through PBSC, because it is less complicated and intrusive than donating solid organs, small amounts of compensation can have a positive effect on the number of individuals willing to donate. For example, a working paper by three economists written for the National Bureau of Economic Research in August 2012 found that compensating bone marrow donors for their time and leave from work would have a positive effect on the number of donations.<sup>37</sup>

The same authors had an article published in *Science* in 2013 that presented evidence of various studies that had taken place regarding the effect of compensation for blood donations on the amount of donations as well as the quality (health conditions of those that donated) of the donations. Although the article states that much of the evidence collected up until that point was not very reliable, it did mention that out of 19 incentive programs (none offered cash since that was not allowed at the time) that were looked at, 18 were successful in raising the number of blood donations. In programs that the study reviewed, forms of compensation were highly varied, ranging from T-shirts to a day of paid leave from work. When making an analogy between these findings and what it could imply for bone marrow, it is important to note that the incentives were offered for showing up to donate, not for actually donating; this is thought to be the major reason why the quality of blood samples was not negatively affected. However, this model may not be seamlessly applicable to bone marrow donations. The strategy may increase the number of people that register to be potential donors, but it may not do anything to assure that if they are called to donate they would go through with the donation.<sup>38</sup>

Moreover, it is a known fact that platelet donations have been increased by simply giving donors \$5-\$15 gift cards. Because bone marrow donations through PBSC use the same procedure as platelet donations, it is reasonable to expect that the same level of compensation would have similar effects on bone marrow donations.

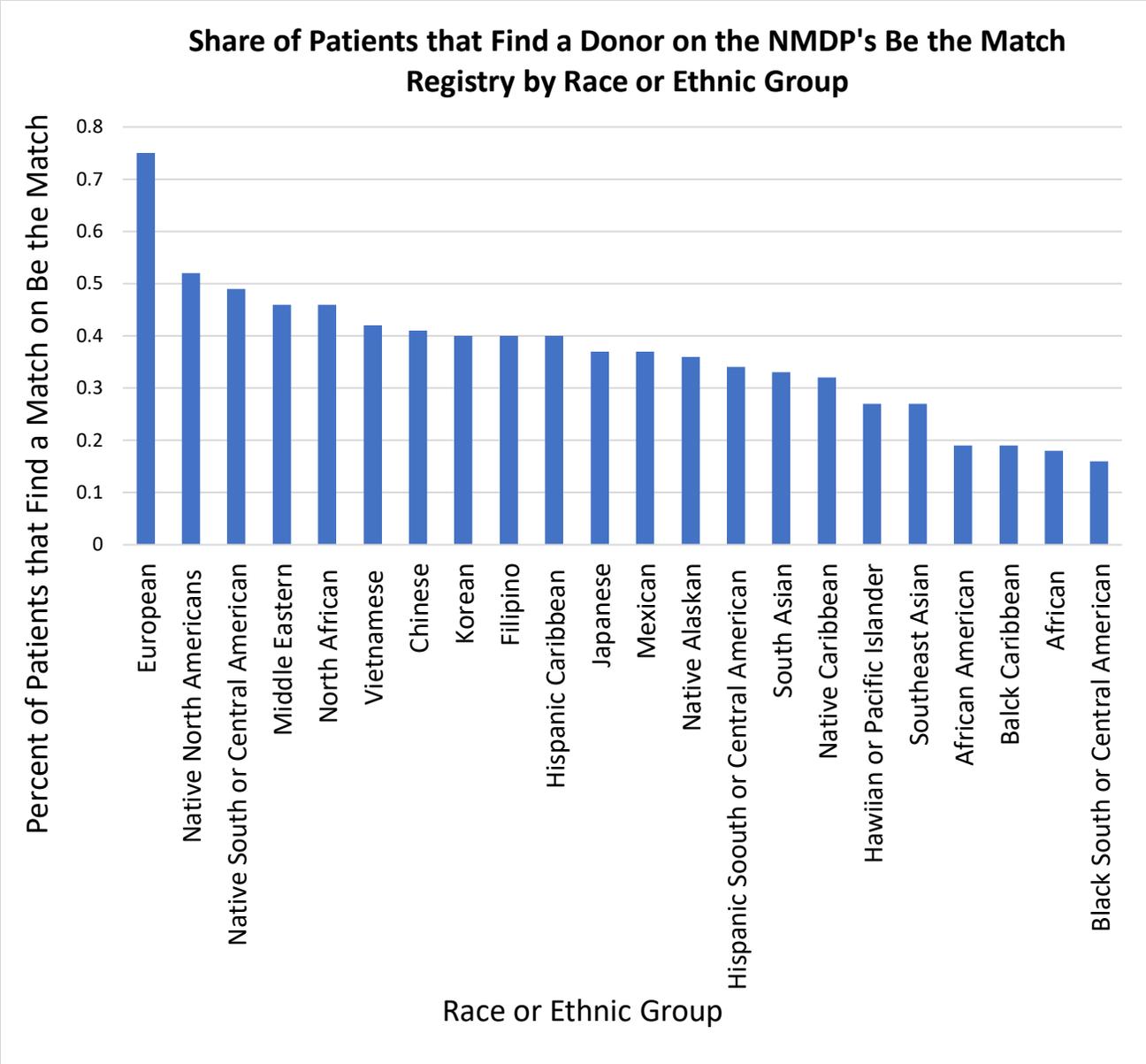
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<sup>37</sup> Lacetera, Nicola, et al. "Removing Financial Barriers to Organ and Bone Marrow Donation: The Effect of Leave and Tax Legislation in the U.S." NBER Working Paper Series, vol. 18299, August 2012, [www.nber.org/papers/w18299.pdf](http://www.nber.org/papers/w18299.pdf).

