

Paid Organ Donations and the Constitutionality of the National Organ Transplant Act

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I. Introduction

Organ transplant is a well-established medical therapy that saves thousands of lives. Yet many people who could survive with transplants die on waiting lists. With ever expanding indications for transplant, the supply of organs will never meet demand.¹ But many more organ transplants could occur than do.

Efforts to increase organ supply have been constant since the advent of allografting organs in the 1960s. Most of these efforts focused on cadaveric sources and led to enactment of brain death statutes, organ donor cards on driver's licenses, required request laws, and the like. Still yielding only about 10,000 transplants a year, the latest move to increase supply has been to retrieve donated organs immediately after cardiac death.² While the distribution of cadaveric organs had initially been a problem, a satisfactory system for distributing cadaveric organs is now in place.³

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1. Developments in regenerative medicine using a person's own stem cells to recreate needed organs or to populate bioartificial ones created with an artificial scaffold may eventually meet some current needs for organs. Henry Fountain, *A First: Tailor-Made With Body's Own Cells*, N.Y. TIMES, Sept. 16, 2012, at A1.

2. Robert Steinbrook, *Donations after Cardiac Death*, 357 NEW ENG. J. MED. 209 (2007).

3. The United Network for Organ Sharing ("UNOS") allocates cadaveric donations. Even former Vice-President Dick Cheney had to do his time on the waiting list to receive a new heart. Living donors, however, ordinarily designate who the recipient is. For information on UNOS, see UNOS, <http://www.unos.org/> (last visited Oct. 1, 2012). The authority for such a system originated in the provisions of the organ procurement and

Living donors are also an important part of the supply picture. Bone marrow donors and family kidney donors are usually still living.⁴ An important part of kidney donation is now the use of unrelated live donors, some of whom have had no prior connection with the recipient. Donation of part of a liver, which will then regenerate, is also occurring from live donors, most notably to family members.⁵ However, the donation of other solid organs, such as hearts and lungs, requires the death of the donor.⁶

A recurring issue in talk of ways to increase organ supply has been the use of financial incentives. Since money works so well in allocating goods and services in markets, why not allow a market system for organ donations?⁷

The anti-money crowd decries payment, claiming that it will lead to the coercion and exploitation of poorer persons, the drying up or crowding out of altruism, less safe organ transplants, and that transacting for donor organs is immoral because the body and its

transplantation network envisioned in the National Organ Transplantation Act of 1984. 42 U.S.C. § 274 (2006). Periodically issues about allocation do arise. Benjamin E. Hippen et al., *Risk, Prognosis, and Unintended Consequences in Kidney Allocation*, 364 NEW ENG. J. MED. 1285 (2011).

4. Living donors have averaged about 6,500, and deceased donors about 7,500, for the last decade. Deceased donors, however, yield more transplanted organs (22,158 in 2011) than the single kidney or occasionally partial liver transplant obtained from a living donor (6,019 in 2011). See U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES, HEALTH SERVICES RESEARCH ADMINISTRATION, ORGAN PROCUREMENT AND TRANSPLANTATION NETWORK, available at <http://optn.transplant.hrsa.gov/latestData/step2.asp>. (last visited Oct. 1, 2012).

5. Partial liver donation has a higher morbidity rate than living kidney donation because it is a more invasive procedure. The fourth death in 4,126 living liver donor transplants since 1998 occurred in Denver on August 14, 2010, three months after a similar death in Massachusetts. Kirk Mitchell, *Rare Death of Liver Donor at CU Hospital Prompting Concern*, DENVER POST, Aug. 14, 2010, http://www.denverpost.com/news/ci_15775015 (last updated Aug. 14, 2010, 8:35 AM).

6. Under the dead donor rule, the donor of such vital organs must be deceased before the organs can be removed because the law of homicide prohibits such sacrificial deaths. John A. Robertson, *The Dead Donor Rule*, 29 HASTINGS CENTER REPORT 6 (Nov./Dec. 1999). Recall J.B.S. Haldane's quip that "I'd lay down my life for two brothers or eight cousins." JOHN BURDEN SANDERSON HALDANE, THE OXFORD DICTIONARY OF SCIENTIFIC QUOTATIONS (W.F. Bynum & Roy Porter, eds., Oxford University Press 2006).

7. Buying organs for transplant also raises problems, e.g., the wealthy could outbid the less wealthy, thus skewing the distribution of recipients. It could also expand the possibilities for extortion where the matched donor keeps raising the price of the organ since the recipient is so much in need. The UNOS system avoids those problems. See UNOS, *supra* note 3.

parts should not be sold.⁸ The pro-payment lobby cites the inadequacy of altruism to meet needs for transplant. They believe that the safety and exploitative aspects of a paid system can be managed with informed consent and screening laws, and price controls on the amount paid. Also, social norms about reciprocity in gift giving argue for something more tangible than a “thank-you,” particularly when most other participants in the transplant system (doctors, nurses, hospitals,) profit from organ transplants, and research subjects, surrogate mothers, and blood, sperm, and egg donors are paid for taking on risk.⁹

Public policy in the United States settled the issue in 1984 with the enactment of the National Organ Transplant Act (“NOTA”).¹⁰ A proposed international kidney brokerage operation, which would have matched willing buyers and sellers for a fee of \$5,000, focused Congress’ attention on the problems with a market in organs.¹¹ The resulting legislation made it a federal felony to provide “valuable consideration” for organs, but kept an exception for renewable or plentiful tissue such as blood, sperm, and eggs.¹² Bone marrow, which is renewable, is not on that list of exceptions. As a result, no payment can be offered for organ or marrow donations or even for joining a registry of persons who are willing to donate for a fee. The federal ban applies even if the reward is a scholarship, help with rent or a home mortgage, or donation to a charity of one’s choice.¹³

Despite literature more favorable toward paid donations than in the past, there has hardly been a budge in this position.¹⁴ In 1996,

8. Drawing on work of Michael Sandel, Glenn Cohen calls these “corruption” concerns. I. G. Cohen, Note, *The Price of Everything, the Value of Nothing: Reframing the Commodification Debate*, 117 HARV. L. REV. 689, 691 (2003-2004).

9. See e.g., Richard A. Epstein, *The Human and Economic Dimensions of Altruism: The Case of Organ Transplantation*, 37 J. LEGAL STUD. 459 (2008).

10. 42 U.S.C. § 274e(a) (2006).

11. H. Barry Jacobs, a de-licensed doctor, had testified before Congress regarding his plans to set up a brokerage system for profit that would obtain Third World donors for the United States market. See I. G. Cohen, *Can the Government Ban Organ Sale? Recent Court Challenges and the Future of US Law on Selling Human Organs and Other Tissue*, 12 AMER. J. TRANSPLANTATION 1983 (2012).

12. 42 U.S.C. § 247e(a). Note that NOTA bans payment both for donating and receiving organs.

13. They would count as “valuable consideration.”

14. Julia D. Mahoney notes the growing academic and professional literature that finds that “financial incentives for organ sources offer a morally acceptable and potentially effective means of augmenting the organ supply.” Julia D. Mahoney, *Altruism, Markets, and Organ Procurement*, 72 LAW & CONTEMP. PROBS. 17, 18, n.7 (2009). She also notes that the mainstream media often has editorials in favor of payment and that the American

Pennsylvania did create a fund to be used for the funeral expenses of cadaveric donors, but the hovering presence of NOTA discouraged state officials from implementing it.¹⁵ In 2008, NOTA was amended to clarify that paired living donor chains were not covered by the Act's ban on payment and consequently, some expansion of what counts as a compensable expense has occurred.¹⁶ Despite the clamor of more voices in favor of payment, no major change in NOTA may occur for years to come, even for experimental programs.¹⁷

Might a constitutional attack on NOTA advance the process?¹⁸ The idea is rooted in the notion of self-defense as a basic right. An organ transplant is critically important to a person with end-stage organ disease who is fighting for her life against the depredations of trauma, illness, and disease. Some argue that the Supreme Court's interpretation of the Second Amendment as protecting an individual right to possess a handgun in the home for self-defense should extend to medical self-defense as well.¹⁹ Others rely more directly on substantive due process for a negative right to safe and effective medical care to protect life and liberty.²⁰

Medical Association ("AMA"), once implacably against any use of payment, now favors further study of financial rewards for deceased donors. *Id.* See also R.S. Gaston et al., *Limiting Financial Disincentives in Live Organ Donation: A Rational Solution to the Kidney Shortage*, 6 AMER. J. TRANSPLANTATION 2548 (2006); but see M. D. Fox, *The Price Is Wrong: The Moral Cost of Living Donor Inducements*, 6 AMER. J. TRANSPLANTATION 2529 (2006).

15. Up to \$3,000 could be paid for "reasonable . . . funeral expenses . . . incurred by the donor or the donor's family in connection with making a vital organ donation." 20 PA. CONS. STAT. ANN. § 8622. (West 2012).

16. 42 U.S.C. § 274e(a). A living donor who is willing to donate to a family member, A, but is not a good match promises to donate to a nonfamily member, B, in return for B's family donor who is not a good match for B donating to A. They are defined as "human organ paired donations" and not covered by the ban on paying valuable consideration for organs. § 274e(a), (c)(4); see also Kevin Sack, *60 Lives, 30 Kidneys, All Linked*, N.Y. TIMES, Feb. 19, 2012, at A1.

17. Indeed, one legislative solution would be to exempt from NOTA's ban on payment an organization certified by federal or state departments of health and human services that meet high standards of review of consent, voluntariness, protect against injury, and are limited in their payment scheme. See discussion *infra* Part VIII. Modification of 42 U.S.C. § 273 (2006) may also be necessary (limiting the availability of organs for transplant to qualified nonprofit organ procurement organizations).

18. See discussion *infra* Part II.

19. *District of Columbia v. Heller*, 554 U.S. 570, 590 (2008).

20. Eugene Volokh, *Medical Self-Defense, Prohibited Experimental Therapies, and Payment for Organs*, 120 HARV. L. REV. 1813 (2007). Situations of self-defense draw on a deeper sense of the importance of life to an individual when threatened by others or by disease or illness. Both situations thus involve the right to life—the individual's right to protect or preserve his life.

Whatever the theory, it will be a hard slog—but not an impossible one—to get courts to recognize such a right. On the procedural side, it would require an as-applied challenge either by a would-be recipient and paid donor that avoided the larger problems that an unfettered market in organs would pose or an organization that would broker or otherwise acquire and distribute paid organs in a highly regulated way with health, safety, consent, and background screens of donors and caps on payment.

On the substantive side, recognizing new rights is controversial and difficult. Still, because organ transplantation is a well-accepted treatment for many life-threatening conditions, the idea that the state cannot prohibit a person from using an accepted therapy to save or defend his life should have some appeal. Since bans on paid donation make it difficult, if not impossible, for many persons to receive transplants, NOTA's prohibitions substantially burden that right. This means that some form of heightened scrutiny beyond rational basis should apply to NOTA. NOTA supporters can satisfy a stricter scrutiny if the alternative is a free, unregulated market in organs. NOTA fares less well in other applications discussed below.

This article analyzes the constitutionality of NOTA when applied to privately run regulated systems that strive to meet objections to payment for organs. Part II discusses *Flynn v. Holder*'s validation of NOTA on rational basis review. Part III presents the case for strict scrutiny when a safe and effective medical treatment is available. Part IV meets objections to strict scrutiny based on *Washington v. Glucksberg*'s denial of a patient's right to physician-assisted suicide. Part V shows that *Abigail Alliance v. Eschenbach*, a D.C. circuit case denying a terminally ill patient access to an experimental drug, also is no bar to a right to access medically accepted organ transplants. Part VI addresses standing and burden issues in as-applied challenges to NOTA. Part VII assesses how three payment programs (free market libertarianism, paid kidney donations, and paid cadaveric donations) would fare if the government had to meet a stricter scrutiny than rational basis to apply NOTA to them. Part VIII argues that the deference to legislative judgment should not continue when as-applied challenges based on a right of medical self-defense require government to meet strict scrutiny to limit that right.

II. *Flynn v. Holder*: Playing the Rational Basis Card to Challenge NOTA

Shaka Mitchell and some colleagues had a clever idea. As a lawyer in Nashville who had worked at the libertarian Institute for Justice in Washington, he was familiar with the difficulties that patients had in getting matched bone marrow donations. Mitchell and a few others decided to challenge NOTA's exclusion of payment for bone marrow tissue.²¹ Although it was a renewable tissue, NOTA made paying money to bone marrow donors illegal, even though payment for other renewable tissue like blood, sperm, and eggs was permitted, and marrow donation was of low risk.

Together with Jeff Rowes at the Institute of Justice, Mike Hamel, a bone marrow recipient in Colorado, and others, Mitchell created MoreMarrowDonors.org ("MMD.org"), an organization that would offer designated rewards of \$3,000 for scholarship, charitable contribution, or housing expenses if someone registered with the organization and followed through with a bone marrow donation if matched.²² Because NOTA would make paying such "valuable consideration" a crime, that organization and others filed suit in federal district court in California, seeking to have the ban on paying for bone marrow donations found unconstitutional on equal protection and substantive due process grounds.²³

The suit was dismissed in the district court for failure to state a claim,²⁴ but was reversed in part by the Ninth Circuit, which held that the ban on paying for "bone marrow" in NOTA applied only to extraction by aspiration and not retrieval by peripheral blood apheresis.²⁵ The court found that apheresis was essentially a blood donation, and paying for blood was excluded from NOTA's ban.²⁶

21. LAW OFFICE OF SHAKA MITCHELL, http://www.mitchelllawpractice.com/?page_id=80t (last visited Oct. 8, 2012).

22. Author's telephone conversation with plaintiff and cofounder Mike Hamel, Sept. 13, 2012.

23. They were represented by the Institute for Justice, which had been instrumental in creating the organization and enlisting plaintiffs.

24. *Flynn v. Holder*, CV 09-7772-VBF(AJWx), document no. 33 (C.D. Cal. Mar. 12, 2010) (<http://www.pacer.gov/>).

25. *Flynn v. Holder*, 684 F.3d 852 (9th Cir. 2011). The plaintiffs limited their appeal to a lack of a rational basis, not pressing the substantive due process claim made and rejected by the district court on the basis of *Abigail Alliance v. Eschenbach*, 495 F.3d 695 (D.C. Cir. 2007).

26. The significance of each method of obtaining hematopoietic stem cells had not been briefed by the parties, suggesting that the circuit court came up with the importance

The court, however, held that bone marrow donation by aspiration fell within the act and satisfied rational basis review. As the first attempt to mount a constitutional challenge to NOTA, the case bears careful study.

