Flynn v. Holder, a Narrow Interpretation of National Organ Transplant Act (NOTA) Reached Positive Policy Effects

Lingyun Kao, LL.B, LL.M candidate
llkao@central.uh.edu

On October 28, 2009, six plaintiffs, including adults with deadly blood diseases, the parents of sick children, a California nonprofit organization and a world-renowned medical doctor who specializes in bone marrow research, filed Flynn v. Holder in the U.S. District Court for the Central District of California. The complaint challenges the constitutionality of National Organ Transplant Act’s ban on compensation for bone marrow transplants on both equal protection and substantive due process grounds. The suit was first dismissed in the District Court for failure to state a claim but was later reversed in part by the Ninth Circuit, which held that NOTA’s ban does not apply to one of the bone marrow stem cells harvesting process—peripheral blood stem cell (PBSC) donation. The Court found that PBSC donation is essentially a blood donation and NOTA’s ban does not apply to blood donation. The Court, however, held that bone marrow donation fell within the Act and still being prohibited from being compensated.

The decision from the Ninth Circuit may have positive policy consequences, as it could increase the number of “PBSC” donors, thereby improving the odds of locating matching donors for patients who suffer from fatal diseases and need bone marrow transplants to survive. However, in reaching its decision, the Court adopted a narrow interpretation of the statue and possibly overlooked some essential medical facts of the new PBSC donation procedure.

Bone marrow is the soft, sponge-like material found inside bones. It contains blood-forming stem cells maturing into one of three types of blood cells: white blood cells, which fight infection; red blood cells, which carry oxygen; and platelets, which help the blood to clot. Most bone

---

2 Id.
3 Id. at 855. The significance of each method of obtaining bone marrow stem cells had not been briefed by the parties, suggesting that the circuit court came up with the importance of this distinction on its own. The court pointed out in its opinion: 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 PBSC donation. This is a relatively new method of bone marrow transplant that avoids the need to invade the bone for marrow.
marrow stem cells are found in bone marrow only, but a small number of them, called peripheral blood stem cell (PBSC), also exist in the bloodstream. Generally, when we talk about “bone marrow transplant,” what we refer to is in fact “bone marrow stem cells transplant” whose goal is to replace damaged or destroyed bone marrow with healthy bone marrow stem cells.

Bone Marrow Harvesting

Bone marrow stem cells can be collected in two ways besides the cord blood donation: 1) bone marrow donation by aspiration and 2) peripheral blood stem cell (PBSC) donation.

The stem cells harvesting process in bone marrow donation by aspiration is invasive and painful. The donor is given either general anesthesia, which puts the person to sleep during the procedure, or regional anesthesia, which causes loss of feeling below the waist. Needles are inserted through the skin over the pelvic (hip) bone or, in rare cases, the sternum (breastbone), and into the bone marrow to draw the marrow out of the bone. The harvested bone marrow is then processed to remove blood and bone fragments, and frozen to keep the stem cells alive when they are needed. 

Collecting stem cells through PBSC donation appears to be much easier on the donors. It begins with four to five days of injections of a medication called a “granulocyte colony-stimulating factor” into the donor’s blood to accelerate PBSC production in the marrow and mobilize PBSCs into the bloodstream. When it is time to harvest PBSCs, a very thin flexible tube is put into one of the donor’s veins and attached to tubing that carries the blood to a special machine. The machine separates the blood, and keeps only the stem cells. The rest of the blood goes back to the donor. This procedure normally takes several hours and may need to be repeated for a few days to get enough stem cells. The stem cells are filtered, stored in bags, and frozen until the patient is ready for them.

Both stem cell sources can be used for the same goal: to give the patient healthy bone marrow stem cells that will mature into healthy blood cells. Often, doctors are able to harvest more stem

---


5 Stem Cell Transplant (Peripheral Blood, Bone Marrow, and Cord Blood Transplant), American Cancer Society.
cells from blood than from bone marrow.\textsuperscript{6} It’s also easier for donors to give PBSCs than bone marrow. Another plus for peripheral blood stem cell transplants is that the recipient’s blood count often recovers faster than with a bone marrow transplant. PBSC donation was not used for donating bone marrow stem cells until the early 1990s.\textsuperscript{7} From 2001 to 2010, approximately 70% to 90% of patients who are more than 20 years old received bone marrow stem cells transplant through PBSC donation, and the number is still increasing. For patients who are under 20 years old, by contrast, PBSC donation was not their major resource of bone marrow stem cells; bone marrow donation by aspiration constituted about 50% to 60% of the bone marrow stem cell sources.\textsuperscript{8}

\textbf{NOTA}

The National Organ Transplant Act (NOTA) of 1984\textsuperscript{9} prohibited human organ sales by providing, in part:

\begin{quote}
The term “human organ” means the human kidney, liver, heart, lung, pancreas, bone marrow, cornea, eye, bone, and skin, and any other human organ specified by the secretary of Health and Human Services by regulation.\textsuperscript{10}
\end{quote}