<sup>38</sup> Lacetera, Nicola., et al. "Economic Rewards to Motivate Blood Donations." *Science*, vol. 340, no. 6135, 2013, pp. 927-928., doi:10.1126/science.1232280.

## **Statistics on Bone Marrow Shortages**

Statistics regarding the availability of bone marrow donations make it clear that increasing the number of people who register to be potential donors and who go through with their donation is crucial. Seventy percent of patients in need of a bone marrow transplant from someone other than themselves do not have a match within their family. Only 30 percent of patients have family members who are good enough matches for a bone marrow transplant.



The graph shows the current share of matches by race and ethnicity. These shares are smaller for mixed-race patients. This is one of the primary reasons why some of the biggest registries that work with the Be the Match registry, such as the Gift of Life and Asian American Donor Program, are of a specific cultural or ethnic origin. Many of these types of registries were started as grass-roots efforts to improve recruitment within communities that have large populations of these minorities.<sup>39</sup>

<sup>39</sup> Kaster, Elizabeth C. et al. "Getting to the Heart of Being the Match: A Qualitative Analysis of Bone Marrow Donor Recruitment and Retention Among College Students." *Health Educator: Journal of Eta Sigma Gamma* 46.1 (2014): 14–19. Print.

Given these data, it is evident that the Be the Match Registry needs to become more diverse to best serve the bone marrow diversity present in American society today. One of the biggest arguments given in support of compensation is that the many patients of minority racial or ethnic descent need others of the same origin to register with Be the Match and to be willing to donate. Oftentimes, these minorities would also significantly benefit from small non-monetary forms of compensation proposed by MoreMarrowDonors.Org, such as scholarships or housing allowances. For these reasons, it is expected that if compensation were to be made commonplace, many of the shares presented above could be significantly increased and the lives of more patients in those groups could be saved.

## **Ethical Issues**

Registries that aim to compensate bone marrow donors will also face ethical issues. Various ethical arguments that have been made against compensation for bone marrow. These include that compensation lessens the altruistic nature of the donation since people may be inclined to donate not to save the life of a dying patient but in order to be paid or compensated; that it implies that the human body is a commodity that can be bought and sold, which in turn lessens the value of a life; that it would put those of lower socioeconomic status in greater danger of being taken advantage of; and that compensating donors from other countries could present an issue of informed consent.<sup>40</sup>

Regarding the argument that compensating bone marrow donors would detract the altruistic nature of the action, some critics of bone marrow compensation argue that compensation could lead to a decrease in the population of bone marrow donors.<sup>41</sup> They argue that by compensating the donation, the donation would no longer be an altruistic action, and therefore those who donate their bone marrow because it is a “good deed” might cease to do so. This, according to those that argue this position, would decrease the number of donors on Be the Match, thus aggravating the shortage of bone marrow. Supporters of compensation reply that the current altruistic-only model of bone marrow donations does not provide a large enough donor pool for all of those looking for donors. Supporters of compensation argue the current altruistic model will never allow for a registry that large, since currently only about 2 percent of the U.S. population is registered as prospective bone marrow donors.

