On October 2, in the midst of the government shutdown—either HHS somehow managed to convince itself that the rule was “necessary for the protection of life” or, more likely, it had already been scheduled for printing—HHS quietly published a Notice of Proposed Rulemaking. The proposed rule would effectively moot the recent Ninth Circuit case of *Flynn v. Holder* by criminalizing the compensation of bone marrow donors, even when the life-saving stem cells are extracted through a newer, minimal risk procedure. In this post, I’ll explain the medicine, the Ninth Circuit’s decision, and what HHS proposes to do in response. In my next post, I’ll have some reaction to HHS’s policy arguments, about which I’m skeptical, and perhaps a few thoughts about where plaintiffs might go from here.

Section 301 of the National Organ Transplant Act (NOTA) of 1984 criminalizes the transfer of “human organs” for “valuable consideration.” Reimbursement of reasonable out-of-pocket expenses associated with travel and lost wages are okay—as are, since the 2008 amendment of NOTA, paired living donor chains—but any other “valuable consideration” that might incentivize sources of organs is not. Under NOTA, as amended,

> ‘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

(emphases added). HHS has since added to this list “intestine, including the esophagus, stomach, small and/or large intestine, or any portion of the gastrointestinal tract.”

So-called “bone marrow transplants”—in reality, infusions of hematopoietic (blood) stem cells (HSCs)—are often life-saving procedures for those with, for example, leukemia or aplastic anemia. (See these sobering statistics compiled by the Institute for Justice, which represented the plaintiffs in *Flynn.*) When NOTA was passed, the only way to obtain HSCs was through bone marrow aspiration using a long needle thick enough to suck liquid marrow directly from the donor’s pelvic bone. HSCs are then harvested from the marrow. The procedure is done under general anesthesia and so the donor is subject to the usual risks of anesthesia. Although the donor can return to usual activities in two to seven days, discomfort may linger for up to two weeks. During the past twenty years or so, however, a new method of obtaining HSCs has emerged—apheresis—that avoids the need to invade...
the bone for marrow. (Kim Krawiec had a helpful post a while back with short videos that explain the differences between the two methods.) Today, something like two-thirds of HSC donation occurs through apheresis (traditional aspiration is medically indicated in some cases). Using this method, the donor receives five daily injections of a drug that accelerates blood stem cell production and coaxes the stem cells to move from the bone marrow into the bloodstream, where they are called peripheral blood stem cells (PBSCs). On the fifth day, the donor sits in a recliner for up to eight hours while blood is drawn from one of her arms, recycled through an apheresis machine that harvests the stem cells, and returns the remaining blood to the donor in her other arm. Possible side effects of the drug in the five-day run-up to the procedure include headaches and bone or muscle aches. After harvesting, the donor can return to her normal routine in one or two days, and complications are, according to the 9th Circuit, “exceedingly rare.”

Still, insufficient numbers of willing, compatible donors (there are just four blood types but millions of marrow cell types) exist. Those in need of transplants who have diverse genetic backgrounds, such as African Americans and those of multiple races/ethnicities, are especially difficult to match.

In Flynn v. Holder, a group of plaintiffs challenged the ban on compensating bone marrow donors. Plaintiffs included parents of children with leukemia and aplastic anemia; a parent of mixed-race children; and MoreMarrowDonor.org, a California nonprofit that wanted to test a pilot program in which it would offer bone marrow providers $3,000 awards in the form of scholarships, housing allowances, or gifts to a charity of their choice. They pressed two arguments before the Ninth Circuit—one based on the Equal Protection Clause, and one based on statutory interpretation. (A third argument, that the ban violates substantive due process, was rejected by the district court by fairly dubious analogy to Abigail Alliance, and plaintiffs did not raise it on appeal.)

Plaintiffs’ first argument was that NOTA, as applied to MoreMarrowDonor.org’s pilot program, violates the Equal Protection Clause by distinguishing, without rational basis, blood, sperm, and eggs (which do not come within NOTA’s definition of “human organ,” and donors of which may be compensated) and HSCs (donors of which may not be compensated under HHS’s interpretation of NOTA, regardless of the method of procurement). Plaintiffs argued that HSC donors—like blood and gamete donors, but unlike solid organ donors—are exposed to little risk and quickly regenerate what they have donated.

As applied to HSCs donated through aspiration, the court held that NOTA’s compensation ban might have any number of rational (if imperfect) bases and, therefore, does not violate the Equal Protection Clause. However, the court avoided the constitutional question as applied to HSCs donated through apheresis, holding that “the statute contains no prohibition.” According to the court, Congress could not have intended for NOTA’s reference to “bone marrow” to encompass the harvesting of HSCs through apheresis (that is, PBSCs), because that procedure did not exist in 1984.

As for what the statute implies about apheresis-derived PBSCs, the question came down to whether PBSCs should (as the government argued) be considered “bone marrow” or a “subpart thereof,” both of which are covered by NOTA’s ban, or (as plaintiffs argued) “blood,” which is not. The court sided
with plaintiffs, finding among other defects in the government’s argument that it “proved too much”; after all, if HSCs are “part of” bone marrow because they are formed there, then so are the white and red blood cells that the government concedes fall outside of NOTA’s scope. In short, the court found,

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.

In its petition for rehearing (here’s Kim again), the government raised a fairly weak new argument (Kim again) based on the fact that Congress—in an entirely different Title of the U.S. Code, pertaining to entirely different issues—defined “bone marrow” to include PBSCs. The court rejected the government’s petition for rehearing but did amend its opinion to reflect its rejection of the state’s new argument. The court concluded:

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 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.

In its notice of proposed rulemaking this week, of course, HHS seeks to use just this regulatory authority. (Comments, by the way, are due by December 2, 2013.) The agency proposes to “explicitly incorporate hematopoietic stem cells (HSCs) within peripheral blood in the definition of ‘bone marrow,’ so that the prohibition on transfers of human organs for valuable consideration applies to HSCs regardless of whether they were recovered directly from bone marrow (by aspiration) or from peripheral blood (by apheresis).”

As I said, in my next post, I’ll talk about the policy arguments for underlying HHS’s use of its regulatory authority. They include the usual suspects—commodification, coercion of PBSC vendors, exploitation of the sick, and concerns about compensation crowding out altruism and incentivizing vendors to conceal infectious diseases.

[Cross-posted at The Faculty Lounge]
Wrong, wrong, wrong!

Sorry, but this is what happens when anonymous paper pushing robotic bureaucrats make decisions via wikipedia page insights.

Outlawing a process because it didn’t exist when some law was passed in the ’80s proves that government only HINDERS medical science, and can not possibly help.