

**FOR PUBLICATION**  
**UNITED STATES COURT OF APPEALS**  
**FOR THE NINTH CIRCUIT**

DOREEN FLYNN; AKIIM DESHAY;  
MIKE HAMEL; MARK HACHEY;  
KUMUD MAJUMDER;  
MOREMARROWDONORS.ORG; JOHN  
WAGNER, M.D.,

*Plaintiffs-Appellants,*

v.

ERIC HOLDER Jr., Attorney General  
of the United States, sued in his  
Official Capacity,

*Defendant-Appellee.*

No. 10-55643

D.C. No.  
2:09-cv-07772-  
VBF-AJW

OPINION

Appeal from the United States District Court  
for the Central District of California  
Valerie Baker Fairbank, District Judge, Presiding

Argued and Submitted  
February 15, 2011—Pasadena, California

Filed December 1, 2011

Before: Alfred T. Goodwin, Andrew J. Kleinfeld, and  
Susan P. Graber, Circuit Judges.

Opinion by Judge Kleinfeld

**COUNSEL**

Jeff Rowes, Institute for Justice, Arlington, Virginia, for the appellants.

Helen L. Gilbert, U.S. Department of Justice, Washington, D.C., for the appellee.

Aneal R. Ganta, Gibson, Dunn & Crutcher LLP, Irvine, California, for the amici curiae.

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**OPINION**

KLEINFELD, Senior Circuit Judge:

This is a challenge to a criminal statute prohibiting compensation for “bone marrow” donations.<sup>1</sup>

**I. Facts.**

The district court dismissed the complaint for failure to state a claim upon which relief could be granted.<sup>2</sup> We take the

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<sup>1</sup>42 U.S.C. § 274e.

<sup>2</sup>Fed. R. Civ. P. 12(b)(6).

facts from the allegations in the complaint to determine whether, if proved, they would state an actionable claim.<sup>3</sup>

The complaint challenges the constitutionality of the ban on compensation for human organs in the National Organ Transplant Act, as applied to bone marrow transplants.<sup>4</sup> Plaintiffs seek declaratory and injunctive relief to allow harvesting of “hematopoietic stem cells.” The complaint is not crystal clear on whether plaintiffs claim that compensation for all bone marrow transplantation is constitutionally protected, but the focus of the arguments is on cells extracted by “peripheral blood stem cell apheresis.” This is a relatively new method of bone marrow transplant that avoids the need to invade the bone for marrow.

Some plaintiffs are parents of sick children who have diseases such as leukemia and a rare type of anemia, which can be fatal without bone marrow transplants. Another plaintiff is a physician and medical school professor, and an expert in bone marrow transplantation. He says that at least one out of five of his patients dies because no matching bone marrow donor can be found, and many others have complications when scarcity of matching donors compels him to use imperfectly matched donors. One plaintiff is a parent of mixed race children, for whom sufficiently matched donors are especially scarce, because mixed race persons typically have the rarest marrow cell types. One plaintiff is an African-American man suffering from leukemia who received a bone marrow transplant from his sister. She was an imperfect match and, though the transplant saved his life, he continues to suffer from life-threatening and disabling complications on account of the slight genetic mismatch.

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<sup>3</sup>*Newcal Indus., Inc. v. Ikon Office Solution*, 513 F.3d 1038, 1043 n.2 (9th Cir. 2008).

<sup>4</sup>42 U.S.C. § 274e.

Another plaintiff is a California nonprofit corporation that seeks to operate a program incentivizing bone marrow donations. The corporation proposes to offer \$3,000 awards in the form of scholarships, housing allowances, or gifts to charities selected by donors, initially to minority and mixed race donors of bone marrow cells, who are likely to have the rarest marrow cell type. The corporation, MoreMarrowDonors.org, alleges that it cannot launch this program because the National Organ Transplant Act criminalizes payment of compensation for organs, and classifies bone marrow as an organ.<sup>5</sup>

We generally use the word “marrow” to refer to the soft, fatty material in the central cavities of big bones, what some people suck out of beef bones. Bone marrow is the body’s blood manufacturing factory. Bone marrow transplants enable sick patients, whose own blood cells need to be killed to save their lives, to produce new blood cells. For example, patients with leukemia, which is cancer of the blood or bone marrow, may need chemotherapy or radiation to kill the cancer cells in their blood. The treatments kill the white blood cells essential to their immune systems. The patients will die if the killed cells are not quickly replaced with healthy cells. And they cannot be replaced without the stem cells, which we describe below, that can mature into white blood cells. These stem cells can only be obtained through bone marrow transplants.