The plaintiffs consisted of three groups: patients or parents of children with Fanconi anemia or leukemia that was treatable with bone marrow transplants, a noted hematologist-oncologist who specialized in bone marrow transplant treatments, and a nonprofit corporation that “intend[ed] to use financial incentives to combat the shortage of bone-marrow donors.”²⁷ The diseases involved were all successfully treatable by matched bone marrow transplants, but persons of mixed race or African American ancestry face an acute shortage of matching donors.²⁸

The case rested on the special role of bone marrow. Blood and the many other components of bone marrow are replenished from hematopoietic stem cells. If cancer or other diseases interrupt the production of a continuous supply of fresh blood cells, a transplant of the hematopoietic cells in bone marrow can restore that system. Marrow cells were traditionally removed by the insertion of a long needle into the bones of the hip and aspirating the marrow.²⁹ While this is still performed in 25% of cases, it is now more common to obtain hematopoietic stem cells by peripheral blood stem cell through a process called PBSC apheresis. That process occurs after five days of drug injections to stimulate a donor’s stem cell production in the marrow. The donor’s blood is then removed as in a blood donation and run through a separator to collect the blood stem cells. The donor’s blood is then reinjected into the donor and the separated blood stem cells into the recipient. Over several hours, the donor’s own blood stem cells will self-renew from the reinjected components,

of this distinction on its own. Cohen, *Can the Government Ban Organ Sale?*, *supra* note 11. Unless Congress acts, valuable consideration may now be paid for hematopoietic stem cells obtained by peripheral blood apheresis in the states covered by the Ninth Circuit.

27. Complaint at 13, *Flynn v. Holder*, No. 2:09-cv-07772 (C.D. Cal. Oct. 26, 2009). MoreMarrowDonors.org (“MMD.org”) is the nonprofit. All of the named plaintiffs are members of MoreMarrowDonors.org, and two of them are board members.

28. *Id.* at 8–9. Plaintiff Mark Hachey is the father of a child who is Caucasian-Filipino. Plaintiff Akim DeShay is African American. Shaka Mitchell, cofounder and President of MMD.org is African American.

29. For a detailed description of what is involved in donation by apheresis and donation by aspiration *see Flynn*, 684 F.3d at 861.

while the infusion of the donor's blood stem cells will hopefully reconstitute the recipient's immune system.³⁰

The great success of bone marrow transplants for blood disorders is due to the ability to match donors and recipients with sufficient specificity to reduce the chance of rejection or "graft vs. host" ("GVH") disease, in which the newly transplanted blood and immune system cells attack the host recipient's tissues. GVH can be fatal or result in serious lifelong medical complications. It will occur to some extent in all transplants except those from an identical twin, but its intensity will depend on the closeness of the match. Finding a nonsibling close match is extremely difficult for patients with a more diverse genetic heritage, such as African Americans or those of mixed race parents, because they have the most heterogeneous or rarest marrow-cell types.

Other than having a well-matched donor within one's family, it is all but impossible for a patient to find a compatible unrelated donor on her own. The only practical way of matching donors and recipients is to create an enormous database cataloguing the marrow-cell types of people who have agreed to serve as donors if the need ever arises for their specific marrow-cell type.³¹ Since 1986, the federal government has funded a national registry of prospective donors that now lists over seven million potential donors. However, a sizeable fraction of donors cannot be located when they are matched with a recipient, and some fraction of those who can be located are not willing to donate. Caucasian patients can find an available and willing matched donor about 75% of the time, Hispanic patients about 45% of the time, Asian Americans, 40% of the time, and African-American patients only 25% of the time.³²

MoreMarrowDonors.org thought that a pilot program offering "strategic financial incentives to marrow-cell donors" would increase the number of donors, especially for hard to find African-American matches.³³ It hoped that by providing compensation more individuals

30. About 25% of donations are now by aspiration, which provides a purer product than the more recently developed PBSC apheresis. The statistics on risk do not distinguish between the two methods. No deaths have been reported from 35,000 stranger donations in the United States over the last twenty-five years and the number of adverse events, most of which clear up in a few hours, is less than 1%.

31. Complaint at 25, *Flynn v. Holder*, No. 2:09-cv-07772.

32. *Id.* at 26-27.

33. *Id.* at 27. The patient, family, and physician plaintiffs are members of MMD.org, are willing to use donors recruited in this way, and support creation of the program. Like MMD.org, they are deterred by the threat of NOTA's criminal sanctions from doing so.

with rare marrow-cell types would be encouraged to sign up for the national registry, stay in touch, and then if matched, follow through with the donation process. Third-party philanthropists would provide the funds for the awards, which would be paid only to individuals who signed up with MMD.org and its national registry, notified the transplant doctor of their participation, and presented medical proof that the donation occurred. In its initial phase, compensation would be paid only to minorities and persons of mixed race since they were the most likely to have the rarest marrow-cell types.

MMD.org's plan to offer strategic compensation to minority marrow-cell donors is defined as organ-selling under NOTA, making it a felony punishable by up to five years in prison.³⁴ Section 274(e) defines "human organ" as among other things, "any subpart" of human "bone marrow," which necessarily includes loose marrow cells and stem cells, which are the components actually removed from a donor's bone marrow and transplanted into the patient.³⁵ The specific incentives of MMD.org's pilot program—the scholarship, housing allowance, or charitable gift—do not fall under any of the statutory exceptions for expenses and thus, are illegal under the act.³⁶

The complaint asserted that Congress included bone marrow in NOTA by "mistake." The bill sent to President Reagan in 1984 for his signature stated that the "term 'human organ' is not intended to include replenishable tissues such as blood or sperm."³⁷ The Act's final language excluded blood, sperm, and eggs from its prohibitions, but for no apparent reason left out an exception for paying marrow donors. Yet bone marrow is replenishable and retrieving it whether by aspiration or apheresis poses no risk beyond that found in blood or egg donation.³⁸ This made little sense since the main goal in enacting the ban was to outlaw markets in solid organs such as kidneys to prevent wealthy patients from exploiting poor donors and leaving them with a permanent organ deficit after invasive surgery.³⁹

34. 42 U.S.C. § 274e(a)-(b) (2006).

35. 42 U.S.C. § 274e(c) (2006).

36. These exceptions are for processing, transportation, and other medical expenses and for renewable or plentiful tissue such as blood, sperm, and eggs. 42 U.S.C. § 274e(c)(2).

37. Complaint at 34–35, *Flynn v. Holder*, No. 2:09-cv-07772.

38. *Id.* at 34. The complaint alleged that donation of marrow cells by needle aspiration is "no more dangerous than getting one's wisdom teeth pulled," and has less risk to the donor than the hyperstimulation of the ovaries and transvaginal aspiration of oocyte follicles needed to obtain donor eggs.

39. *Id.* at 33.

A. Apheresis Not Within Ban on Payment

The Ninth Circuit Court of Appeals reversed the district court's dismissal of the complaint in *Flynn* for failure to state a claim.⁴⁰ It upheld on statutory grounds the complaint's argument that retrieving hematopoietic stem cells by PBSC apheresis was not illegal under the statute, but rejected its claim that the ban on paying for bone marrow by aspiration was not covered by the law and was constitutional under a rational basis standard.⁴¹

Because the apheresis method did not exist in 1984, the court had to construe the words of the statute to see what they implied about extraction of stem cells by apheresis.⁴² Most significant here is that NOTA omits "blood" from its list of "human organs" in the statute and regulations.⁴³ The court rejected the government's argument that the statute's inclusion of "bone marrow" in its ban on payment included "any subpart thereof," which would include hematopoietic stem cells formed in the bone marrow.⁴⁴ The government argued that since those stem cells mature into blood cells and platelet cells in the marrow, they are "'subparts' of the bone marrow, even when those stem cells are obtained through apheresis, which is to say, from blood flowing through the veins."⁴⁵ The court found that this proved too much. If everything that came from the bone marrow is a "subpart thereof," the statute would prohibit compensating blood donors since the red and white blood cells that flow through the veins come from the bone marrow, just like hematopoietic stem cells.⁴⁶ Yet the government conceded that the statute doesn't cover blood donations.⁴⁷

The court also found that such an interpretation conflicts with ordinary usage.⁴⁸ The bloodstream consists of plasma containing red and white blood cells, stem cells that will mature into either cell type, and other substances that come from elsewhere in the body, such as vitamin B12, which is found in the blood after it binds with an

40. *Flynn v. Holder*, 684 F.3d 852, 865 (9th Cir. 2011).

41. *Id.* at 862. The legal significance of this difference was not briefed by the parties. *See supra* note 26.

42. *Id.*

43. 42 U.S.C. § 274(e) (2006).

44. *Flynn*, 684 F.3d at 861.

45. *Id.* at 863.

46. *Id.*

47. *Id.* at 864.

48. *Id.* at 863.

intrinsic factor in the small intestine. The government's argument would treat vitamin B12 as "a subpart" of the intestine, and ban it under regulations that prohibit paying donors for their intestines "or subparts thereof."⁴⁹ As the court notes, "every blood draw contains some vitamin B12, and we still call the red liquid 'blood,' not 'guts.'"⁵⁰ Likewise, every blood draw includes some hematopoietic stem cells. All that differentiates the blood draw in PBSC apheresis from the blood drawn from a compensated blood donor, other than the filtration process, is the drug given before the draw to stimulate stem cell production.

The court then concluded that the word "subpart" refers to the organ from which the material was taken, not the organ in which it was created.⁵¹ Thus, once the stem cells are in the bloodstream, they are a "subpart" of the blood, not the bone marrow. By contrast, paying for part of the liver for a liver donation would violate the statute because of the "subpart thereof" language—a liver lobe is a subpart of the liver. But taking something from the blood that was created in the marrow takes only a subpart of the blood, and thus is not part of the ban on paying money for "an organ . . . or any subpart thereof."⁵²

This statutory interpretation, narrow though it may be and applicable only in the states covered by the Ninth Circuit, opens the door to paying donors for extraction of hematopoietic stem cells from the bloodstream through apheresis. It is not clear whether MMD.org will go forward with their plan limited to donation by apheresis. In any case, other bone marrow registries might use financial incentives for their efforts within the states of the Ninth Circuit to recruit people to their registry and then to have them donate if they are a match.⁵³

49. *Id.*

50. *Id.*

51. *Id.*

52. *Id.* The court also rejected the government's argument that Congress did intend "bone marrow" to mean something different from ordinary usage because of the enactment of the Stem Cells Therapeutic and Research Act of 2005 "to provide for the collection and maintenance of human cord blood stem cells for the treatment of patients and research." *Id.* at 864. The definition of bone marrow in that statute, however, was contained in a different "part" of 42 U.S.C. § 274-1, and thus did not alter the meaning of "bone marrow . . . and any subpart thereof" in the section of the statute at issue. *Id.*

53. Although the bone marrow registries have been united against payment, there is competition among them, and some might decide to pay for donations by apheresis. For the efforts of a large private registry to recruit donors, see Thomas Caywood, *Officials Rip Health Chain's Aggressive Bone-Marrow Campaign*, WORCESTER TELEGRAM & GAZETTE, Dec. 17, 2010, available at <http://www.boston.com/news/local/massachusetts/>

Because it is not within the statutory ban, there was no need for the court to decide whether prohibiting compensation for PBSC apheresis was constitutional. If Congress chooses to revise NOTA to undo this interpretation, then constitutional issues of rational basis and stricter scrutiny will arise.

B. Rationality of NOTA's Ban on Paid Marrow Donations by Aspiration

Although the plaintiffs directed most of their arguments to the apheresis method, they also attacked the ban on payment for stem cells obtained by the traditional method of aspiration. The court found that NOTA banned payments for bone marrow aspiration because it was the bone marrow itself that was recovered, not just blood that had been derived from bone marrow as in the apheresis method. Addressing the plaintiffs' claim that such coverage is a violation of equal protection because the act exempted other forms of renewable tissue, such as blood and sperm from the ban, and riskier procedures such as egg donation, the court applied rational basis review and upheld its application to aspirated bone marrow.

As noted above, the inclusion of bone marrow in NOTA's prohibitions on payment may very well have been an oversight or mistake. Bone marrow cells are renewable and inexhaustible, and there is almost no risk in removing them either by apheresis or needle aspiration, though the latter is more intrusive than donating blood or sperm.⁵⁴ Paid donation of eggs, which are plentiful but not renewable, is also intrusive and more risky, and yet legal in all but one state.⁵⁵

articles/2010/12/17/officials_rip_health_chains_aggressive_bone_marrow_campaign.
(Describing a recruitment drive for Caitlin Raymond International Registry by a Massachusetts hospital chain conducted in New Hampshire that used models in short skirts and spike heels to entice people to sign up for its bone marrow registry while allegedly misleading consumers about the costs of testing, which were then billed to their insurance companies for as much as \$4,300 per test).

54. One registry states that thirty to forty hours of time may be required for a donation. Cell collection by apheresis will require daily injection of filgrastim for four days before collection, which takes about four to six hours during one or two consecutive days. Many donors experience flu-like symptoms, such as headaches, bone and muscle achiness, and fatigue. Most side effects subside within 48 hours of donating. Donation by aspiration is a half-hour procedure done under general anesthesia, and most donors are discharged at the end of the day. Many donors experience some pain, bruising, and stiffness for up to two weeks after their donation. Within a week of donating most donors are able to return to work, school, and most regular activities. DKMS AMERICAS, *Get Educated*, available at <http://www.dkmsamericas.org/educate>.

55. See IND. CODE ANN. § 35-46-5-3 (West 2012). Several states, however, make it a crime to pay for an egg donation for research, even as they allow payment of eggs for use by infertile women.

There are advantages to the aspiration method since a richer, more concentrated sample of stem cells is obtained than would be in peripheral blood, and donation by that method may be necessary for younger recipients.

Nevertheless, it is a truism of both due process and equal protection analysis that the state need not be perfect in drawing lines. Regulatory legislation “is not to be pronounced unconstitutional unless in the light of facts made known or generally assumed it is of such a character as to preclude the assumption that it rests upon some rational basis within the knowledge and experience of the legislators.”⁵⁶ The standard drawn by *Williamson v. Lee Optical Co.* is even more forgiving of roughly drawn measures.⁵⁷ The Court will not intervene even if a measure “exact[s] a needless, wasteful requirement.”⁵⁸ It is enough that the legislature “might have concluded” that it served a useful purpose, even if the law is not “in every respect logically consistent with its aims.”⁵⁹ As the Court famously stated, “[i]t is enough that there is an evil at hand for correction, and that it *might have been thought* that the particular legislative measure was a rational way to correct it.”⁶⁰

Under the generous rational basis tests of *Carolene Products* and *Lee Optical*, the Ninth Circuit had an easy time finding that the exclusion of paid marrow-cell donations from NOTA’s exceptions—that is, that the act banned payment for them—was constitutional. The court found that either policy or philosophical concerns about paid donation satisfied rational basis review.

On the policy side, the court found it enough that Congress “may have been concerned that exploitive market forces could be triggered” if bone marrow or other organs could be bought or sold.⁶¹ Existing illegal markets in organs extracted by fraud or force by organ thieves might be stimulated by paying for organ donation (including bone marrow by aspiration). Compensation might also degrade the quality of organ supply by inducing potential donors to lie about their medical history in order to make their organs marketable. The \$3,000

56. *United States v. Carolene Products*, 304 U.S. 144, 152 (1938). This begs the question of what “an ordinary commercial transaction” is, but the category is broad and capacious and would easily encompass payments for bone marrow donations.

57. 348 U.S. 483 (1955).

58. *Id.* at 487.

59. *Id.*

60. *Id.* at 488 (emphasis added).