The argument that compensating for bone marrow donations devalues human life is in practice rooted in religious beliefs, especially from Roman Catholic beliefs, although it is also possible to make a purely secular argument to the same effect. Many people, including those at Be the Match, believe that paying up to \$3,000 for lifesaving cells would lead to a commodification of life. Supporters of compensation point to all the other forms of legal and acceptable

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<sup>40</sup> London, Brian. “Should Bone Marrow Donors Be Paid to Save Lives? An Assessment of the Legal Ban on Donor Compensation and Other Obstacles Facing Domestic and International Bone Marrow Registries.” Temple University, 2017, [sites.temple.edu/ticlj/files/2017/02/24.2.London-TICLJ.pdf](https://sites.temple.edu/ticlj/files/2017/02/24.2.London-TICLJ.pdf).

<sup>41</sup> Hammond, Samuel. “Bone Marrow Mismatch: How Compensating Bone Marrow Donors Can End the Transplant Shortage and Save Lives.” Niskanen Center, 2016, <https://niskanencenter.org/wp-content/uploads/2016/11/Bone-Marrow-Mismatch-1.pdf>.

compensation of bodily parts: eggs, sperm, hair, and uterus, in the case of surrogate mothers. Furthermore, Samuel Hammond of the Niskanen Center argues that allowing the compensation of participants in a clinical trial that may very well lead to life-saving discoveries is another form of compensating bodily parts. Because compensation for these body parts has yet to lead to an obvious devaluing of human life, it is unrealistic to assume that compensating bone marrow donations would be different.<sup>42</sup>

With regard to exploitation, opponents of compensation argue that allowing it would lead to a system where poor people would subject themselves to potentially dangerous procedures just to meet their basic needs. Supporters of compensation counterargue that this thought process is flawed in the case of bone marrow for two main reasons. (1) Preventing people of lower socioeconomic status from earning income in any way they can perpetuates their existing circumstances. (2) Bone marrow donors are not compensated immediately upon registering; thus current need would not increase the probability of registration or of receiving compensation. Supporters of compensation further argue in fact, that people of lower socioeconomic status may not be as willing to donate as critics think, because of the costs that donating may impose on them. Oftentimes, individuals with lower socioeconomic status have jobs paid by the hour that are less flexible than salaried jobs when it comes to taking paid time off from work. By compensating these donors for their time, the cost of loss of wages would no longer be a potential reason for which they would be prevented from donating. Furthermore, because there is a significant lag time between when a potential donor actually registers to be a donor and the time they may be called to donate, those looking for a guaranteed way of making quick capital could not turn to bone marrow donation.

### **Cost-Benefit Analysis**

It is important to look at the value added of finding a patient's ideal match and from the patient being able to have a bone marrow transplant, comparing it to the case of a patient who is not able to have a bone marrow transplant (potentially because she could not find an adequate match on Be the Match). Most patients (about 58 percent) who need a bone marrow transplant undergo autologous transplants, therefore they do not need a donor since the cells come from themselves. In 2017, 12,160 patients underwent autologous bone marrow transplants.

Patients who cannot use their own cells for the bone marrow transplants then look to family for a match. If no one in the patient's family is a match, the most common option is to look for an ideal match on Be the Match. Unfortunately, not all patients can find ideal matches there. In 2017, 9,284 patients underwent allogenic bone marrow transplants. However, it is reported that more than 3,000 died because they could not find a suitable match on the registry.<sup>43</sup>

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<sup>42</sup> Hammond, Samuel. "Bone Marrow Mismatch: How Compensating Bone Marrow Donors Can End the Transplant Shortage and Save Lives." Niskanen Center, 2016, <https://niskanencenter.org/wp-content/uploads/2016/11/Bone-Marrow-Mismatch-1.pdf>.

<sup>43</sup> Institute for Justice. "Bone Marrow Statistics." (n.d.), [ij.org/bonemarrowstatistics/](http://ij.org/bonemarrowstatistics/).

For patients who cannot find a donor on Be the Match, their remaining options are to undergo either a transplant from cord blood or a haploidentical transplant. As previously discussed, the benefit of both of these types of transplants is that the HLA match does not have to be as exact, thereby significantly increasing the chances of the patient finding a donor. However, patients who use either of these methods are at higher risk for bad outcomes than patients who find ideal matches. The biggest risk is that the patient may not take the transplant well, in which case the body can develop serious graft-versus host disease, which may be fatal.