Until about twenty years ago, bone marrow was extracted from donors’ bones by “aspiration.” Long needles, thick enough to suck out the soft, fatty marrow, were inserted into the cavities of the anesthetized donor’s hip bones. These are large bones with big central cavities full of marrow. Aspiration is a painful, unpleasant procedure for the donor. It requires hospitalization and general or local anesthesia, and involves commensurate risks.

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<sup>5</sup>*Id.*

The complaint explains that a new technology has superseded this technique during the last twenty years, after enactment of the National Organ Transplant Act. With this new technique, now used for at least two-thirds of bone marrow transplants, none of the soft, fatty marrow is actually donated. Patients who need bone marrow transplants do not need everything that the soft, fatty substance from bone cavities contains, just some of the marrow's "hematopoietic stem cells." These stem cells are seeds from which white blood cells, red blood cells, and platelets grow.

These are not the embryonic stem cells often the subject of controversy. Those stem cells, taken from human embryos, are "pluripotent," that is, they can turn into any kind of cell — brain, blood, retina, toenail, whatever.<sup>6</sup> The stem cells at issue in this case are "hematopoietic stem cells." "Hema" refers to blood, and "poietic" means "pertaining to production."<sup>7</sup> Hematopoietic stem cells turn into blood cells and nothing else. Humans and other large mammals produce these blood stem cells constantly in vast numbers, because our blood cells die within a few months and need continual replacement.<sup>8</sup> The dead blood cells are flushed out in the spleen, the body's garbage disposal for used-up blood cells,<sup>9</sup> and new ones are made in the bone marrow, as long as we live.

Most blood stem cells stay in the bone marrow cavity and grow into mature blood cells there, before passing into the blood vessels. But some blood stem cells flow into and circulate in the bloodstream before they mature. These are called "peripheral" blood stem cells, "peripheral" meaning outside the central area of the body.<sup>10</sup> The new bone marrow donation

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<sup>6</sup>*Taber's Cyclopedic Medical Dictionary* 1809 (21st ed. 2009).

<sup>7</sup>*Id.* at 1033, 1819.

<sup>8</sup>*See id.* at 284.

<sup>9</sup>*See id.* at 2177.

<sup>10</sup>*Id.* at 1752.

technique, developed during the past twenty years, is called “peripheral blood stem cell apheresis.” “Apheresis” means the removal or separation of something.<sup>11</sup> This procedure begins with five days of injections of a medication called a “granulocyte colony-stimulating factor” into the donor’s blood. The medication accelerates blood stem cell production in the marrow, so that more stem cells go into the bloodstream. Then, with no need for sedatives or anesthesia, a needle is inserted into the donor’s vein. Blood is withdrawn from the vein and filtered through an apheresis machine to extract the blood stem cells. The remaining components of the blood are returned to the donor’s vein. The blood stem cells extracted in the apheresis method are replaced by the donor’s bone marrow in three to six weeks. Complications for the donor are exceedingly rare.

The main difference between an ordinary blood donation and apheresis is that instead of just filling up a plastic bag with whole blood, the donor sits for some hours in a recliner while the blood passes through the apheresis machine. This same apheresis technique is sometimes used for purposes other than bone marrow donations, such as when the machine is set up to collect plasma or platelets, rather than stem cells, from a donor’s blood. When it is used for these other purposes, the identical technique is called a “blood donation” or “blood plasma donation.” When used to separate out and collect hematopoietic stem cells from the donor’s bloodstream, apheresis is called “peripheral blood stem cell apheresis” or a “bone marrow donation.”