61. *Flynn v. Holder*, 684 F.3d 852, 859 (9th Cir. 2011).

housing subsidy, scholarship or charitable donation is not too small for people of low income to have these effects. Or so Congress might believe.⁶²

Note that the court addressed the potential problems with paid organ donations in a general manner and assumed that they would also apply to paid marrow donation by aspiration, even though the risk and harm profile is quite different than paid donation of solid organs.⁶³ For example, the risks of paid donation for a renewable tissue like bone marrow are much less pronounced than the risks of paid kidney donation, and depending on the amount of compensation, the incentive to lie about medical history or the potential for unfair exploitation may be much lower. Under *Carolene Products*, the inclusion of a particular item or article would have to meet the rational basis test, not just the overall statute. While it's unclear whether the *Flynn* court is addressing the larger question of solid organ donation or marrow donation by aspiration, presumably its analysis would apply to both kinds of paid donation.

On the philosophical side, Congress might have been concerned about the instinctive revulsion people feel at denial of bodily integrity and removal of flesh from one human for use by another, especially when "commodification" or money is involved. Hence our use of the term "donor" rather than "vendor" or "seller," and the qualms that one feels at someone selling their kidney to feed their family.⁶⁴ It doesn't matter that these philosophical reasons are "in some respects vague, in some speculative, and in some arguably misplaced," and that there are strong contrary views.⁶⁵ Congress need have only a rational basis, not a perfect fit, for its categories, and may treat

62. *Id.* It did not mention additional grounds for the ban cited by leading transplant and transfusion organizations, such as the effect of paid marrow donors replacing those willing to donate for purely altruistic reasons or the ethical problem of putting a physician in the morally dubious position of carrying out medical procedures solely or partially so that sellers might profit. See *Leading Transplant and Transfusion Organizations Join Forces in Effort to Keep Bone Marrow Donation Voluntary*, BUSINESS WIRE, Mar. 22, 2010, available at <http://www.businesswire.com/portal/site/home/permalink/?ndmView>.

63. The same question would arise if Congress acted to bring paid apheresis within the NOTA's prohibitions. See *infra* Part III.A.

64. The court here drew heavily on Leon Kass' reliance on taboos against cannibalism, defilement of corpses, and necrophilia. *Flynn*, 864 F.3d at 861; LEON R. KASS, LIFE, LIBERTY AND THE DEFENSE OF DIGNITY: THE CHALLENGE FOR BIOETHICS 183 (2002). Of course, the revulsion may stem less from analogies to cannibalism and necrophilia than from a social system that leaves persons in a situation in which selling their tissue or organs is a rational choice. *Id.* at 862.

65. *Id.* at 861.

comparable or riskier cases, such as paid egg donation, differently. The distinction that Congress drew between bodily material that is and is not compensable has a rational basis, and that is all that is needed to satisfy equal protection.⁶⁶

Again, the philosophical arguments seem more applicable to paid donation of solid organs from live or cadaveric sources, rather than aspiration of bone marrow, which is hardly cannibalistic and not inconsistent with many other paid practices, such as payments to research subjects, surrogate mothers, egg donors, and workers in risky or arduous settings. A rational basis test, however, allows the state to draw loose lines based on conjecture and speculation and that is what Congress has done.

III. Strict Scrutiny for Bans on Paid Marrow Donations

The ease of satisfying rational basis review in *Flynn v. Holder* for aspirated bone marrow, however, does not settle the matter of constitutionality if heightened scrutiny under due process or equal protection applied.⁶⁷ Before turning to the argument in favor of stricter scrutiny, I will address the effect of strict scrutiny if applied to the ban on paid marrow donations.

Suppose that Congress after *Flynn v. Holder* amends NOTA to cover bone marrow transplants by apheresis, which the Ninth Circuit found to be outside of the statute. The plaintiffs in *Flynn v. Holder* again file suit against NOTA, repeating their arguments about the lack of rational basis and adding arguments about the need for stricter scrutiny.

For the sake of simplicity, I will assume that there is full and proper screening of the donor's health, that the donor understands the risks and voluntarily chooses to undergo them, and that the payments in this case are those originally proposed by MMD, and not

66. Moral revulsion directed at particular groups, such as homosexuals, may not even fit rational basis. See *Romer v. Evans*, 517 U.S. 620, 632 (1996); see also *Lawrence v. Texas*, 539 U.S. 558, 574 (2003).

67. The standard account of strict scrutiny is compelling state interest and no less restrictive alternatives, but the analysis need not be so rigid or doctrinaire. Sometimes the stricter standard might be put in intermediate scrutiny terms as occurs with classifications on the basis of sex: does the statute "serve important governmental objectives and is [the classification] substantially related to achievement of those objectives." See *Craig v. Boren*, 429 U.S. 190, 197 (1976). Ultimately, the question is whether the statute's harm to the protected interest is out of proportion to its goals, with the burden on the government to show that justification. See *United States v. Alvarez*, No. 11-210, slip op. at 1 (U.S. June 28, 2012) (Breyer, J., and Kagan, J., concurring) (holding that the Stolen Valor Act violates the First Amendment).

direct cash payments. However, cash payments may make no difference in the paid marrow donation context because the risks are relatively slight, and NOTA bans both cash and noncash consideration.

A. Ban on Paid Apheresis

Supporters of the ban of paid donation by apheresis would make the same arguments they made in *Flynn v. Holder*, in which the court found a rational basis for banning marrow donations by aspiration though not by apheresis.⁶⁸ Before turning to stricter scrutiny, the court would have to address the rational basis argument in the context of paid apheresis, which its previous statutory analysis had avoided. The outcome would depend on whether the court would apply rational basis with more muscle than is customarily done. A court that is more demanding of rational basis might well find that the ban on paid apheresis is invalid because it is so similar to paid blood donations, but courts are generally reluctant to invalidate on that basis.⁶⁹

Assuming that the court found that rational basis was satisfied, it would be difficult to find that it met stricter scrutiny.⁷⁰ For example, the belief that a marrow donation that rests on a “purely altruistic desire to help others is safer than one that relies on personal gain” is certainly minimally rational in that it is more likely to ensure that donors are truthful about their family and medical history and thus more likely to be free of infectious diseases. But banning apheresis donations may or may not add any significant protection to recipients. The donors, like other blood donors, would be screened for HIV and other infectious diseases. The slight possibility that they would lie or hide something that would not be picked up by other tests seems too speculative to justify banning the payments for apheresis donations that may be necessary to save a patient’s life.

Similarly, the idea that paid donors might be so influenced by possible financial gain to ignore the health risks associated with

68. See *supra* note 40.

69. When the disparity between the state’s purpose and the reasonableness of the statutory classifications is great enough, courts occasionally find that even loose rational basis is not satisfied. Compare *Craigsmiles v. Giles*, 312 F.3d 220 (6th Cir. 2002) (no rational basis for requiring that sellers of caskets be licensed as funeral home operators), with *Powers v. Harris*, 379 F.3d 1208 (10th Cir. 2004) (rational basis satisfied in funeral operator license requirements for casket sellers).

70. A court reluctant to invalidate here under rational basis may be even more reluctant to find the need for strict scrutiny.

donation is at best minimally rational if the risks are the same as donating blood. While the possibility of financial gain may be a factor in a decision to donate, this possibility is such a minimal risk that undue inducement hardly seems to be the proper term.⁷¹ Coercion or compulsion by third-parties who might profit in some way from the designated compensation is also highly speculative.⁷² None of these concerns should satisfy heightened scrutiny in the plaintiffs' as-applied challenge to the amended statute.

Compensating donors might also deter those who are willing to donate for purely altruistic reasons.⁷³ For example, it might make the National Bone Marrow Donor Program and its affiliates less effective in signing potential donors up without payment, but that is one of the advantages of paid donations—that it induces more donors to sign up, even if fewer will volunteer without the incentives. But as seen with blood, the existence of a paid system coexists quite nicely with a truly voluntary system. Also, it is not clear why the threat to a purely altruistic system is so important that it would justify denying needy patients who would not otherwise receive a stem cell transplant unless apheresis was paid.

Finally, there is the additional moral or philosophical concern about transacting for body parts.⁷⁴ But paid blood donations are already allowed, and doctors and health care workers who administer the treatments are paid, so it is difficult to see how the rewards provided to apheresis donors pose a different threat here simply because the donations are used for blood disorders and cancers. It would stretch credulity to say that it does, and no one would pretend that it satisfies a heightened scrutiny.

B. Ban on Paid Donation by Aspiration

A more likely scenario would be that Congress does not amend NOTA to ban paid apheresis, which under *Flynn* would leave NOTA's ban on paid donation by aspiration still applicable. Having seen that ban would meet a minimal rational basis standard, the

71. See Ezekial Emanuel, *Undue Inducement: Nonsense on Stilts*, 5 AMER. J. BIOETHICS 9–13 (2005).

72. Since they would first have to register, and then go through with the donation after a matched donor is found, coercion or compulsion by a third party would be more focused on the latter stage.

73. For more on the “crowding out” issue, see Mahoney, *supra* note 14, at 25–26; see *infra* notes 93 and 193.

74. These are the corruption issues discussed by Michael Sandel and Glenn Cohen. See Cohen, *supra* note 8 at 691.

question is whether banning paid donations by aspiration could meet stricter scrutiny.

One problem for the plaintiffs would be showing that the ban on paid aspiration would interfere or burden the right to receive a hematopoietic stem cell transplant if paying for stem cells by apheresis is legal. Would a patient gain anything by paid aspiration if apheresis would do as well?⁷⁵ In fact, 25% of marrow donations are by aspiration. Doctors may prefer the richer supply of stem cells that is obtained when retrieved directly from the bone marrow, particularly for younger patients or when there are contraindications for the drugs used to stimulate the cells collected by PBSC apheresis.⁷⁶

Inserting a needle into the hip bone under general anesthesia to retrieve marrow is minimally risky to the donor though it may be more painful, leave soreness, and require time off from work, school, or other activities.⁷⁷ So the question is whether these inconveniences and effects are so great that a financial incentive to compensate for them would exploit a potential donor's financial need in such an unacceptable way that justifies denying a lifesaving marrow donation. This question must be asked of the other concerns: less safe marrow, the riskiness of the donation, the threat of fraud, coercion, or compulsion, the loss of a purely altruistic donation system, and the like.⁷⁸ None of those concerns appear to be so substantially advanced by the ban on paid aspiration that they justify denying patients or donors who would benefit from marrow collection that avenue.

There is also the problem that more risky and painful procedures for money are permitted by NOTA, such as paid egg donation for research or infertility treatment, which involves hormonal stimulation, transvaginal retrieval, and the risk of ovarian hyperstimulation syndrome, and surrogate motherhood, which involves the risks of pregnancy and childbirth.⁷⁹ Also, federal law allows research subjects to be paid for painful and intrusive

75. In the abortion setting, the Court held that there may be no difference if the outcome and the risk are the same. See *Gonzalez v. Carhart*, 550 U.S. 124, 162–67 (2007) (slight preference for partial birth abortion as aiding a woman's health did not create an undue burden on the right to abortion when a legislature finds no advantage).

76. Claudia Anasetti, Brent C. Logan, Stephanie J. Lee et al., *Peripheral-Blood Stem Cells versus Bone Marrow from Unrelated Donors*, 367 *NEJM* 16 (2012) (bone marrow may reduce the risk of chronic graft versus host disease).

77. See *DKMS Americas*, *supra* note 54.

78. See *supra* text accompanying notes 72–75.

79. Institute of Medicine, *Assessing the Medical Risks of Human Oocyte Donation for Stem Cell Research: Workshop Report* (7-12 Linda Giudice et al., eds., 2007).

experimental procedures funded by the government.⁸⁰ Arguably the benefits are less direct for the infertile couple, who might have other alternatives, such as adoption or family donors, than is the continued life for the marrow recipient. Also, the benefits of clinical research are much less certain than the benefits of a necessary transplant and are much less direct. At bottom, the different treatment seems to be aimed at the moral objection to paying a person to undergo risk and intrusion for money. Of course, moral sentiments alone do not satisfy strict scrutiny.⁸¹

IV. The Case for Strict Scrutiny

Having seen how heightened scrutiny would require the government to show a much stronger justification to ban paid apheresis or aspiration than it needs under rational basis review, I now address the case for heightened scrutiny. That case rests on whether there is a (negative) constitutional right to medical care from a willing doctor to a willing patient of a safe and effective medical treatment such as organ transplant.

The case for strict scrutiny hinges on the preservation and importance of life and health and whether restrictions on pursuing that interest, such as a ban on paid donations, are unconstitutional without a strong showing of governmental need to limit them. I will focus on the right to have an organ transplant, which would include the right to pay a doctor and donor for the services needed to obtain it, but this same issue would arise with access to cancer drugs, tissue cloned from embryonic stem cells, and many other situations.⁸² Access to these treatments are, of course, only a small part of the health services that people need and pale beside the challenges of providing affordable health care to everyone.⁸³ But they are crucial for those in need of organ transplants or other medical treatments for which they can pay but which the law denies them the

80. See Emanuel, *supra* note 71.

81. See *Griswold v. Connecticut*, 381 U.S. 479, 497–99 (1965) (Goldberg, J., concurring) (moral objection to birth control not a compelling interest); *Lawrence*, 539 U.S. at 577 (moral objection to homosexual sodomy not a rational basis for legislation); see *infra* notes 204–207 and accompanying text.

82. Paying for infertility treatment requiring a gamete donor or gestational surrogate mother is another example, but that right may be independently protected as part of procreative liberty. See John A. Robertson, *Assisting Reproduction, Choosing Genes, and the Scope of Reproductive Freedom*, 76 GEO. WASH. L. REV. 1490–1513 (2008).

83. See Patient Protection and Affordable Care Act, Pub. L. No. 111-148, 124 Stat. 119 (2010) (upheld in part in *Nat'l Fed'n of Indep. Bus. v. Sebelius*, 132 S. Ct. 2566 (2012)).

access to do so. Why should they not have a right to get them from a willing donor or provider when these treatments are essential to preserve their lives?

Eugene Volokh has elegantly presented this case, terming it a right of medical self-defense.⁸⁴ His article draws on the common law tradition of lethal self-defense, which applies even if the attacker is innocent or the defender mistaken that there is a viable threat.⁸⁵ He sees a constitutional basis for the standard case of self-defense and would extend it to medical needs as well.⁸⁶ Indeed, the Supreme Court, in holding that the Second Amendment protected the right to have a handgun in the home drew upon the natural right of self-preservation as the source of its reading of the Second Amendment.⁸⁷ Volokh also argues that the right to abort a viable fetus to protect a woman's life or health is further recognition of such a right, as is the right to have burdensome medical treatment withheld, even at the cost of one's life.⁸⁸ He argues that this right includes the right to take on risks, such as the use of experimental drugs under Phase II FDA approval for clinical research.⁸⁹

Medical self-defense, in one sense, is an apt and resonant term for the right to safe and effective medical care.⁹⁰ To protect one's body from the effects of trauma, virus, cancer, infection, etc., is to defend one's self in that sense. Yet trauma, illness, and disease are not agents or individuals directly attacking one, the usual terrain of self-defense. As Volokh points out, however, self-defense applies against animals and persons who due to infancy or mental illness are not responsible agents.⁹¹ A virus, bacteria, or a cancer cell gone awry is also an intruder or occupant of sorts who is acting outside of

84. Volokh, *supra* note 20. Professor Volokh's article was published before the en banc decision in *Abigail Alliance* rejecting a right to use an unapproved experimental drug, and before the litigation in *Flynn*.

85. *Id.* at 1831.

86. *Id.* at 1819–20.

87. *District of Columbia v. Heller*, 554 U.S. 570, 616 (2008).