According to the Milliman report mentioned earlier, the estimated total cost for an allogenic bone marrow transplant in 2017 was \$892,700. This figure includes pre-procedure hospital stay and medication, the procedure itself, and post-procedure follow-up medication. Given the large cost of an allogenic bone marrow transplant, the amount of \$2,000-\$3,000 that has been suggested for donor compensation is insignificant, especially if it is able to save the lives of around 3,000 Americans. Given that economists have agreed that the monetary value of the average human life varies between \$9 million and \$10 million, saving 3,000 lives a year could bring societal benefits of nearly \$21 billion.<sup>44</sup> This number was determined by valuing a human life at \$9 million, the lower end of the bracket, and assuming that compensation would occur at \$3,000, the higher end of the estimated amount.

A patient who receives bone marrow from an ideal donor – one who is a very close match for her – is much more likely to avoid complications after the transplant. In terms of cost savings this is important because hospital stays, and medications associated with host-versus-graft disease can be costly. Furthermore, patients in need of bone marrow transplants who are unable to find suitable matches and have no other alternatives are left to depend on hospice care, which can cost up to \$10,000 a month.<sup>45</sup> When analyzing this cost as compared to that of a bone marrow transplant plus compensation for the donor, it would be important to know the average life expectancy for patients who cannot find a match, but this does not exist because bone marrow transplantation treats a variety of diseases with varying life expectancies.<sup>46</sup>

## Conclusions

Compensation for bone marrow donations has been a controversial topic for some time now due to its complexity. For thousands of people every year, a bone marrow transplant from an unknown donor represents their only chance for survival. In these cases, patients and their families are desperate to do anything to find a match within the limited time the patient has left. The national bone marrow registry, Be the Match, is unable to find ideal matches for all patients in need. The success rate varies by race and ethnicity: while white patients will find

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<sup>44</sup> Merrill, Dave. "No One Values Your Life More Than the Federal Government." 19 October 2017, <https://www.bloomberg.com/graphics/2017-value-of-life/>.

<sup>45</sup> Andrews, Michelle. "Hospices, Wary of Costs, May Be Discouraging Patients with High Expenses." Kaiser Health News, 21 January 2013, <https://khn.org/news/012212-michelle-andrews-on-hospice-care>.

<sup>46</sup> Nichols, Hannah. "Bone Marrow: Function, Disease, Transplants, and Donation." 15 December 2017, <https://www.medicalnewstoday.com/articles/285666.php>.

their ideal match on the registry about 75 percent of the time, for black patients, who have the lowest match rate, the rate is under 20 percent.

Supporters of compensating bone marrow donors contend that paying about \$3,000 in vouchers to be used for scholarships, housing, or other expenses would drastically decrease the number of patients waiting for a bone marrow transplant. However, significant research has not been done to prove this claim because up until August of 2017 compensating bone marrow donors was either illegal or had not been clearly determined to be legal.

The legal status of bone marrow donations has not always been clear. The reason the compensation of bone marrow donations was regulated in the first place was because of the National Organ Transplant Act. It states that human organs cannot be bought or sold. Although it did not explicitly include bone marrow in its definition of an organ, the law was interpreted as covering bone marrow, in large part because of the way bone marrow was retrieved when the NOTA was written. However, bone marrow donation has changed since 1984. Today, 70 percent of retrievals occur through the same process as blood platelet retrieval, which it is legal to compensate donors for. Because of this, families of patients in need chose to pursue a case in the U.S. District Court for the Central District of California to ask that bone marrow not be included in the NOTA. After years of legislative back and forth, the District Court ruled that organs as referred to in the NOTA should not include bone marrow. However, shortly thereafter, the Department of Health and Human Services redefined organs to include bone marrow, thereby halting experiments in the field of compensation. Nonetheless, the Office of Management and Budget never approved the rule, so the District Court ruling stayed in place. The ambiguity surrounding this issue was finally laid to rest when in August 2017 the Trump Administration officially deregulated the compensation of bone marrow.<sup>47</sup>

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<sup>47</sup> "Definition of Human Organ Under Section 301 of the National Organ Transplant Act of 1984." (n.d.), <https://www.reginfo.gov/public/do/eAgendaViewRule?pubId=201704&RIN=0906-AB02>.

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