Though the new process makes bone marrow donations much like ordinary blood donations, the matching problem remains. Deep genetic compatibility is critical in bone marrow transplants, because our bodies are xenophobic: white blood cells produced from a donor’s imperfectly matched blood stem cells treat the recipient patient’s body as foreign,

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<sup>11</sup>*Id.* at 161.

attacking it. This is graft-versus-host disease, which can be fatal or can result in lifelong medical problems for the transplant recipient. All donations from another person, except for one's identical twin, produce at least some graft-versus-host disease in the recipient, but the closer the genetic match, the less disease. Matching is easy in ordinary blood transfusions, because there are only four basic blood types. But there are millions of marrow cell types, so good matches are hard to find. The more diverse the patient's genetic heritage, the rarer the match. For example, African-Americans have especially great difficulty finding a compatible unrelated donor, as they tend to have a mix of African, Caucasian, and Native-American genes, and fewer potential donors are registered in the national civilian registry.

The establishment of this registry, the National Marrow Donor Program, which is funded by the federal government to assist in finding matches, was an important part of the statute at issue here.<sup>12</sup> But even with this registry, good matches often cannot be found. And even when a good match is found in the registry, tracking down the potential donor from what may be an outdated address may be impossible to accomplish in time to save the patient's life—assuming the potential donor is willing to go through with the process when found.

The plaintiff nonprofit proposes to mitigate this matching problem by using a financial incentive. The idea is that the financial incentive will induce more potential donors to sign up, stay in touch so that they can be located when necessary, and go through with the donations. The nonprofit plans to focus its attention initially on minority and mixed race donors, because their marrow cell types are rarer. The financial incentives would be \$3,000 in scholarships, housing allowances, or gifts to charities of the donor's choice, which the nonprofit

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<sup>12</sup>See 42 U.S.C. § 274k.

acknowledges would be “valuable consideration” under the statutory prohibition.<sup>13</sup>

Plaintiffs argue that the National Organ Transplant Act, as applied to MoreMarrowDonor.org’s planned pilot program, violates the Equal Protection Clause. They claim that blood stem cell harvesting is not materially different from blood, sperm, and egg harvesting, which are not included under the statutory or regulatory definitions of “human organ.”<sup>14</sup> Like donors of blood and sperm, a bone marrow donor undergoing apheresis suffers no permanent harm, experiences no significant risk, and quickly regenerates what is donated. Plaintiffs also argue that any rational basis that Congress had when it passed the statute no longer exists with respect to the pilot program, because of the subsequent development of the apheresis method. Plaintiffs seek declaratory and injunctive relief so that MoreMarrowDonors.org can proceed with the initiative.

## II. Analysis.

We review a 12(b)(6) dismissal de novo.<sup>15</sup>

### A. The arguments.

The core of plaintiffs’ argument is that there is no rational basis for allowing compensation for blood, sperm, and egg donations, while disallowing compensation for bone marrow donations, because bone marrow donations can now be accomplished through apheresis without removing marrow, and the donor’s body quickly regenerates the donated stem cells. Since the distinction, they argue, is without a rational

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<sup>13</sup>42 U.S.C. § 274e(a).

<sup>14</sup>See 42 U.S.C. § 274e(c)(1); 42 C.F.R. § 121.13 (2010).

<sup>15</sup>Fed. R. Civ. P. 12(b)(6). *Barker v. Riverside Cnty. Office of Educ.*, 584 F.3d 821, 824 (9th Cir. 2009).



basis, it violates the Equal Protection Clause, despite highly deferential “rational basis” review.<sup>16</sup>

[1] The Attorney General responds that the statute plainly classifies “bone marrow” as an organ for which compensation is prohibited, and that the congressional determination is indeed rational. The statute makes it a felony “to knowingly acquire, receive, or otherwise transfer any human organ for valuable consideration for use in human transplantation.”<sup>17</sup> And it defines the term “human organ” to include “bone marrow.”<sup>18</sup> Ergo, the statute expressly prohibits compensating bone marrow donors. According to the government’s brief, Congress took the view that “human body parts should not be viewed as commodities,”<sup>19</sup> and had several policy reasons for disallowing compensation to donors, which suffice to serve as a rational basis for the prohibition.

[2] As for plaintiffs’ argument that there is no rational basis for a distinction between peripheral blood stem cell apheresis and blood donations, the government argues that because it is much harder to find a match for patients who need bone marrow transplants than for patients who need blood transfusions, exploitative market forces could be triggered if bone marrow could be bought. The government also asserts that peripheral blood stem cell apheresis poses greater health risks for the donor than blood donations do, because of the side effects of the medicine used to increase stem cell secretion. The government bases this factual assertion on information taken not from the complaint, which says that

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<sup>16</sup>See *Kahawaiolaa v. Norton*, 386 F.3d 1271, 1277-78 (9th Cir. 2004).