88. Volokh, *supra* note 20, at 1825–26.

89. *Id.* at 1814–15 (referring to *Abigail Alliance v. Eschenbach*, 495 F.3d 695 (D.C. Cir. 2007) (en banc), discussed *infra* Part VI).

90. See *Washington v. Glucksberg*, 521 U.S. 702 (1996); see *infra* Part V (discussing the need for narrow specification of a new due process right).

91. Volokh, *supra* note 20, at 1817 (discussing the right to kill threatening bears or rattlesnakes protected by federal law).

ordinary bounds, though strictly speaking, not outside the law.⁹² The concept of self-defense should thus apply to the situation caused by a smaller, biologic attacker, especially when it masses in such multitudes as to overwhelm the body. Self-defense in this instance would be understood as a right to use safe and effective medical treatments to ward off those attacks.

In another way, however, pushing the right of access to safe and effective medical treatment into the category of self-defense is not apt. The cost of self-defense is the life of an innocent attacker (not relevant to disease) or an innocent bystander due to the defensive actions of the person who reasonably thinks she is being attacked. Invalidating a ban on a safe and effective medical procedure that is independent of other persons would not have those costs. However, invalidating a ban on paid organ donations would mean that paid donors would bear the cost of the loss of the organ sold or the morbidity that occurs in the process of obtaining it.⁹³ If the donor is fully informed and makes an intelligent and knowing choice to donate for money, these costs are lessened though they still exist. Such costs may be worth the preservation of the life of the recipient, just as a paid bodyguard knowingly takes on the risk of death or injury as an aspect of the right to self-defense. To be acceptable, however, there must be a further balancing of the donor's interests versus the recipient's interests. The question under strict scrutiny would be whether the interests at stake in barring a system of paid donation are sufficiently greater than allowing the current system of unpaid donation, which denies needy recipients the opportunity to extend their lives through a system that increases organ supply through financial rewards.

With this qualification in mind, medical self-defense thus may be articulated as a right against unjustified governmental interference with access to safe and effective medical treatment. By prohibiting payment for the life-saving medical means to attack disease or organ failure, the Legislature denies patients, and the doctors supporting

92. The innocent attacker's actions are illegal although excusable. *See* TEX. PENAL CODE ANN. § 8.01(a) (West 2011) (providing insanity as an affirmative defense to prosecution). Nonhuman animals are outside of the law in that they are not persons and cannot be held accountable, though they can be killed or confined. The idea of "punishing" a virus, cancer cell, or bacteria is obviously metaphoric.

93. There may also be costs to those who object generally to paid donations or those who, due to such a system, might not receive future transplants from altruistic donors. For further discussion of the crowding out argument against paid donation, *see* Mahoney, *supra* note 14, at 25–26.

them, the right to self-preservation, a right so basic it should be treated by the Court as fundamental—or at least subject to a greater scrutiny than the standard rational basis analysis of *Carolene Products* and *Lee Optical*.

In short, the ban on paid organ donation deprives patients in need of such transplants the “life” and “liberty” specified in the Fifth and Fourteenth Amendments’ clauses.⁹⁴ Being alive is a necessary precondition to the exercise of other rights. Rights to free exercise of religion, to free speech, to assembly, to association, to vote, to raise children, to sexual and reproductive autonomy, or to pursue any right or interest depends on possessing life itself. Because life is a primary good on which realizing all other goods depends, it should have at least the same protection when “life” and “liberty” are specified in the constitutional text.⁹⁵ State deprivation or interference with life, therefore, should require at least as strong a justification as is needed for depriving a person of other fundamental liberties, or at least a scrutiny stricter than rational basis.⁹⁶

A full exposition of the right to use safe and effective medical treatments would extend beyond lifesaving treatments such as organ transplants. One cannot pursue liberty interests if one is unable to participate in ordinary life activities due to severe disability or pain. Thus, the right to use safe and effective medical treatments could also be grounded in liberty rights to be free of pain or disability.⁹⁷ I leave the scope of that right to future analysis.

The Second Amendment cases give support here, but they are distinguishable by the Second Amendment’s more explicit language.

94. See *Cruzan v. Dir., Mo. Dep’t of Health*, 497 U.S. 261, 281 (discussing the right to life of born persons, not whether unborn persons have a right to be born).

95. John Rawls’ term “natural primary good” would include life and health because they are necessary preconditions to realizing all other goods. JOHN RAWLS, *A THEORY OF JUSTICE* 62 (The Belknap Press of Harvard Univ. Press 1971) (“Other primary goods, such as health and vigor, intelligence and imagination, are natural goods; although their possession is influenced by the basic structure, they are not so directly under its control.”). One might think of free speech rights as a constitutional “primary good,” since freedom of thought and speech has been described as “the matrix, the indispensable condition, of nearly every other form of freedom.” *Palko v. Connecticut*, 302 U.S. 319, 326–27. Yet it too cannot exist unless a person is alive and in sufficient health to exercise that freedom—an even more primary good.

96. Indeed, a higher level of procedural correctness is required in capital punishments cases precisely because life is at stake. Although these issues are usually framed in Eighth Amendment “cruel and unusual punishment” terms, they share normative roots with the “right to life” component of the Fourteenth Amendment.

97. *Washington v. Glucksberg*, 521 U.S. 702 (1996).

Yes, *District of Columbia v. Heller*⁹⁸ and *McDonald v. City of Chicago*⁹⁹ draw on a natural right to life, which includes repelling one's attacker and having the means to do so. But because of the Second Amendment text and the presence of a physical assailant, the cases are not directly apposite. Still, the notion of self-defense does lend support to the notion of a (negative) right to established health care from a willing doctor to ward off viral, bacterial, or cellular attacks.¹⁰⁰ An organ transplant occurs at the point of attack when—by analogy—there is a need to wield the gun. Banning payment for organ donations is the equivalent of banning payment to buy a handgun or the ammunition necessary to repel an expected invader. However, buying the handgun per se does not threaten the life or health of third-party individuals in the same way that paying for removal of an organ does.¹⁰¹

Adding rights via substantive due process, even one as narrowly specified as a negative right to safe and effective medical treatment to protect life, is always problematic for the Supreme Court. It is poor consolation that the Court has previously done so with rights of family, marriage, child rearing, sexuality, reproduction, and the like, because each step forward is controversial and bitterly fought over. Indeed, the Second Amendment cases, *Heller* and *McDonald*, take an originalist approach but rest on a traditional acceptance of a deeper right of self-preservation or self-defense against attackers. But why should that deeper right of self-preservation or defense be predicated upon a human or mammal attacker, rather than a virus, bacteria, or an immune system gone awry? If people may buy and use handguns to protect themselves from human attackers, even if innocent lives are lost in taking reasonable defensive action, why shouldn't individuals be able to buy organs for transplant or some other medical service when necessary to defeat an even more imminent viral or bacterial attack, and when the donor,

98. *District of Columbia v. Heller*, 554 U.S. 570, 590 (2008).

99. *McDonald v. City of Chicago*, 130 S. Ct. 3020 (2010).

100. A more precise medical analogy to acquiring a handgun for the home before an attack is imminent, would be the right to have an immunization to prevent infectious disease.

101. It might increase the chance that the purchased gun through accident, negligence, or intentional action would be used to kill or injure another person. Consider also the ironies that would exist if the need for the transplant arose from an encounter with an assailant that was not stopped with the patient's use of a handgun. A handgun could also be used to prevent robbery of a health care worker carrying a donated organ into the operating room for the transplant. A gun shop could advertise special programs and weapons for those who are disabled and awaiting an organ donation.

whether paid or unpaid, has intelligently, competently, and knowingly assumed the risks involved?

In principle, that right should also apply, and if burdened by anti-payment legislation, should be recognized by the courts.¹⁰² To make that leap requires an even greater jump across a gap that the Court is now extremely cautious about taking and appeared to reject in *Washington v. Glucksberg* with regard to physician-assisted suicide.¹⁰³ While the Supreme Court is far from admitting the right to safe and effective medical treatment into the due process pantheon, lower courts might occasionally do so.¹⁰⁴ At the very least, such action might prod Congress and state legislatures to look more kindly on legislative proposals to use financial incentives to spur more organ donation.¹⁰⁵

Before turning to medical self-defense challenges to NOTA's ban on paying bone marrow and organ donors, I examine the barriers to recognition of a substantive due process right to medical care presented by *Washington v. Glucksberg* and *Abigail Alliance v. Eschenbach*. A different outcome in *Glucksberg* or *Abigail Alliance* would not necessarily give a person the right to pay donors for organ or tissue donations, but it would shift the burden on government to show there is a more compelling need to justify NOTA's near total ban on paying donors.

V. Getting Around *Washington v. Glucksberg*

A main hurdle to recognition of the right to pay organ donors is the test elucidated in *Washington v. Glucksberg* for the recognition of new substantive due process rights.¹⁰⁶ In rejecting a due process right of dying patients to have physicians assist them in committing suicide, the Court upheld a state ban on physician-assisted suicide on the basis

102. Conservative judges Richard Posner and J. Harvie Wilkinson have criticized the handgun cases as judicial interference with a workable legislative process that had little textual support, which is the frequent criticism of why *Roe v. Wade* was not a constitutionally sound decision. J. Harvie Wilkinson III, *Of Guns, Abortions, and the Unraveling of the Rule of Law*, 95 VA. L. REV. 254 (2009).

103. See *Washington v. Glucksberg*, 521 U.S. 702 (1996).

104. See *id.* The right in question is a negative right against government interference with services or procedures for which the patient will pay. It is not a positive right to have those services provided regardless of ability to pay.

105. NOTA would preempt state experimentation with payments and rewards to organ and tissue donors.

106. See also *Quill v. Vacco*, 521 U.S. 793 (1997) (the Court dealt with equal protection aspects of the same issue).

of a long history and tradition of preserving life. In doing so, it enunciated a methodology for identifying due process rights that could block courts from recognizing new rights. Neither of these grounds, however, should bar a court from recognizing a fundamental right to have safe and effective medical care essential to save one's life, such as an organ transplant.

The terminally ill plaintiffs in *Glucksberg* wanted prescriptions for drugs from their physicians that they could use if they chose to end their suffering. Doctors willing to treat them and an organization devoted to end-of-life care joined the suit. They were successful in the district court, which found that a fundamental right was involved. A Ninth Circuit panel rejected that conclusion and applied rational basis scrutiny to uphold the law.¹⁰⁷ The en banc panel reversed, finding a "due process liberty interest in controlling the time and manner of one's death" that made the law unconstitutional as applied to "terminally ill competent adults who wished to hasten their deaths with medicine prescribed by their physician."¹⁰⁸

The Supreme Court reversed the en banc court. It began "by examining our Nation's history, legal traditions, and practices" and found in almost every state, and indeed throughout the world, that bans on assisted suicide were based on "longstanding expressions of the States' commitment to the protection and preservation of all human life."¹⁰⁹ Even as states moved away from criminalizing suicide, they retained bans on assisting suicide without exceptions for those who were near death. That bar remained even when such individuals authorized living wills, surrogate decision-makers, and withdrawal or refusal of life sustaining medical treatment for at the end of life.¹¹⁰

The Court recognized the Due Process clause guarantees more than fair process and that liberty protects more than the absence of physical restraint. But the Court has been "reluctant to expand the concept of substantive due process because guideposts for responsible decision-making in this uncharted area are scarce and open-ended."¹¹¹ Finding such rights would remove the matter from the arena of public debate and legislative action and risk subtly transforming the Due

107. *Compassion in Dying v. Washington*, 49 F.3d 586, 591 (1995).

108. *Compassion in Dying v. Washington*, 79 F.3d 790, 798 (1996) (en banc).

109. *Washington v. Glucksberg*, 521 U.S. 702, 710 (1996).

110. The one exception was Oregon, which enacted an assisted suicide law in 1997. OR. REV. STAT. § 127.865 (West 2012). Washington has since done so as well. Massachusetts voters will decide in November 2012 whether to adopt a similar law.

111. *Glucksberg*, 521 U.S. at 720.

Process Clause into the policy preferences of members of this Court.¹¹² Chief Justice Rehnquist then articulated a much-cited view about due process methodology:

The Due Process Clause specifically protects those fundamental rights and liberties which are objectively, “deeply rooted in this Nation’s history and tradition,” . . . and [are] “implicit in the concept of ordered liberty” such that “neither liberty nor justice would exist if they were sacrificed.” Second, we have required a “careful description” of the asserted fundamental liberty interest. Our Nation’s history, legal traditions, and practices thus provide the crucial “guideposts for responsible decision making” that direct and restrain our exposition of the Due Process Clause . . . [This] approach tends to rein in the subjective elements that are necessarily present in due-process judicial review.¹¹³

Applying that standard to physician-assisted suicide, the Court found an “almost universal tradition . . . [against] . . . the asserted right to commit suicide with assistance, even for terminally ill, mentally competent adults.”¹¹⁴ To hold otherwise, the Court would have to reverse centuries of legal doctrine and practice to strike down the considered policy choice of almost every state. It distinguished the right to direct the removal of life-sustaining medical treatment, and thus hasten death, assumed in *Cruzan* as rooted to the common-law rule that forced medication was a battery and a long tradition of protecting the right to refuse unwanted medical treatment. That assumption was not “deduced from abstracts concepts of personal autonomy,” as the *Glucksberg* plaintiffs argued, but was entirely consistent with “this Nation’s history and constitutional traditions.” Language in *Planned Parenthood v. Casey* suggesting that many of the rights and liberties protected by the Due Process clause grounded in personal autonomy did not warrant the conclusion that “any and all important, intimate, and personal decisions are so protected.”¹¹⁵

112. *Id.*

113. *Id.* at 720–722 (internal citations omitted).

114. *Id.* at 723.

115. *Id.* at 727.

With the history of the law rejecting nearly all efforts to permit assisted suicide, the Court found that the asserted right is not a fundamental liberty interest, and therefore that Washington's ban need only be rationally related to legitimate state interests. It found that rational basis in several state interests: the preservation of human life, preventing suicide, protecting the integrity and ethics of the medical profession, protecting vulnerable groups from abuse and neglect, and avoiding a slippery slope slide to voluntary and perhaps even involuntary euthanasia.¹¹⁶

A. Organ Transplant as the Reverse of the Right to Die

Glucksberg, however, should not bar recognition of heightened protection for medical care that preserves life. The plaintiffs in *Glucksberg* were seeking a "treatment" that would enable them to die; organ transplant patients are seeking one that will enable them to live. In that case, there was medical disagreement over whether assisted suicide was an appropriate medical treatment.¹¹⁷ There is no medical disagreement about the appropriateness of organ transplant for end-stage organ disease.¹¹⁸ Of crucial importance to the *Glucksberg* Court was the state's long-standing interest in preserving life and preventing suicide, including protecting the lives of poor, elderly, and disabled persons and avoiding both voluntary and involuntary euthanasia.¹¹⁹ Rather than harm those interests, safe and effective organ transplantation advances them.¹²⁰

116. *Id.* at 732. (At least five justices who voted in *Washington v Glucksberg* to uphold a state ban on physician-assisted suicide noted that their vote in that case assumed that terminal sedation and analgesics to control pain that might themselves hasten death were available to dying patients. If the ban on assisted suicide did prevent effective pain relief, there might have been more acceptance of an as-applied attack on it.)

