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Health Care Law: Chilled To The Marrow - The Legal Ramifications Of Remuneration Of Stem Cell Donors

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The lack of bone marrow or hematopoietic stem cell (HSC) donors is a continuing problem across the globe. Currently only four out of 10 patients in need of a transplant will ever find a matching donor. One possible but controversial idea to increase the donor pool is through donor financial incentives; however, there is a question of whether remuneration is legal under the National Organ Transplant Act (NOTA).

Bone marrow or HSC transplants are used to treat patients with life-threatening blood cancers, diseases that result in bone marrow failure, and other immune system or genetic diseases. There are two methods to donate: apheresis or traditional bone marrow extraction. Under the traditional method, patients undergo general anesthesia, and marrow is extracted from the hip. With the apheresis method, donors remain awake while blood is removed, the stem cells are extracted, and the blood is returned to the body.

Although NOTA explicitly prohibits remuneration for HSC donation using the traditional method, it is unclear whether NOTA covers the apheresis method. In 2012, the Ninth Circuit held in *Flynn v. Holder* that individuals who donate HSC via apheresis may be remunerated. *Flynn v. Holder*, 665 F.3d 1048, 1059 (9th Cir. 2011). The *Flynn* plaintiffs developed a pilot program to incentivize HSC donors through the provision of $3,000 in the form of a scholarship, housing subsidy, or donation to a charity of the donor's choice. I. Glenn Cohen, *Selling Bone Marrow — Flynn v. Holder*, 366 New Eng. J. Med. 296, 296 (2012).

The plaintiffs initially set forth two arguments: (1) NOTA's ban on selling HSC violates substantive due process protections of the Constitution because when an individual needs a transplant to survive

and another individual is willing to supply it for a fee, the government cannot interfere with the transaction, and (2) NOTA violates the Equal Protection Clause of the Fourteenth Amendment of the Constitution because there is no rational basis for permitting remuneration for blood, sperm, and ova while prohibiting it for HSC. *Flynn*, 665 F.3d at 1053. The district court rejected both arguments on those grounds, and the Ninth Circuit affirmed. *Cohen, supra note 4* at 1055-56. The courts identified several rational bases for prohibiting the sale of HSC, including that poor people could be coerced into donating; the rich would be advantaged; and that donors would be incentivized to provide inaccurate medical history to appear healthier and desirable. *Id.*

On appeal, the Ninth Circuit considered a third argument: that the term "bone marrow" does not include stem cells obtained through the apheresis process. *Id.* It is on this ground that the Ninth Circuit ruled for the plaintiffs. *Flynn*, 665 F.3d at 1057. The court determined that Congress could not have intended to address the apheresis process because it did not exist at the time NOTA was passed. *Id.*

The attorney general declined to petition the Supreme Court to review the *Flynn v. Holder* decision. However, in 2013, the Health Resources and Services Administration issued a proposed rule to explicitly incorporate apheresis-extracted HSC in NOTA's definition of "bone marrow." 42 CFR § 121. As of the time of this writing, the final rule had not been issued but was expected in December 2014.

It is unclear how many groups or institutions have taken advantage of this loophole to provide some form of remuneration to HSC donors. However, should the final rule indicate that HSC are explicitly included in the NOTA ban on remuneration, the point will be moot, for now, and donor remuneration for any method of stem cell donation will be prohibited. *Originally published in Hillsborough County Bar Association's Lawyer magazine, February 2015.*

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