<sup>17</sup>42 U.S.C. § 274e(a).

<sup>18</sup>“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.” *Id.* § 274e(c)(1).

<sup>19</sup>Citing S. Rep. No. 98-382, at 17 (1984).

there is no significant risk, but from a patient handout called “Now That You Are a Match,” published by the National Marrow Donor Program.<sup>20</sup> Since the case was dismissed on a 12(b)(6) motion, the complaint controls.<sup>21</sup> If material allegations of fact are mistaken, summary judgment or trial can so establish. We do not imply that patient risk is material to what the statute means and whether the distinctions it draws are constitutionally permissible. There are significant risks from egg donations,<sup>22</sup> but the government concedes that the statute allows them. The statute does not prohibit trials of new medicines, which often involve risks and create discomfort or worse for participants. Other provisions of law and medical ethics may address these concerns, but the statute before us does not.

### **B. Bone marrow transplants by aspiration.**

[3] Plaintiffs address their arguments largely to the peripheral blood stem cell apheresis method of extracting hematopoietic stem cells, but their complaint appears to challenge the prohibition on bone marrow transplants regardless of method. They do not, in their complaint or their brief, confine their challenge to transplants by means of apheresis. They apparently propose to give compensated donors the choice between aspiration and apheresis. To the extent that plaintiffs challenge the constitutionality of the compensation ban on bone marrow donation by the old aspiration method — where a long needle is inserted into the cavity of the hip bone to extract the soft, fatty marrow — the challenge must fail.

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<sup>20</sup>National Marrow Donor Program, *Now That You Are a Match: What You Need To Know About Becoming a Donor* (2006).

<sup>21</sup>*Maktab Tarighe Oveyssi Shah Maghsoudi, Inc. v. Kianfar*, 179 F.3d 1244, 1246 (9th Cir. 1999).

<sup>22</sup>See Kara N. Maxwell et al., *The Incidence of Both Serious and Minor Complications in Young Women Undergoing Oocyte Donation*, 90 *Fertility and Sterility* 2031, 2165 (2008).

[4] The statute says that the term “human organ” includes “bone marrow.”<sup>23</sup> The soft, fatty stuff that the needle extracts is bone marrow. It is irrelevant that the legislative history indicates that Congress viewed certain types of regenerable tissue, such as blood, as falling outside the statutory definition of “human organ.”<sup>24</sup> It may be that senators themselves, their staffs, or lobbyists for blood banks argued for an exception for body substances that can regenerate, and persuaded committee staffers to put that reason in the legislative history. But the statute does not say that compensation is permitted for organs or body parts that regenerate and prohibited for those that do not. Nor is the statute consistent with such a construction. The statute defines the liver “or any subpart thereof” as an organ for which compensation is prohibited.<sup>25</sup> The drafters doubtless knew that a partial resection of a liver can yield a donation that will save the recipient’s life, and that the donor’s liver will grow back.<sup>26</sup> So the statute does expressly prohibit compensation for at least one explicitly denoted “human organ” that will regenerate.

[5] As for whether the distinction between the organs or other body substances for which compensation is permitted and those for which it is prohibited has a rational basis, there are two classes of rational basis here: policy concerns and philosophical concerns. The policy concerns are obvious. Some are mentioned in the legislative history, though they

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<sup>23</sup>42 U.S.C. § 274e(c)(1).

<sup>24</sup>See S. Rep. No. 98-382, at 16-17 (1984) (stating that the organ sale prohibition was not “meant to include blood and blood derivatives, which can be replenished and whose donation does not compromise the health of the donor”); H.R. Rep. No. 98-1127, at 16 (1984) (Conf. Rep.) (stating that “the term ‘human organ’ is not intended to include replenishable tissues such as blood or sperm”).

<sup>25</sup>42 U.S.C. § 274e(c)(1).