117. The AMA and other physician groups rejected physician-assisted suicide ("PAS") as inconsistent with the doctor's duty to do no harm and blurring the line between harm and treatment. Other doctors thought that PAS was consistent with a doctor's duty to best meet her patient's needs.

118. Nor is there disagreement about whether doctors should be paid for doing organ transplants, though some physician groups may object to paying donors.

119. The Court spoke of the "unqualified interest in the preservation of human life," which existed even though it was "symbolic and aspirational as well as practical." *Id.* at 729. While the reasons cited provide a rational basis for laws against physician-assisted suicide, they would not in all cases provide a compelling justification for such laws. Nor would they prevent reasonable regulation akin to that contained in Oregon's statute authorizing assisted suicide when there has been a two-week delay, a further request, two physician certification of terminal illness, lack of mental impairment or depression, record-keeping and the like. OR. REV. STAT. § 127.865 (1997). Since the law was passed in 1997, 935 people have had prescriptions written and 596 (71 in 2011) have died from ingesting prescribed medications. OR. DEATH WITH DIGNITY ACT ANNUAL REPORT (2011),

A right to use safe, effective, and established medical treatment to save life, such as by organ transplantation, is thus the reverse of the right claimed in *Glucksberg* to end life by assisted suicide. While end-of-life cases involve rights to bring about death, a right to use safe, effective, and accepted medical treatments involve the right to avoid death. Given the long tradition of protecting life, it would be odd if the state were free to adopt laws that threatened life, such as bans on or interference with safe and effective organ transplantation, without a showing of a compelling need for such laws. Unless it showed that need, those laws should be unconstitutional.

In short, the state's commitment to preservation of life should support rather than prevent courts from recognizing a due process right to safe and established medical treatments necessary to protect life. If there is such a right, the state would have the burden of showing sufficiently strong grounds to justify laws that interfere with its exercise beyond conjecture and speculation about harmful effects, as it might do where no fundamental right is involved.¹²¹

B. *Glucksberg's* Due Process Methodology: Ordered Liberty and Narrow Specification

Glucksberg rested heavily on the need to find a right in "our Nation's history and traditions" or what is "implicit in the concept of ordered liberty" such that "neither liberty nor justice would exist if

available at <http://public.health.oregon.gov/ProviderPartnerResources/EvaluationResearch/DeathwithDignityAct/Pages/index.aspx>.

120. Indeed, the availability of transplants will deter people with end-stage organ disease from taking their own life. The state may have reasons related to the interests specified in *Glucksberg* to limit means of organ retrieval for transplant, but not to ban or limit transplants themselves. Once use of transplants is recognized as a protected liberty interest or fundamental right, then the state must show a compelling justification and no less restrictive way for limiting access to them.

121. Nothing in a right to established medical care prevents the state from enacting regulations that are reasonably related to protecting the health and safety of patients through drug approval, medical licensure, and other regulatory efforts. As noted in *Gonzalez v. Carhart*, 550 U.S. 124, 163–64 (2007), "state and federal legislatures [have] wide discretion to pass legislation in areas where there is medical and scientific uncertainty" and "[m]edical uncertainty does not foreclose the exercise of legislative power in the abortion context any more than it does in other contexts." *Id.*

they were sacrificed.”¹²² And it required “a careful description of the asserted fundamental liberty interest.”¹²³

This part of *Glucksberg* brings us directly into the debate over the level of generality in a tradition or historical practice to find that history or tradition supports a claimed new right. One problem is that history and tradition is partially mute and never univocal. One can point to specific past practices that appear to support one’s claim or distinguish them as not fully applicable.

Supporters of a right to medical treatment will argue that a right to use safe and effective medical treatments to extend life or reduce pain and disability is also “deeply rooted in this Nation’s history and tradition.”¹²⁴ Medical practice was not regulated by the states in 1789. Medical licensure began in the 1830s, spurred by the drive to oust itinerant and irregular healers.¹²⁵ The right of licensed doctors to use their clinical judgment in treating the ills of patients has long been recognized as part of their professional domain, even if their professional judgment could not help patients until the development of sulfa drugs and antibiotics in the 1930s.¹²⁶ Unlike claims of rights to abortion and assisted suicide, which had to confront extensive state restriction of those practices at the time of the enactment of the Fourteenth Amendment, there is no comparable tradition of legislative restriction on medical practice other than licensure until well into the twentieth century.¹²⁷ The Food and Drug

122. *Glucksberg*, 521 U.S. at 721. Other courts might approach the matter in a less historicist way, e.g., the more expansive view contained in the plurality opinion in *Planned Parenthood of Southeastern Pennsylvania v. Casey*, 505 U.S. 833 (1992), which *Glucksberg* specifically rejected.

123. *Id.* Recall that the votes for this statement depended on there being adequate alternatives to control pain.

124. *Moore v. City of Cleveland*, 431 U.S. 494, 503 (1977).

125. Paul Starr, *The Social Transformation of American Medicine* 3–60 (Basic Books, 1982).

126. Relying heavily on empirics, medicine in 1868 was still ignorant of Koch’s germ-theory, and had minimally effective anesthesia and antiseptics for surgery. Indeed, doctors relied on leeches, blistering, and bleeding well into the late 1800s. *See id.*; MICHAEL BLISS, *HARVEY CUSHING: A LIFE IN SURGERY* 17–18 (Oxford, 2005). Tort law has generally granted physicians the right to determine what was acceptable practice. *See W. KEETON, D. DOBBS, R. KEETON & D. OWEN, PROSSER AND KEETON ON THE LAW OF TORTS* (5th ed. 1984).

127. The first federal drug law passed in 1914 to control nonmedical drug abuse left physicians free to prescribe cocaine and opiates for legitimate medical purposes. Harrison Narcotics Act of 1914, Pub. L. No. 63-223, 38 Stat. 785; WILLIAM BUTLER ELDRIDGE, *NARCOTICS AND THE LAW; A CRITIQUE OF THE AMERICAN EXPERIMENT IN NARCOTIC DRUG CONTROL* 9 (Chicago 1967); ALFRED R. LINDESMITH, *THE ADDICT AND THE LAW* 5 (Indiana 1965).

Administration, created in 1906, did not begin to exercise premarket approval of the safety and efficacy of drugs and biologics until the thalidomide scandal in 1962.¹²⁸ Those changes did not prevent a doctor from using any approved drug “off-label” for other medical purposes.

The first organ transplant occurred between identical twins in 1954.¹²⁹ Allografting—the use of a non-twin organ usually after death—began soon after and took off in the 1960s with improved tissue matching and immunosuppression.¹³⁰ Laws to enable cadaveric donations and anatomical gifts were passed, making consent and brain death the main focus of legal constraints on organ donation. It was not until 1984 that the first law against paid donations was enacted. While most states have now passed such laws, it is a relatively new tradition, and must be weighed against a deeper and longer tradition of recognizing the right of persons to protect themselves against aggression from human or other sources, and using otherwise legal medical assistance when available.¹³¹ With bone marrow and organ transplants not part of medicine until relatively recently, a judge is perforce constrained to consider the larger principle at stake and how it would apply to laws against paid marrow and organ donations, when they would interfere with access to safe and established lifesaving treatments.

One can read “implicit in the concept of ordered liberty” in a restricted way, but it is equally plausible and reasonable to think of any governmental system of regulating liberty—giving order to the exercise of liberty—as requiring that there be live persons for whom that liberty matters and needs to be “ordered.” If so, a right to use widely accepted safe and effective medical treatments, such as

128. PHILIP HILTS, *PROTECTING AMERICA’S HEALTH: THE FDA, BUSINESS, AND ONE HUNDRED YEARS OF REGULATION* 158–65 (Knopf 2002). After the scandal in 1937 of more than 100 deaths of children given an antimicrobial sulfanilamide preparation dissolved in diethylene glycol, a lethal solvent, the 1938 amendments to the act did require that manufacturers provide drugs that are safe. *Id.*; see Jerry Avorn, *Two Centuries of Assessing Drug Risks*, 367 N. ENG. J. MED. 193 (2012).

129. Joseph E. Murray and J.H. Harrison, *Surgical Management of Fifty Patients with Kidney Transplants Including Eighteen Pairs of Twins*, 105 AMER. J. SURG. 205–18 (1963). Dr. Joseph Murray received the Nobel Prize in Medicine for this work. See also Stefan G. Tullius et al., *Moving Boundaries—The Nightingale Twins and Transplantation Science*, 366 N. ENG. J. MED. 1564 (2012).

130. Murray and Harrison, *supra* note 129.

131. It was a tradition of self-preservation and self-defense that led to the individual Second Amendment right found in *Heller* and then incorporated into the Fourteenth Amendment in *McDonald*.

marrow-cell transplants for blood and immune system disorders and live or cadaveric organ transplants for end-stage organ failure should follow. In that case, the justification for laws that burden access to such treatments, such as bans on paid donation, should be stronger than if the right to defend and prolong one's life were not involved. Limiting the right to safe and effective and widely recognized medical treatments would also satisfy the "narrow specification" prong of *Glucksberg*. In this case it is the right to use safe and effective medical treatments, such as organ transplantation, unless there is a compelling justification for laws that burden access to that treatment.

As a general proposition, courts should defer to legislative choice. There is a wide realm of legislative discretion over the practice of medicine in areas where there is medical and scientific uncertainty, but judicial deference need not mean judicial withdrawal from the field.¹³² Courts do have a role in policing the boundary between an individual's life or liberty and legislative authority.¹³³ Judges, however, will differ on how they read *Glucksberg* and how welcoming they are to new unenumerated rights.

Consider Justice Scalia, a skeptic about most substantive due process rights. In a noteworthy foray into the level of generality debate in *Michael H. v. Gerald D.*, a case involving the childrearing rights of an adulterous father, he argued that one must look to the "most specific level at which a relevant tradition protecting, or denying protection to, the asserted right can be identified."¹³⁴ He went on to note that if "there were no societal tradition either way . . . we would have to consult and [if possible] reason from, the traditions regarding natural fathers in general."¹³⁵ Given the absence of a tradition of state restriction of licensed doctors determining whether to use safe and effective medical treatment, might even Justice Scalia recognize the larger principle of self-preservation and defense against threats to life from illness and disease when there are safe and established medical treatments to counter them?

Most likely not. Judges inclined to a large measure of deference to legislatures will often find originalist or textual reasons for refusing recognition of a "right to receive medical care." Traditions rarely

132. See case cited *supra* note 121 and accompanying text.

133. Laurence C. Tribe, Forward: Toward A Model of Rules in the Due Process of Life and Law, 87 HARV. L. REV. 1, 10–11 (1973).

134. See 491 U.S. 110, 127 n.6 (1989) (state law presuming husband the father of child conceived in adulterous relationship is valid).

135. *Id.*

speak with a single voice. Such a move toward rights status could call into question many aspects of federal or state regulation of drugs, medical and surgical procedures, organ transplantation, and medical licensure. A Supreme Court leery of substantive due process lawmaking might be reluctant to interfere in legislative judgments about tradeoffs between health, safety, and patient needs for therapy, even as they apply heightened scrutiny.

Even if heightened scrutiny is required, the Court might find that government has adequate justification for enforcing such limits on organ donation. Although it is clear that a system of paid organ donations without any regulation would not be viable, a more carefully constructed program to avoid those excesses is a different matter. The paid organ donation proposals discussed below come with protective regulations in place.¹³⁶ Because they could induce donation of more organs and thus save lives, they deserve a closer scrutiny from courts than mere rational basis and conjecture about symbolic and aspirational harms.

VI. *Abigail Alliance v. Eschenbach* and Access to Experimental Drugs

Another barrier to recognition of the right of access to medical treatment is *Abigail Alliance v. Eschenbach*, a case in which a circuit court panel with a conservative justice found such a right but then was reversed by the en banc court.¹³⁷ While *Abigail Alliance* is only one court and other circuits might decide the matter differently, that circuit is particularly influential. That court's reasoning, however, would not bar recognition of such a right when the medical treatment at issue was an established safe and effective treatment, as is organ transplant for end-stage disease.

Abigail Alliance grew out of a young woman's losing battle with late-stage esophageal cancer. She had failed several chemotherapy regimens and wanted to receive a new drug called Iressa, which the FDA had approved only for a Phase II study of efficacy. She was denied access to that drug, and died a few months later. Iressa was eventually approved for lung and colon cancers. Oncologists now use it off-label for other cancers. Iressa, of course, is not a magic bullet.

136. These programs include health and safety screening, robust informed consent, insurance policies and protection for paid donors, and price caps or designated noncash rewards to reduce the chance of coercion, undue inducement, or overly optimistic decisions by people in need of money.

137. 445 F.3d 470 (D.C. Cir. 2006), *rev'd en banc* 495 F.3d 695 (D.C. Cir. 2007).

It was approved based on evidence that it delayed tumor growth for esophageal cancer, not that it extended life significantly. It may or may not even have had that effect for the young woman that sought it.

As a result of this experience the patient's father, the families of cancer patients, and others who thought that the FDA had been too restrictive about approving new cancer drugs formed an organization that sought expanded access to experimental drugs for the terminally ill.¹³⁸ Finding that that access was often barred by the investigational new drug and clinical testing program required by the FDA, the Alliance submitted its own proposals and then a "citizen petition" to the FDA, arguing that there is a "different risk-benefit tradeoff facing patients who are terminally ill and who have no other treatment options," and that a lower evidentiary standard for safety and efficacy should be applied in those cases.¹³⁹ The FDA never responded to the Alliance's citizen petition. The Alliance then sued, arguing that the United States Constitution provided terminally ill patients without other treatment options a right of access to experimental drugs that had passed Phase I clinical testing unless strict scrutiny of the need to deny that access could be shown. The district court rejected its claim, but the circuit court upheld it in a 2-1 decision.¹⁴⁰ The circuit court en banc then reversed the panel decision.

A. The Court's Reasoning

The en banc court began its analysis by citing the current go-to precedent on the reach of substantive due process, *Washington v. Glucksberg*, and the Court's observation that "The Due Process clause specially protects those fundamental rights and liberties which are, objectively, deeply rooted in this Nation's history and tradition and implicit in the concept of ordered liberty, such that neither liberty nor justice would exist if they were sacrificed."¹⁴¹

The Alliance argued that the right it claimed could be found in that history and tradition because the government never interfered with the judgment of individual doctors about the medical *efficacy* of

138. *Abigail Alliance*, 495 F.3d at 697.

139. *Id.* at 699.

140. One of the two votes in favor was from Judge Douglas Ginsburg, generally known as a judicial conservative.

141. *Washington v. Glucksberg*, 521 U.S. 702, 720-21 (1996). It also required a "careful description of the asserted fundamental right interest." *Id.* But that requirement played no further role in *Abigail*, nor does it in most other cases.

particular drugs until amendments to the FDCA in 1962. The court, however, found that “it must show not only a tradition of access to drugs that have not yet been proven effective, but also a tradition of access to drugs that have not yet been proven safe.”¹⁴² Examining that history, legal tradition, and practice on both safety and efficacy grounds, the court found that “our Nation has long expressed interest in drug regulation, calibrating its response in terms of the capabilities to determine the risks associated with both safety and efficacy.”¹⁴³

The court also rejected the Alliance’s claim that completion of Phase I testing shows that drugs are safe enough for terminally ill patients. The fact that a drug is then safe “for limited clinical trial testing in a controlled and closely-monitored environment after detailed scrutiny of each trial participant does not mean that a drug is safe for use beyond supervised trials.”¹⁴⁴ It found that FDA regulation of post-Phase I drugs is entirely consistent with an historical tradition of prohibiting the sale of unsafe drugs. It also found concerns with efficacy addressed before the 1962 amendments, with concern increasing as technology evolved and new risks were seen.