Two amendments in this section of NOTA have been made since then: In 1988, Congress amended Subsection (c)(1) by inserting “or any subpart thereof” behind the enumerated list of organs which may not be sold and also expanding the definition of “human” to include fetuses. The other amendment occurred in 2007, creating the new definition of “human organ” under 42 U.S.C.S. § 274e which states:

\begin{quote}
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.\textsuperscript{11}
\end{quote}

\begin{thebibliography}{9}
\bibitem{6} Id.
\bibitem{7} Paolo Anderlini et al., Allogeneic Blood Stem Cell Transplantation: Considerations for Donors, supra note 51, at 690.
\bibitem{8} Pasquini MC, Wang Z. Current use and outcome of hematopoietic stem cell transplantation: CIBMTR Summary Slides, 2012. Available at: \url{http://www.cibmtr.org}.
\bibitem{9} National Organ Transplant Act of 1984, Pub. L. No. 98-507
\bibitem{10} National Organ Transplant Act of 1984, Pub. L. No. 98-507 Title III § 301(c)(1).
\bibitem{11} 42 U.S.C. § 274e (2007).
\end{thebibliography}
The promulgation of NOTA did not mean the end of the debate over compensation for organ donors. Quite the contrary, even though Congress’s intention in enacting NOTA was to increase available organ supply, there remains a huge gap between organ supply and demand. In 2007, more than 7,000 Americans died while awaiting an organ transplant—almost double the number of American soldiers killed in Iraq between 2003 and 2008.

Analysis for Flynn

On September 1, 2010, the plaintiffs in Flynn v. Holder appealed their case to the United States Court of Appeals for the Ninth Circuit. The panel converted plaintiffs' equal protection arguments into an interpretation of the statute. The panel declared: “[w]e 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.”12 It seems very obvious that the PBSC withdrawn from the blood stream in PBSC donation process is not bone marrow. The government argued that PBSCs in the veins are “subparts” of the bone marrow and therefore fall within the statute. But the Court rejected this argument “because it proved too much.” Since all blood cells that flow through the veins come from the bone marrow, just like PBSCs, if the government’s argument was correct, then the statute would prohibit compensating blood donors. Additionally, every blood draw includes some PBSCs. Since the word “subpart” refers to the organ from which the material is taken, not the organ in which it was created, the PBSCs in the veins during PBSC donation process are a “subpart” of the blood, not the bone marrow.13

Although the Court’s reasoning may sound persuasive, there are still questions marks left if we take the entire PBSC donation process into consideration.

As mentioned above, the body is able to direct bone marrow stem cells to develop into the blood components needed at any given moment. This is a very active process, with the bone marrow producing millions of different cells every hour. Most of the bone marrow stem cells stay in the marrow until they are transformed into the various blood components, which are then released into the blood stream. Small numbers of bone marrow stem cells can be found in circulating blood, but the number of bone marrow stem cells in the blood is not sufficient enough

---

13 Id.
for transplant. Therefore, both bone marrow donation by aspiration and PBSC donation share one goal in common is to obtain the PBSCs that will not voluntarily leave the bone marrow without drug intervention. Bone marrow donation by aspiration collects the bone marrow stem cells through inserting a long needle to remove the liquid marrow containing most bone marrow stem cells, and PBSC donation through medication to mobilize those PBSCs produced in the bone marrow into the blood veins. Both the needle and the medication are man-made methods to remove the HSCs out of bone marrow. In PBSC donation, the PBSCs in bone marrow are not only created in bone marrow but also taken from bone marrow by man-made medication. Therefore, according to the court, HSCs taken from bone marrow should be seen as a “subpart” of bone marrow.

Despite of the narrow interpretation of NOTA as it applies to bone marrow, it is still inspiring that the federal court had the wisdom and courage to embrace the new medical innovation and potentially opened the door for PBSC donation compensation. As the court indicated in Flynn v. Holder,

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…or it may live on… Either way, when PBSC method is used, it is not a transfer of a human organ or a subpart thereof as defined by the statute and regulations, so the statute does not criminalize compensating the donor.

Even though the decision will only be effective within the several states within the Ninth Circuit’s jurisdiction, the door of compensation for PBSC donations has been opened. Compensation will increase the organ donors’ pool as it has been proven by blood donation system, egg donation system, and sperm donation system. The Ninth Circuit’s ruling offers hope for the plaintiffs in Flynn, along with the thousands of people waiting for a bone marrow stem cell transplant, that perhaps the legal system will allow compensation for PBSC donation. Meanwhile, it is necessary for Congress to reevaluate NOTA in order to take into account the increasing pressure from developing technologies and the unnecessary loss of life that has resulted from our current laws.
Health Law Perspectives (June 2013)
Health Law & Policy Institute
University of Houston Law Center
http://www.law.uh.edu/healthlaw/perspectives/homepage.asp

The opinions, beliefs and viewpoints expressed by the various Health Law Perspectives authors on this web site do not necessarily reflect the opinions, beliefs, viewpoints, or official policies of the Health Law & Policy Institute and do not constitute legal advice. The Health Law & Policy Institute is part of the University of Houston Law Center. It is guided by an advisory board consisting of leading academicians, health law practitioners, representatives of area institutions, and public officials. A primary mission of the Institute is to provide policy analysis for members of the Texas Legislature and health and human service agencies in state government.