<sup>26</sup>Pierre-Alain Clavien et al., *Strategies for Safer Liver Surgery and Partial Liver Transplantation*, 356 *New Eng. J. of Med.* 1493, 1545 (2007).

need not be.<sup>27</sup> Congress may have been concerned that if donors could be paid, rich patients or the medical industry might induce poor people to sell their organs, even when the transplant would create excessive medical risk, pain, or disability for the donor. Or, looking from the other end, Congress might have been concerned that every last cent could be extracted from sick patients needful of transplants, by well-matched potential donors making “your money or your life” offers.<sup>28</sup> The existing commerce in organs extracted by force or fraud by organ thieves<sup>29</sup> might be stimulated by paying for donations. Compensation to donors might also degrade the quality of the organ supply, by inducing potential donors to lie about their medical histories in order to make their organs marketable.<sup>30</sup> Plaintiffs argue that a \$3,000 housing subsidy, scholarship, or charitable donation is too small an amount to create a risk of any of these evils, but for a lot of people that could amount to three to six months’ rent.

Congress may have had philosophical as well as policy reasons for prohibiting compensation. People tend to have an instinctive revulsion at denial of bodily integrity, particularly

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<sup>27</sup>“The government need not state its purposes at the time it acts. It is sufficient that the government could have had a legitimate reason for acting as it did.” *Kim v. United States*, 121 F.3d 1269, 1274 (9th Cir. 1997).

<sup>28</sup>“[Bone marrow donors] are very difficult to match with recipients, . . . [and bone marrow donations] may represent a last resort to potential recipients.” H.R. Rep. No. 98-1127, at 17 (1984) (Conf. Rep.).

<sup>29</sup>See Sally Satel, *The Market for Kidneys, Livers and Lungs*, Wall St. J., Nov. 8, 2011, at A17.

<sup>30</sup>See *National Organ Transplant Act: Hearing on H.R. 4080 Before the Subcomm. on Health of the H. Comm. on Ways & Means*, 98th Cong., 2d Sess. 26 (1984) (statement of Rep. Waxman) (“If [people are allowed to sell their kidneys], I believe our efforts to promote voluntary organ donations would collapse, and health risks to transplant patients would greatly increase. Human organs should not be treated like fenders in an auto junkyard.”). See also Maurice McGregor, *Pragmatic Altruism*, 160 *Can. Med. Ass’n J.* 5, 91 (1999) (“The need for money is a disincentive to honest disclosure, a disincentive whose force will increase with the strength of the need.”).

removal of flesh from a human being for use by another, and most particularly “commodification” of such conduct,<sup>31</sup> that is, the sale of one’s bodily tissue.<sup>32</sup> While there is reportedly a large international market for the buying and selling of human organs,<sup>33</sup> in the United States, such a market is criminal and the commerce is generally seen as revolting. Leon Kass examines the philosophical issue of commodification with his observation that nonprofit hospitals, donor registries, and physicians are permitted to make a lot of money from organ transplants, and the only people who get nothing are those whose organs are donated:

[A]lthough we allow no commerce in organs, transplant surgeons and hospitals are making handsome profits from the organ-trading business, and even the not-for-profit transplant registries and procurement agencies glean for their employees a middleman’s livelihood. Why . . . should everyone be making money from this business except the person whose organ makes it possible? Could it be that [the] real uneasiness [lies] with organ donation or with transplantation itself, for if not, what would be objectionable about its turning a profit?<sup>34</sup>

Kass suggests that the revulsion for commodification of human flesh is reflected in our language:<sup>35</sup> we call donors who are paid for their organs “donors” rather than “sellers” or “vendors.” To account for why most of us are revolted by the notion of a poor person selling a kidney to feed his family,

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<sup>31</sup>See S. Rep. No. 98-382, at 17 (1984) (“[H]uman body parts should not be viewed as commodities[.]”).

<sup>32</sup> See *Coyote Publ’g, Inc. v. Miller*, 598 F.3d 592, 603 (9th Cir. 2010), cert. denied, 131 S. Ct. 1556 (2011).

<sup>33</sup>See Satel, *supra* note 29.

<sup>34</sup>Leon R. Kass, *Life, Liberty and the Defense of Dignity: The Challenge for Bioethics* 177 (2002).

<sup>35</sup>See *id.* at 195.