The court did note, however, that lack of government interference “might be some evidence that a right is deeply rooted. But standing alone, it cannot be enough.”¹⁴⁵ Otherwise one could use such a premise “to support sweeping claims of fundamental rights.”¹⁴⁶ The relatively recent regulation, for example, of marijuana and opium did not alone support a fundamental right to use them. Nor does it follow that we have a fundamental right to drive at any speed because speed limits are a recent innovation. Otherwise, the prior lack of regulation would “undermine much of the modern administrative

142. *Abigail Alliance*, 495 F.3d at 703.

143. *Id.* at 703–05. The court found evidence of safety concerns as far back as 1736 in Virginia, Louisiana (1803), South Carolina (1817), Georgia (1825), and Alabama (1852), with 25 states or territories by 1870 having some form of regulation about safety, usually about adulteration. Federal legislation on issues related to safety was passed in 1848 and 1902, and most significantly with the landmark Pure Food and Drugs Act of 1906. The current regime of federal drug regulation began to take shape with the 1938 FDACA, requiring that drug manufacturers provide proof that their products were safe before they could be marketed. In 1962 the efficacy requirement was added. *Id.*

144. *Id.* at 706.

145. *Id.*

146. *Id.* at 706–07.

state, which like drug regulation, has increased in scope as changing conditions have warranted.”¹⁴⁷

The court then addressed the common law doctrines of necessity, tortious interference with rescue, and the right of self-defense. The Alliance had claimed that those doctrines supported “recognition of a right of self-preservation [that] would give the terminally ill a constitutionally protected right of access to experimental drugs.”¹⁴⁸ Among the problems with the Alliance’s necessity argument is the legislature’s power to eliminate a necessity defense that might otherwise be available when it so chooses—a choice that the court found Congress had done with its detailed requirements for approval of new drugs. It also found that the tort of noninterference with rescue was not applicable because the experimental drugs had not been shown to be safe, let alone effective, for prolonging the life of terminally ill patients.¹⁴⁹

Nor did the common law right of self-defense that allows one to use “a reasonable amount of force against his adversary when he reasonably believes (a) that he is in immediate danger of unlawful bodily harm from his adversary and (b) that the use of force is necessary to avoid this danger” help the Alliance.¹⁵⁰ The defense permits the victim to take the risk both that he will kill the attacker and that fighting back may increase the harm to the victim. If victims are allowed to assume these risks in defending their lives, the Alliance argued that terminally ill patients should also be allowed to assume the risk that an experimental drug may hasten their death. Given that self-defense principles permit a woman to abort a fetus even after viability if “doing so is necessary to preserve her life or health,” a terminally ill patient should be able to use whatever medical means are necessary to defend herself, even one that is prohibited by law, just as the doctrine of self-defense justifies an assault on an attacker otherwise prohibited by law.

The court rejected this analogy because the Alliance’s case was not about “using reasonable force to defend oneself nor was it about access to life-saving treatment.”¹⁵¹ Rather it was about a person’s

147. *Id.* at 707. *Cf.* *United States v. Mazarella*, 614 F.3d 85 (3rd Cir. 2010) (law banning obliteration of handgun serial numbers not a violation of Second Amendment even though serial numbers did not exist in 1790).

148. *Id.* at 707.

149. *Id.* at 708.

150. Wayne F. LaFare, *Substantive Criminal Law* (4th ed. 2003).

151. *Abigail Alliance*, 495 F.3d at 710.

constitutional right to assume “enormous risk,” in pursuit of potentially lifesaving drugs. Unlike a situation in which the doctrine of self-defense might properly apply, this case involves “risk from drugs with no proven therapeutic effect, which at a minimum separates this case from the abortion life of the mother exception.”¹⁵² Because terminally patients “cannot fairly be characterized as using reasonable force to defend themselves when they take unproven and unsafe drugs, the Alliance’s desire that the terminally ill be free to assume the risk of experimental drugs cannot draw support from the doctrine of self-defense.”¹⁵³

Because the Alliance’s patients had no fundamental right at stake, the government need only satisfy rational basis scrutiny. The government’s interest in protecting terminally ill patients from the harm of unsafe drugs, which the Supreme Court had recognized in *United States v. Rutherford*, is rationally related to protecting terminally ill patients from drugs that may harm them and even hasten death.¹⁵⁴

B. Inapplicability of *Abigail Alliance* to Organ Transplants

Abigail Alliance’s holding that experimental or unproven therapies are not within a due process or medical self-defense right of a terminally ill patient should not prevent a scrutiny stricter than rational basis to apply to bans on payment for safe and effective therapies such as organ and tissue transplants. Although there is always the question of whether a transplant will be successful for a given patient, organ and tissue transplants are not experimental or unproven for blood disorders and end stage organ disease.¹⁵⁵

As a result, the en banc court’s rejection in *Abigail Alliance* of self-defense and tortious interference with a rescue as precedents for the right claimed in that case would not be applicable to a ban on safe and effective organ transplants or any other established therapy. Established treatments such as organ transplant are appropriate for a rescue since we know they work. They also are a form of self-

152. *Id.*

153. *Id.*

154. 442 U.S. 544, 555–59 (1979).

155. Of course, as the frontiers of transplantation are expanded, some organ and tissue transplants may rightly be classified as experimental and thus would not fit within the category of established therapies. This is the case with composite transplants, now being done for the face and limbs. See Tullius et al., *supra* note 129. However, there is no FDA system for determining safety and efficacy for new surgical and medical procedures and treatments that do not involve drugs and devices within the jurisdiction of the FDA.

defense, in that they are as effective against a “medical intruder”—a virus, bacteria, or cellular system gone awry—as a handgun against an attacker. Indeed, someone who stole or destroyed the container with the organ that has been donated to another, causing the death or increased suffering of the intended recipient would be liable criminally for homicide and civilly liable for tortious interference with a rescue.¹⁵⁶ A law that barred transplantation or substantially burdened access to it should thus be subject to a scrutiny stricter than rational basis.¹⁵⁷

The established nature of organ transplantation sidesteps *Abigail Alliance*’s reasoning about access to unproven treatments, but it still leaves open the question of whether there is a due process negative right to safe and effective medical treatments. As we have seen, that issue will turn on whether *Glucksburg*’s requirements of being “deeply rooted in this nation’s history” and “essential to ordered liberty” are met when a person’s life is at stake and he seeks an established medical treatment to defend it.¹⁵⁸

VII. Burdens and Standing in Litigating the Right to Paid Donation

Recognition of a constitutional right to access organ transplants presents reasons why Congress should rethink NOTA’s sweeping ban on paid donations. If there is a right to use such treatments, then a law prohibiting or greatly burdening their use would have to withstand a higher level of scrutiny than rational basis. I will assume that stricter scrutiny in such a case will entail the fundamental right, compelling state interest, and no less restrictive means requirements that have become standard in substantive due process analysis, despite some hesitation by the Court in using such language.¹⁵⁹

156. See TEX. PENAL CODE ANN. § 19.01(a) (West 2011). The defendant in such a case would have culpably caused the death of the person awaiting the transplant.

157. The same point would apply to embryonic stem cells therapies if they were banned because they derived from intentionally destroyed embryos. In that case they would have had to be approved by the FDA as safe and effective. The FDA would not be authorized to prohibit their use on moral grounds alone, e.g., a moral objection to obtaining the cells or tissue from embryonic stem cells. See John A. Robertson, *Embryo Culture and the “Culture of Life”: Constitutional Issues in the Embryonic Stem Cell Debate*, 2006 UNIVERSITY OF CHICAGO LEGAL FORUM 1 (2006).

158. See *supra* note 141 and accompanying text.

159. See *supra* note 67. Note also that *Heller* and *McDonald* did not spell out the standard of scrutiny that would be applied to gun regulations. *Heller* did note that “nothing in our opinion should cast doubt on the longstanding prohibitions on the possession of firearms by felons and the mentally ill, or laws forbidding the carrying of

The argument might not immediately spur legislative action, but it could lead to a judicial challenge that would have that effect. A facial attack on the ban would not work because there are situations of paid donation that should be subject to prohibition.¹⁶⁰ An as-applied attack, however, is another matter. One strategy would be for an individual in need of an organ donation, e.g., a kidney, to come forward with a live donor who is willing to donate only if paid and challenge the Act on an as-applied individual basis. His case would be stronger if he could show that the would-be donor was fully aware of the risks of donation, had been carefully screened, was in good health, was not especially poor, felt strongly that there should be some reward for what he is doing, etc.¹⁶¹ Another approach would be to have a private organization create a system to recruit paid live kidney or cadaveric donors, screen and protect them, and pay rewards with price caps—along the lines of MMD.org approach—for patients in need of organ transplants. Those healthy informed donors would also join the suit under the premise that they will only donate if they are paid.

The ban on payment may substantially burden patients in particular situations unless there are paid donors, thus satisfying the standing requirements of injury in fact, causation, and redressability.¹⁶² Banning payment to an identified living donor of marrow or a kidney who is the best match for a plaintiff presents the clearest case of standing.¹⁶³ In the case of kidney transplant, dialysis is more onerous and has serious health effects, which a transplant will alleviate.¹⁶⁴ Banning payment to a scheme that encourages persons to register as potential donors and then follow through to receive the reward is less directly harmful to a specific patient and could have

firearms in sensitive places such as schools and governmental buildings or laws imposing conditions and qualifications on the commercial sale of firearms.” *District of Columbia v. Heller*, 554 U.S. 570, 626–627 (2008). For regulations that do not fall within this list of those that are outside the reach of the Second Amendment, at the very least intermediate scrutiny would apply if not also strict scrutiny. *See United States v. Mazzeo*, 614 F.3d 85 (3rd Cir. 2010).

160. *See infra* Part VIII.A.

161. *See infra* Part VIII.B.

162. *See Lujan v. Defenders of Wildlife*, 504 U.S. 555, 560–61 (1992); *see also Allen v. Wright*, 468 U.S. 737, 751 (1984).

163. Unless aspiration of bone marrow gave medical advantages over apheresis, a ban on payment for aspirated bone marrow is burdensome to any person in need of a marrow donation. *See supra* note 76 and accompanying text.

164. In that sense it is life saving, even if not immediately needed to save life.

presented standing problems in *Flynn v. Holder*.¹⁶⁵ But there is no question that it will affect some persons on organ waitlists even if they are not identifiable at the time of the suit, so that current plaintiffs, who are less immediately threatened, may raise their interests.¹⁶⁶ Their interest is close enough that the plaintiffs should withstand objections to standing based on causation or redressability, if in fact paid donation would materially increase their chance of a transplant.¹⁶⁷

VIII. Three Payment Programs and Their Constitutionality Under NOTA

Having examined the case for access to organ donation as a fundamental liberty right or a right of medical self-defense, I here examine how NOTA's ban on three payment schemes would fare under strict scrutiny. I conclude that an unregulated free market in organ sales and purchases could be constitutionally banned, as could a program that paid living donors for partial liver donations, but two other privately regulated schemes with protective features could not be banned.

A. Free Market Libertarianism

The most expansive position would be to have no governmental restrictions at all on payment—a market approach without any regulation except for fraud and deception. Whatever the libertarian appeal of unfettered markets, few proponents of financial incentives would go so far.

The ills of an unregulated market are many, from organ theft and robbery to not paying the donors, misleading them about the risks of the operation, and subjecting them to long term medical and

165. So the government argued in its petition for rehearing by the panel or an en banc hearing by the entire Ninth Circuit. See Cohen, *supra* note 11, at 1986. Indeed, one of the plaintiffs had already received an autologous bone marrow transplant and was doing reasonably well with it. His claim of standing rested on access to a closely matched donor in case his autologous transplant failed. See *supra* note 22. (Author's telephone conversation with Mike Hamel.)

166. As a comparison, whites challenging affirmative action programs in higher education have to show that they would have been admitted if a race neutral scheme had been used. Grutter v. Bollinger, 539 U.S. 306 (2003); Gratz v. Bollinger, 539 U.S. 244, 262 (2003); Fisher v. Univ. of Tex. at Austin, 631 F.3d 213 (5th Cir. 2011), *cert. granted*, 132 S. Ct. 1536, 182 L. Ed. 2d 160 (2012).

167. An unpaid donation would also redress their need, but it is the scarcity of nonpaid donations that has created the need for payment.

employment harm that they had not fully appreciated at the time of choice because of their poverty. This has been the experience in India, Pakistan, China, and Eastern Europe with donors who are poor, ill-informed, and deceived.¹⁶⁸ Donors may not receive the promised fee and even if they do, they often end up with on-going medical problems without any care or further compensation, and have greater difficulty with employment. Similar concerns drove the passage of NOTA, and they are valid considerations.¹⁶⁹ When payment moves beyond kidneys to liver lobe and cadaveric donations the problems multiply. NOTA may have painted with too broad a brush, but some regulatory brush strokes were needed.

Instructive here is the case of Levi Itzhak Rosenbaum, the first person ever criminally charged with a violation of NOTA.¹⁷⁰ Rosenbaum is an Israeli citizen living in New York. He acted as a kidney broker, finding poor donors through newspaper advertising in Israel, and then arranging for them to come to the United States and have the donation occur in U.S. hospitals falsely claiming that they were altruistic unrelated donors. Three recipients paid \$120,000-\$150,000 for their transplants arranged by Rosenbaum, \$10,000 of which went to the donor. A fourth case was arranged for \$160,000, but the recipient's agent negotiating the deal was an undercover FBI agent who arrested Rosenbaum. He eventually pleaded guilty and was sentenced to two-and-a-half years in prison, fined, and made to disgorge his profits because of his knowing and intentional violation of NOTA.¹⁷¹

One of the recipients testified at his sentencing hearing that Rosenbaum deserved sainthood and not prison, because he had saved

168. See generally Madhav Goyal et al., *Economic and Health Consequences of Selling a Kidney in India*, 288 JAMA 1589 (2002) (selling a kidney does not lead to a long-term economic benefit and may be associated with a decline in health). This study found that women were often pressured by their husbands to sell their kidneys, such that 60% to 70% of the sellers were women. *Id.* The financial need driving them was to pay off debts to moneylenders. *Id.* at 1590-91. Glenn Cohen provides many more details of the effects on donors and recipients of selling and buying kidneys on the black market in India and elsewhere. See I. G. Cohen, *Transplant Tourism*, J. L. MED. & ETHICS (2012).

169. See Cohen, *supra* note 11, at 1983 (proposal for an international paid kidney exchange led to the enactment of NOTA).

170. John Thomas Didymus, *Illegal Kidney Transplant Case Exposes Human Organs Black-Market*, DIGITAL JOURNAL (Oct. 29, 2011), www.digitaljournal.com/article/313570.

171. Reuters, *Israeli Sentenced to 2.5 Years in Prison in U.S. for Dealing Kidneys*, HAARETZ (July 12, 2012, 3:06 AM), <http://www.haaretz.com/jewish-world/jewish-world-news/israeli-sentenced-to-2-5-years-in-prison-in-u-s-for-dealing-kidneys-1.450543>.

her father's life when he was going downhill from long-term dialysis.¹⁷² On the other hand, a donor said that he changed his mind at the last minute on the operating table before the anesthesia was administered and communicated that to Rosenbaum who did not stop the operation, depriving him of a wanted kidney.¹⁷³

If Rosenbaum had not pled guilty, but instead challenged the application of NOTA to him because the kidney transplants were essential to save the recipient's lives and there was no compelling interest and less restrictive alternatives, his case would be much weaker than the paid kidney program described below. The compelling interest would be the risks to donors and recipients of unregulated broker arrangements for sale of a kidney that led to the passage of NOTA in the first place. The countervailing concern would be extortion of the needy recipient by the seller, but it could work the other way: the offer to the donor who would be ill-informed, exploited or coerced. The concerns about such unregulated arrangements might well meet a stricter scrutiny than rational basis in an as-applied setting.

Rosenbaum's hypothetical constitutional defense would be stronger if he could show that he had implemented protections to address all of the problems that lie behind an unregulated free market approach. But it was clear he had not done so and it is unlikely that many private for-profit brokers would install such protections. A regulated system of payment that protects against those concerns, whether privately or publicly imposed, would be a more appealing alternative.¹⁷⁴

B. Paid Live Kidney Donations

Hedge Fund Honcho is a generous billionaire. He is committed to improving organ donation because of the suffering of family members and friends who died waiting for kidney transplants in a situation where no live or cadaveric organs were found.¹⁷⁵ As a believer in the power of markets yet cognizant of the need for

172. *Id.*

173. *Id.*

174. Proponents of physician-assisted suicide and active euthanasia have developed protocols to meet the abuses that such practices could spawn. The Oregon Death with Dignity Act has become the model for physician-assisted suicide in the United States. OR. REV. STAT. ANN. §§ 127.800-127.897 (West 2012).

175. Honcho was inspired in part by the efforts of other rich people who support health endeavors with their money, e.g., the Bill and Melinda Gates Foundation and its support of cures and vaccines for HIV.

regulation, he is willing to put his money where his head and heart are, and will initially donate \$25 million to the MoreKidneyDonors Foundation (“MKD”), which will pay rewards to live kidney donors to get more kidneys into the system.

Honcho understands the importance of careful screening for health and informed consent, does not want to exploit financial need or create situations of coercion, and will require that MKD accept as paid donors only those who meet those rigorous requirements—including that they be U.S. citizens.¹⁷⁶ Recipients will be those without a family member able or willing to make an unpaid live donation and who have been on a waiting list for at least a year. A hospital ethics and consent transplant committee will have to approve the consent process as well and be willing to participate in the overall program.¹⁷⁷ Health and lost wages insurance will be provided to the donor to cover any medical problems that occur as a result of the donation.¹⁷⁸

MKD will make cash payments to those selected as donors, who will have the option of directing them to charitable, housing, or educational uses as they choose. More important than the form of the paid consideration is the amount. Honcho and MKD settle on a reward cap of \$20,000. The amount is based on a comparison of what egg donors are paid (maximum of \$10,000) and the greater intrusiveness and risk of the surgery.¹⁷⁹ More details will be needed before going operational, but there is enough now to assess whether NOTA could constitutionally be applied to stop MKD’s program or a comparable one operating on a lesser scale.

MKD’s payment program is compensation for some of the costs in time, inconvenience, risk, and physical burden that a live kidney donor undergoes, but it is still less than the value of a kidney. R. S.

176. This requirement is meant to prevent foreigners from being recruited as kidney donors and the problems that have surfaced in such transactions and in transplant tourism generally. *See* Reuters *supra* note 171 (discussing the Rosenbaum case where he recruited noncitizens to serve as donors in the United States).

177. *See infra* note 185 (discussion of effect of international declarations against organ trafficking and their effect on United States health care providers participating in MKD’s program).

178. There is the issue of what the paid donor’s priority will be for a kidney transplant if his one remaining kidney becomes dysfunctional.

179. Ethics Comm. of the Am. Soc’y for Reproductive Med., *Financial Compensation of Oocyte Donors*, 88 FERTILITY & STERILITY 305, 307 (2007). While payments as high as \$8,000 to \$10,000 might now occur in the Northeast and West regions, a 2007 study found that the national average was \$4,217. Sharon N. Covington & William E. Gibbons, *What Is Happening to the Price of Eggs*, 87 FERTILITY & STERILITY 1001 (2007).

Gaston et al., had proposed expanding the concept of paid expenses under NOTA to include the costs of life and health insurance for the donor, the donor's out-of-pocket expenses, and lost wages.¹⁸⁰ It also added \$5,000 compensation for "inconvenience, anxiety, and/or pain."¹⁸¹ MKD's payment for "inconvenience, anxiety, and/or pain" is greater than the Gaston group proposed, based on egg donation payment rates and the greater risks and inconvenience of kidney surgery. It is also probably less than what a kidney would fetch on an open market for a donor.¹⁸²

The amount as such is less important than the principle of some payment for their donation. It does mean that there will be "valuable consideration" paid beyond expenses as presently defined. But that "valuable consideration" is intended to cover some of the intangible costs incurred by the donor and is not a premium or amount above those costs.¹⁸³ The argument will be whether that is reasonable compensation for recognized burdens or a sale of a kidney for money beyond reasonable compensation.

Having set up its program with its screening system in place and doctors and hospitals that are willing to participate if the legal threat is removed, MKD has now filed suit against the United States government on behalf of those recipients who might receive a kidney donation under this program. The first question would be whether NOTA in this as-applied challenge burdens a fundamental right by preventing potential recipients from receiving life-sustaining kidney transplants. If there is no fundamental right, then the easily met rational basis test will apply and MKD will lose. On the other hand, if the due process arguments presented above are accepted, NOTA would interfere with the right of the potential recipient to receive a life-saving kidney transplant. Would the government be able to satisfy the stricter scrutiny then required?

180. See Gaston et al., *supra* note 14, at 2551.

181. *Id.*

182. MKD's system thus has donors subsidizing recipients, a perennial problem with trying to limit fees or prices to prevent exploitation, coercion, or undue inducement of persons of lesser means providing the good or service in demand.

183. See Epstein, *supra* note 9, at 478 for a definition of what is a sale beyond the donor's costs.

I. Protection of Donors and Recipients

Live kidney donation is not risk-free. Few deaths have occurred, but complications may occur in 1% to 3% of the cases.¹⁸⁴ There is insufficient data to know for sure, though it is said that being a live kidney donor does not affect life or health insurance rates, although contact sports are not recommended. Careful medical screening of the donor is essential to make sure the donor is in good health. Retrieval by laparoscopy will minimize the risk and intrusiveness even further. The hospital where the surgery will be performed may add an additional medical and ethical screen if needed to ensure protections for the donor.¹⁸⁵ Health and life insurance will also be provided to donors to cover the medical costs of the procedure and any costs attributable to it.

MKD will take steps to ensure that there is informed consent and no coercion, exploitation, or undue inducement.¹⁸⁶ The risk of fraud on the donor will be minimized, an insurance policy to take care of their health and medical needs in the future will be provided, and living related donors will still donate without money. With a price cap, the worse cases of exploitation or coercion will also be prevented. Still, some of the unrelated donors drawn by this scheme will be doing it because of their need for money.

Careful screening to protect the donor will also protect the recipient from a donor medical or family history that is kept secret to gain the financial reward offered. A full informed consent would make any donor rethink the bargain—\$5,000 to \$20,000—for the hours spent and pain and intrusiveness of the paid donation. Whole genomic sequencing will uncover other risk factors. A center using

184. Dorry L. Segev et al., *Perioperative Mortality and Long-Term Survival Following Live Kidney Donation*, 10 JAMA 959 (2010). A death occurred in 2012 due to a faulty clip used in cutting off the renal artery, a problem that the device maker has now presumably fixed. John Bonifield & Elizabeth Cohen, *Kidney-Donor Deaths Linked to Surgical Clips Raises Issues of Alerts, Warning*, CNN (June 21, 2012, 11:09 AM EDT), <http://www.cnn.com/2012/06/20/health/kidney-clips/index.html>.

185. The cooperation of hospital and doctors with MKD's program may conflict with professional declarations and guidelines against organ trafficking or commercialization. See Cohen, *supra* note 168. Those declarations may have to be rethought for paid donations in the United States when there are protections in place to prevent the harms that occur in black market international transplant tourism. *Id.*

186. These measures will alleviate the need for the paternalism that Cohen backs for poor and uneducated persons in India, Pakistan, and elsewhere who are now selling their kidneys in black market transactions through brokers to transplant tourists. See Cohen, *supra* note 168.

paid donors will have incentives to take extra steps to uncover risks to recipients that paid donors may be tempted to hide.

The government burden will be to show that the risks and harms of live donations are acceptable when there is no payment but become so when there is payment, even with the thorough, multi-tiered screening that will be done to protect both the donor and the recipient. If so, it cannot be because the risks and harms differ. Rather, it must be because the prospect of payment leads to coercion, undue inducement, or coercion problems, that payment will crowd out altruistic donors, or that payment is unacceptable on other moral grounds.

2. *The Fairness Argument: Coercion, Exploitation, and Undue Inducement*

With the many levels of health and consent screening at both MKD and then at the hospital where the donation will occur, the donor should be well aware of the risks of kidney donation. For an unrelated donor, the question will be whether the compensation for “pain, inconvenience, and anxiety” is so coercive, unduly inducive, or exploitative that preventing it would satisfy the strict scrutiny needed to uphold a ban on such payments.

It may well be that only low income persons would consider donating a kidney for money. In that case financial need is a relevant, if not the driving, force of their participation. Other nonrelated donors who had rejected unpaid kidney donors might now find that MKD’s reward makes donation now so attractive that they are willing to go forward, just as some women find payment a decisive factor in their choosing to serve as a surrogate mother.¹⁸⁷ In neither case, however, does the offer of money alone “coerce” them into participation. MKD is not compelling them by an unlawful or unreasonable threat. True, they are being offered something valuable that hopefully will induce them to take on risk and harm that they would not otherwise agree to.¹⁸⁸ But there is no widely accepted account of coercion, undue inducement, and possibly not even exploitation that would make MKD’s offer wrong on any of those grounds.¹⁸⁹

187. Data on the motivations of nonrelated kidney donors and surrogate mothers is needed, as is data on who opts for the MKD program if even created.

188. Cohen, *supra* note 8, at 690.

189. See A. Wertheimer, Coercion 192–208, 267, 272–74 (1987); see also A. Wertheimer, *Exploitation in Clinical Research*, in J. S. Hawkins and E. J. Emanuel,

The risk they are taking is not unreasonable, because altruistic donors have long assumed them without paid inducement. Nor is it irresistible, as a threat to their life or as a very great payment in light of their circumstances would be. But the offer of payment is tempting and is intended to make a difference. Still, it is not necessarily an unfair exploitation, when viewed *ex ante* from the prospects before them.¹⁹⁰ They expect to be made better off, even at some physical cost to themselves, but after they have been fully informed of the burdens involved, some will find it in their interests to do so. It is hard, also, to find payment for a kidney donation—with its protections for reducing harm and informing the donor of what she will in fact experience—so different than the payments made to research subjects, egg donors, surrogate mothers, and persons in highly risky work.¹⁹¹

The cap on payment at \$5,000 to \$20,000 should additionally prevent the worst cases of exploitation in that it does not so entice them that they overlook the health risks. On the other hand, setting a cap is itself exploitive in that it may deprive them of the full benefit of what they are doing.¹⁹² Yet increasing the cap or setting none at all risks creating undue inducements, e.g., offering so much that it becomes hard to say no. Other requirements, such as being free of debt and having an income of at least \$25,000 a year, would avoid the worst problems seen in India.

In short, given other accepted practices with comparable risks, it is hard to see how prevention of exploitation or undue inducement is such a threat that it would satisfy strict scrutiny. A price cap on such payments would mean that the donor would have to internalize certain costs in order to protect some people who might be driven by their need for money. Those with less wealth may be more willing to

Exploitation in Developing Countries: The Ethics of Clinical Research 63, 71 (2008); Ezekiel Emanuel, *Undue Inducement: Nonsense on Stilts*, 5 AMER. J. BIOETHICS 9, 13 (2005). The question of exploitation is more complicated. See Cohen, *supra* note 8, at 690. The answer may also be different in the context of a very large ongoing government-funded program and the government threatens to cut off all funding unless the recipient takes on another obligation. See generally *Nat'l Fed'n of Indep. Bus. v. Sebelius*, 132 S. Ct. 2566, 183 L. Ed. 2d 450 (2012) (Affordable Care Act provision to cut off all existing Medicaid funding unless states expand coverage an unconstitutional compulsion of the states).

190. Wertheimer, *supra* note 189; Cohen, *supra* note 8, at 690–91.

191. The risks and the amounts vary in each of these endeavors. It is hard to say that paid kidney donation is riskier than paid surrogacy, which is legal.

192. Margaret Jane Radin, *Market-Inalienability*, 100 HARV. L. REV. 1849, 1910–11 (1997).

take on these costs than those with more wealth, but that is true of other paid endeavors as well. Why the money-for-kidney situation should be treated differently when protections are in place and other concerns dealt with remains unclear. With the screens and regulation that MKD provides, concerns about coercion, exploitation, and undue inducement should not satisfy heightened scrutiny.

3. *Crowding Out Altruism*

A main argument against paid organ donation is that it will undermine or crowd out the unpaid altruistic system, which itself is a public good. People who would otherwise donate without payment will now refuse to do so because others are paid, or will do so only if they are paid as well.

Richard Epstein, Julia Mahoney, and others have examined this claim and have found that the main data used to support it are drawn from situations that are greatly different than organ donation.¹⁹³ As Mahoney notes, “[w]hether a particular reward will ‘crowd out,’ ‘crowd in,’ or have a ‘crowding neutral’ effect . . . is hard to predict.”¹⁹⁴ She goes on to note that “most situations in which researchers have detected ‘crowding out’ differ markedly from organ procurement.”¹⁹⁵ She concludes that “[u]ntil far more work is done, ‘crowding out’ must remain an interesting, but unconvincing, hypothesis.”¹⁹⁶ Richard Epstein also agrees.¹⁹⁷ At the very least such speculation would not in itself satisfy the stronger justification needed to ban paid live kidney donations when necessary to protect another person’s life.

4. *Additional Moral Concerns*

The same goes for the moral reasons per se against payment—that payment for undergoing surgery and losing a kidney is immoral because of its corrupting effects on traditional attitudes toward the body.¹⁹⁸ The *Flynn* court noted the “instinctive revulsion [people feel]

193. As both Epstein and Mahoney note, the oft-cited examples of the Swiss case of rejecting payment for a nuclear waste dump, and paying a fine for late pick up of children at an Israeli day care center, among others, simply aren’t comparable to organ donation. See Epstein, *supra* note 9, at 480–81; Mahoney, *supra* note 14, at 25–26.

194. Mahoney, *supra* note 14, at 25–26.

195. *Id.* at 26.