Kass cites the taboos we have against cannibalism, defilement of corpses, and necrophilia.<sup>36</sup> Kass points to the idea of “psychophysical unity, a position that regards a human being as largely, if not wholly, self-identical with his enlivened body,” so that, as Kant put it, to “‘dispose of oneself as a mere means to some end of one’s own liking is to degrade the humanity in one’s person.’”<sup>37</sup> In this view, “organ transplantation . . . is — once we strip away the trappings of the sterile operating rooms and their astonishing technologies — simply a noble form of cannibalism.”<sup>38</sup>

[6] These reasons are in some respects vague, in some speculative, and in some arguably misplaced. There are strong arguments for contrary views.<sup>39</sup> But these policy and philosophical choices are for Congress to make, not us. The distinctions made by Congress must have a rational basis, but do not need to fit perfectly with that rational basis, and the basis need merely be rational, not persuasive to all.<sup>40</sup> Here, Congress made a distinction between body material that is compensable and body material that is not. The distinction has a rational basis, so the prohibition on compensation for bone marrow donations by the aspiration method does not violate the Equal Protection Clause.

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<sup>36</sup>*Id.* at 183.

<sup>37</sup>*Id.* at 181-82, 185.

<sup>38</sup>*Id.* at 185.

<sup>39</sup>*See, e.g.,* Virginia Postrel, . . . *With Functioning Kidneys For All*, The Atlantic, July 9, 2009, <http://www.theatlantic.com/magazine/archive/2009/07/with-functioning-kidneys-for-all/7587>.

<sup>40</sup>*See Heller v. Doe*, 509 U.S. 312, 321 (1993) (stating that “courts are compelled under rational-basis review to accept a legislature’s generalizations even when there is an imperfect fit between means and ends . . . [and a] classification does not fail rational-basis review because it is not made with mathematical nicety” (internal quotation marks omitted)); *Doe v. United States*, 419 F.3d 1058, 1063 (9th Cir. 2005).

### C. Bone marrow transplants by apheresis.

[7] The focus, though, of plaintiffs' arguments is compensation for "bone marrow donations" by the peripheral blood stem cell apheresis method. For this, we need not answer any constitutional question, because the statute contains no prohibition. Such donations of cells drawn from blood flowing through the veins may sometimes anachronistically be called "bone marrow donations," but none of the soft, fatty marrow is donated, just cells found outside the marrow, outside the bones, flowing through the veins.

[8] Congress could not have had an intent to address the apheresis method when it passed the statute, because the method did not exist at that time. We must construe the words of the statute to see what they imply about extraction of hematopoietic stem cells by this method. This issue has not been addressed by any of our sister circuits.<sup>41</sup>

[9] Since payment for blood donations has long been common, the silence in the National Organ Transplant Act on compensating blood donors is loud. "Blood" is omitted from the list of examples of "human organs" in the statute and the regulation. The statute says "human organ" is defined as a human "kidney, liver, heart, lung, pancreas, bone marrow, cornea, eye, bone, and skin or any subpart thereof and any

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<sup>41</sup>We have cited the National Organ Transplant Act in other contexts. See *Newman v. Sathyavaglswaran*, 287 F.3d 786, 794 (9th Cir. 2002); *Coyote Publ'g, Inc. v. Miller*, 598 F.3d 592, 603 (9th Cir. 2010). Some district courts have considered related questions in the context of insurance claims. See *Nesseim v. Mail Handlers Benefit Plan*, 792 F. Supp. 674, 678 (D.S.D. 1992), *rev'd*, 995 F.2d 804, 807 (8th Cir. 1993); *Duckwitz v. Gen. Am. Life Ins. Co.*, 812 F. Supp. 864, 867 (N.D. Ill. 1993); *Healthcare Am. Plans, Inc. v. Bossemeyer*, 953 F. Supp. 1176, 1185 (D. Kan. 1996). No decision by any court addressing whether the National Organ Transplant Act prohibits compensation for hematopoietic stem cells, or anything analogous, has been cited to us, and we have found none.

other human organ . . . specified by the Secretary of Health and Human Services by regulation.”<sup>42</sup> The regulation adds intestines and the rest of the gastrointestinal tract to the list: “kidney, liver, heart, lung, pancreas, bone marrow, cornea, eye, bone, skin, and intestine, including the esophagus, stomach, small and/or large intestine, or any portion of the gastrointestinal tract.”<sup>43</sup> Neither the statute nor the regulation defines “human organ” to include “blood.” The government concedes that the common practice of compensating blood donors is not prohibited by the statute.

The government argues that hematopoietic stem cells in the veins should be treated as “bone marrow” because “bone marrow” is a statutory organ, and the statute prohibits compensation not only for donation of an organ, but also “any subpart thereof.”<sup>44</sup> Hematopoietic stem cells are formed in the bone marrow, and most are found there because they generally mature into blood cells and platelets in the marrow. Therefore, the government argues, they should be viewed as “subparts” of the bone marrow, even when these stem cells are obtained through apheresis, which is to say, from blood flowing through veins.

We reject this argument, because it proves too much, and because it construes words to mean something different from ordinary usage. If the government’s argument that what comes from the marrow is a subpart of the marrow were correct, then the statute would prohibit compensating blood donors. The red and white blood cells that flow through the veins come from the bone marrow, just like hematopoietic stem cells. But the government implicitly concedes that these red and white blood cells are not “subparts” of bone marrow under the statute, because it explicitly concedes that the statute does not prohibit compensation for blood donations.

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<sup>42</sup>42 U.S.C. § 274e(c)(1).

<sup>43</sup>42 C.F.R. § 121.13 (2010).

<sup>44</sup>42 U.S.C. § 274e(c)(1).



[10] As for ordinary usage, the bloodstream consists of plasma containing red cells, white cells, platelets, stem cells that will mature into one of these, and other material. We call this liquid as a whole “blood.” No one calls it “bone marrow,” even though these cells come from the marrow. There is no reason to think that Congress intended “bone marrow” to mean something so different from ordinary usage. Also, the blood contains not only blood cells and stem cells, but also other substances that come from elsewhere in the body. For example, the blood contains vitamin B<sub>12</sub>, which enters the bloodstream after binding with intrinsic factor and being absorbed from the small intestine.<sup>45</sup> The government’s argument would treat vitamin B<sub>12</sub> as a “subpart” of the intestines, and the regulation prohibits paying donors for their intestines or subparts thereof.<sup>46</sup> But every blood draw contains some vitamin B<sub>12</sub>, and we still call the red liquid “blood,” not “guts.”

Likewise, every blood draw includes some hematopoietic stem cells. All that differentiates the blood drawn in peripheral blood stem cell apheresis from the blood drawn from a compensated blood donor, other than the filtration process, is the medicine given to donors in the days before the blood draw to increase hematopoietic stem cell secretion. Once the stem cells are in the bloodstream, they are a “subpart” of the blood, not the bone marrow. The word “subpart” refers to the organ from which the material is taken, not the organ in which it was created. Taking part of the liver for a liver donation would violate the statute because of the “subpart thereof” language. But taking something from the blood that is created in the marrow takes only a subpart of the blood.

[11] We construe “bone marrow” to mean the soft, fatty substance in bone cavities, as opposed to blood, which means the red liquid that flows through the blood vessels. The statute

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<sup>45</sup>*Harrison’s Principles of Internal Medicine* 601-02 (16th ed. 2005).

<sup>46</sup>42 C.F.R. § 121.13 (2010).

does not prohibit compensation for donations of blood and the substances in it, which include peripheral blood stem cells. The Secretary of Health and Human Services has not exercised regulatory authority to define blood or peripheral blood stem cells as organs. We therefore need not decide whether prohibiting compensation for such donations would be unconstitutional.

### **III. Conclusion.**

[12] It may be that “bone marrow transplant” is an anachronism that will soon fade away, as peripheral blood stem cell apheresis replaces aspiration as the transplant technique, much as “dial the phone” is fading away now that telephones do not have dials. Or it may live on, as “brief” does, even though “briefs” are now lengthy arguments rather than, as they used to be, brief summaries of authorities. Either way, when the “peripheral blood stem cell apheresis” method of “bone marrow transplantation” is used, it is not a transfer of a “human organ” or a “subpart thereof” as defined by the statute and regulation, so the statute does not criminalize compensating the donor.

REVERSED. The judgment is VACATED and the case REMANDED for such additional proceedings as may be appropriate. Costs on appeal awarded to Plaintiffs-Appellants.