196. *Id.*

197. See Epstein, *supra* note 9, at 480–81.

198. The concern that it is part of the growing monetization of daily life, while perhaps true, must be weighed against the monetization of every other part of the transplant process and the patient’s need for a lifesaving transplant. See MICHAEL J. SANDEL,

at denial of bodily integrity, particularly removal of flesh from a human for use by another, and most particularly ‘commodification’ of such conduct, that is, the sale of one’s bodily tissue.”¹⁹⁹ It noted that commerce in organs is “generally seen as revolting.”²⁰⁰ To explain why “most of us are revolted by the notion of a poor person selling a kidney to feed his family,” the court relied on Leon Kass’ analogy to the “taboos we have against cannibalism, defilement of corpses, and necrophilia,” and the idea that “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.”²⁰¹ Kass goes on to say that 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.”²⁰²

The *Flynn* court did note that “these reasons are in some respects vague, in some speculative, and in some arguably misplaced,” and that “[t]here are strong arguments for contrary views.”²⁰³ For the *Flynn* court, however, it was enough that there were mixed views, because Congress needed only meet a rational basis test, and might appropriately take the moral high ground on commodification if it so chose.²⁰⁴

When stricter scrutiny is applied, the outcome is different. Even if government under rational basis review may take one side in a moral controversy, strict scrutiny would defang those views of their legislative priority. The Supreme Court has held this to be the case

WHAT MONEY CAN’T BUY: THE MORAL LIMITS OF MARKETS (2012); Michael Ignatieff, *The Price of Everything*, THE NEW REPUBLIC, June 7, 2012, at 23, available at <http://www.tnr.com/article/books-and-arts/magazine/103336/michael-sandel-philosophy-liberalism-democracy-market-economy-morality-income-inequality#> (criticizing Sandel for not providing a politics to correct the ills he decries).

199. *Flynn v. Holder*, 684 F.3d 852, 861 (9th Cir. 2011) (citing S. REP. NO. 98-382, at 17 (1984), reprinted in 1984 U.S.C.C.A.N. 3975, 3982 (“[H]uman body parts should not be seen as commodities[.]”).

200. *Id.*

201. *Id.* (citing LEON R. KASS, LIFE, LIBERTY AND THE DEFENSE OF DIGNITY: THE CHALLENGE FOR BIOETHICS 181–83, 185 (2002)). Of course, the revulsion may be less from analogies to cannibalism and necrophilia than to a social system that does not provide for basic necessities.

202. KASS, *supra* note 201, at 185.

203. *Flynn*, 684 F.3d at 861 (citing Virginia Postrel, . . . *With Functioning Kidneys For All*, THE ATLANTIC (July 9, 2009) available at <http://www.theatlantic.com/magazine/archive/2009/07/with-functioning-kidneys-for-all/7587>).

204. *Id.* at 862. Even moral distaste will not satisfy rational basis if the distaste is directed to a minority, such as homosexuals. See *Romer v. Evans*, 517 U.S. 620 (1996); *Lawrence v. Texas*, 539 U.S. 558 (2003).

with reproductive rights concerning birth control and abortion, and interracial marriage, and would be likely to do so with regard to same-sex marriage if it ever had reason to apply a scrutiny stricter than rational basis to such prohibitions.²⁰⁵

There may be some moral taboos, such as those against incest or cannibalism, that are so deeply rooted that few disagree with them.²⁰⁶ But that is not the case for paying for money for transactions involving the body. Except for the first step in organ transplantation—donation of the organ—every other step is paid, including the procurement and acquisition organization, the doctors, nurses, hospitals, and others involved with transplanting organs.²⁰⁷ There is a huge market in bones and other tissues. No one argues that they are “commodifying” the human body. Recall the many other instances in which we tolerate payment for bodily intrusions—from blood, sperm, and egg donation to surrogate motherhood and paying subjects in clinical research for the prodding and poking and risks that they undergo. We also pay risk premiums for dangerous work. Drawing a moral line against paying the living, unrelated kidney donor to undergo risk, inconvenience, anxiety, and pain while permitting egg donors, surrogate mothers, research subjects, and workers in hazardous jobs to be paid cannot be justified by moral distaste alone. Leon Kass, Michael Sandel, and others may be revolted by these practices, but societal acceptance or legalization of them deprives Kass and Sandel of a claim that revulsion at paying for organs is as deeply rooted as incest or cannibalism taboos. Indeed, many people do not share the revulsion or think that they are corrupting at all.²⁰⁸

205. The government’s moral or essentialist corruption concerns that are not directed toward a particular group may provide a rational basis for government action but fall short of the stricter scrutiny applied to violation of a fundamental rights.

206. Even this claim has to be qualified. Adult sibling incest is different than parent child, and has its proponents. One could also slice the cannibalism taboo into before and after death, with or without consent, and other variations. See *The Queen v. Dudley & Stephens*, 14 Q.B.D. 273 (1884) (Q.B.); see also Mark Landler, *Eating People is Wrong! But Is It Homicide? Court to Rule*, N.Y. TIMES (Dec. 26, 2003), www.nytimes.com/2003/12/26/international/26CANN.html; Mark Landler, *German Court Convicts Internet Cannibal of Murder*, N.Y. TIMES (Jan. 21, 2004), www.nytimes.com/2004/01/31/world/german-court-convicts-internet-cannibal-of-manslaughter.html.

207. See Mahoney, *supra* note 14, at 23.

208. Volokh, *supra* note 20, at 1843–44.

C. Rewards for Cadaveric Donations

The discussion has focused on live donors of kidneys, and argued that a regulated system of cash payments run by a private organization such as MKD would prevent the government from satisfying the stricter scrutiny that it would have to show to apply NOTA to those programs. Would that analysis change if the rewards were paid for cadaveric donations?

Cadaveric donations are a mainstay of solid organ transplantation since the heart, lungs, whole liver, and other organs cannot be removed without causing the donor's death—a violation of the dead donor rule.²⁰⁹ Until interest revived in donation after cardiac death (“DCD”), it was thought not possible to retrieve those organs without legal recognition of whole brain death. A brain dead person would still have artificially maintained cardiopulmonary activity but would have no brain function and thus would be declared dead. With legal recognition of brain death and state anatomical gift laws to clarify who had decisional authority over the remains, cadaveric donation and organ transplantation took off in the 1970s, spurred by the discovery of cyclosporine and more effective immunosuppressive agents. Organ procurement organizations sprang up, required request laws became part of Medicare certification, and the harvest of cadaveric organs increased. Even though the number of cadaveric organs is limited by those in a situation of brain death (or who would qualify under DCD), the procurement system has not yet reached that limit.²¹⁰ An offer of financial reward may produce more consents to donation than are now forthcoming.

An acceptable program for paid cadaveric donations presents different problems than paid programs for blood stem cells or kidneys. Hedge Fund Honcho again would step into the breach. He would fund a nonprofit foundation, More Cadaveric Donors (“MCD”), which would provide rewards to the estate of a person who had previously signed an organ donor directive and a cadaveric

209. That rule is reflected in homicide law, which would punish a physician and hospital that performed a voluntary donation of a heart, when doing so would cause the donor's death. See TEX. PENAL CODE ANN. § 19.01(a) (West 2011); John A. Robertson, *The Dead Donor Rule*, 29 HASTINGS CTR. REP. 6, (No. 6, 1999).

210. Ellen Sheehy et al., *Estimating the Number of Potential Organ Donors in the United States*, 349 NEW ENG. J. MED. 7 (2003) (suggests increasing consent from requests for organ donation in large hospitals).

donation resulted, or in the absence of a directive the family or next of kin agreed to a cadaveric donation.²¹¹

Many details would have to be worked out. Ideally the MCD program would work in coordination with existing organ procurement programs. After they informed the family of their option to donate, procurement personnel would then inform them that they might qualify for a one-time payment to the estate from MCD. Procurement professionals, however, may object to any money paid to cadaveric donors, and distance themselves from MCD.²¹² This would leave MCD to contact the family on its own, perhaps with hospital cooperation, or have donors contact MCD. With publicity and hospital cooperation, MCD's program will eventually become known to many people. Still few families or people have ever thought of being in this situation, much less about being paid for donation of their loved one's organs.²¹³ Out of fairness to them, some way of being informed of MCD's reward program should exist as they consider making a donation.

A key question is how much the reward should be. A cadaveric donation is much more valuable than a live marrow or kidney donation. The heart, lungs, liver, both kidneys, and skin and bone could be harvested, possibly saving the life of six or more persons, as well as skin, bones, corneas, and other parts that would help others. MCD, however, will not try to compensate the estate to that extent, just as the other payment programs have not paid the full value of what is donated. Instead it proposes to make a \$5,000 payment to the estate if the donation occurs.²¹⁴

Here, risks to the donor and recipient are not applicable.²¹⁵ A cadaveric donation can occur only after brain death is declared, which

211. I put aside payment in cases of donation after cardiac death, where there may be a greater risk of improper influence.

212. See Mahoney, *supra* note 14, at 30.

213. See generally Newman v. Sathyavaglswaran, 287 F.3d 786 (9th Cir. 2002) (state cornea-removal law deprives next-of-kin of quasi-property interest in disposal of body unless they have been notified in advance).

214. Pennsylvania authorizes payment from a state fund "for reasonable hospital and other medical expenses, funeral expenses and incidental expenses incurred by the donor or donor's family in connection with making a vital organ donation. Such expenditures shall not exceed \$3,000 per donor and shall only be made directly to the funeral home, hospital or other service provider related to the donation . . . The advisory committee shall develop procedures, including the development of a pilot program, necessary for effectuating the purposes of this paragraph." PA. CONS. STAT. § 8622(b)(1) (West 2000).

215. The idea of compensation for "inconvenience, pain, and anxiety" of physical intrusion is not applicable here, since there is none. There may, however, be psychological

is a medical decision. At that point the deceased donor has no interests to be protected. The screening for infections and other risks for the recipient will be the same whether or not there is a payment to the estate. The family, however, has an interest in being approached respectfully, not exhorted, and their decision not to donate respected.

1. *Undue Inducement of Family*

There is the question of whether the family will be induced to change what they otherwise would have decided about organ donation because of the payment to the estate. That of course is the point, but the question is whether there is anything unfair or unreasonable about asking them to do so. They are not being paid to undergo bodily risk or intrusion, but their decision-making will be complicated if money is involved. Since organ donation at death has long been acceptable, there are no risks of informing them of that option, other than the need to grapple with the complications that money beyond decisional costs if there is no payment would bring.²¹⁶

Will the poor and less well off be more likely to accede to donation because of the payment? The amount is relatively small. Still, for many people with no estate and/or creditors it will be tempting.²¹⁷ Indeed, such an inducement might in the long run benefit them or their community (some ethnic groups have low donation rates and a high need for transplants), but in the short run it may seem exploitive. Nor will they be bearing an unfair share of contributing to organ transplants, since better-off persons may donate anyway.

2. *Crowding Out Altruism*

Is there a stronger claim here that with live unrelated kidney donors a financial reward system will drive out altruistic cadaveric donations? There is no special reason why this will occur, nor that people will decide not to donate at all. If payments do occur and weaken altruism, it will also increase the cost of transplantation. But the costs of transplant will be much less than the costs of maintaining

turmoil and guilt over whether to accept or reject payment. These could be significant in complex family situations and lead to counseling costs. Of course, conflict and guilt may occur regardless of payment.

216. See Mahoney, *Should We Adopt a Market Strategy to Organ Donation*, THE ETHICS OF ORGAN TRANSPLANTATION 65, 77 (Wayne Shelton & John Balint, eds., 2001) (discusses exhortation costs).

217. The legislature could protect this payment from creditors. Cf. Goyal et al., *supra* note 168, at 1590 (role of creditors in pushing debtors to undergo paid organ donations).

someone without transplant—either keeping them alive longer while they remain on the waiting list or until they die. Neither fears of crowding out altruism nor the increased costs of transplant seem great enough to constitute a compelling state interest.

3. *Commodifying Death*

Here the concern is not harm to the donor or the pool of altruism, but to the moral notion of profiting from death. The notion is that the prospect of filthy lucre is contaminating the dead body. But there is monetary “contamination” of death throughout the system, from the transfer of wealth that occurs through inheritance, the medical procedures ordered to stave off death, and the benefit to all those who profit from organ donation and transplantation. How one frames the question is key. In this case, payment may be seen as less a sale of the body or the organs than a sharing in some of the good that the donation will bring to others. Some would question this idea of reciprocity, finding the idea of “rewarded gift” a contradiction in terms. Others would find it fair that the donor and donor family receive something for the great contribution that they have made to the wellbeing of others. Given these differing opinions and the commercialized practices that surround death anyway, it is doubtful that these concerns are strong enough to satisfy strict scrutiny.

4. *Paid Cadaveric Donation: A Closer Question*

Assuming that MCD has standing to raise the issue and there is enough burden on prospective recipients, whether the government may meet heightened scrutiny in the as-applied situation outlined here is closer than with paid donations for blood stem cells and kidneys. If there are adequate protections for informed consent, a free choice is certainly possible. Exclusion of donations after cardiac death lessens the risk of conflicts of interest in decisions to terminate life support due to the prospect of payment.²¹⁸ Some families will be drawn to the prospect of a \$5,000 reward to the estate or for funeral and medical expenses, especially if there is otherwise no estate to speak of. Yes, they may be tempted by the money to do something that they would not otherwise do, but an inducement to donate beyond pure altruism is not itself coercive, unduly inducive, or exploitive. Others will find it appropriate that if everyone else in the organ transplant system makes a profit, the family should in some

218. See discussion *supra* Part VIII.C.1–4.

modest way as well. At the very least, there is an argument for trying such an approach and studying its effects on the cadaveric donation rate.

Is the application of NOTA to MCD's cadaveric payment scheme unconstitutional? The question is closer than with paid blood stem cell and kidney donations, but it is still reasonable to conclude that it is. If the burden is on government to show a strong case that the payment system will likely have the harmful effects that drove NOTA, it may be hard for defenders of the law to make that case. Speculation and conjecture about crowding out and moral distaste alone will not do. In the end it may turn on whether judges, who otherwise agree that a protected liberty interest in receiving necessary medical treatment is at stake, find that there is enough of a payoff—given the gap between availability of cadaveric donors and what is already harvested—that MCD's cadaveric payment schemes will make a significant difference in saving lives without causing undue harm. If so, they should not constitutionally be banned.²¹⁹

IX. Conclusion: Change by Courts or Legislatures

Legislative action to modify NOTA to permit the programs discussed above is unlikely in the immediate future. If change is to occur it will result from private actors organizing financial reward programs that regulate away the main concerns with paid donation and then litigate whether NOTA can constitutionally be applied to ban them. There will be both procedural and substantive hurdles to getting this claim heard.

The main obstacle will be the reluctance of judges to move beyond rational basis to a stricter scrutiny of a law that substantially burdens a person's ability to protect his life or liberty with a safe and effective medical treatment. That move means extending the right of self-defense against human attackers to defending one's self against viral and bacterial threats from disease, illness, or trauma. Strict originalists and textualists will not make this move, but moderate

219. See discussion *supra* note 137 and accompanying text. There, the question of medical self-defense was itself at issue because of the unproven nature of the efficacy of the treatment sought, a Phase II drug not yet studied for efficacy. Here, there is no question of the safety and efficacy of organ transplant for end-stage liver disease. Rather, the question is the likelihood of the net harmful effects, which the state asserts justifies the burden on that right. Still, the need for an experimental program to gather such data, if not legislatively authorized, is too distant from burdening the fundamental right to be found unconstitutional and may not even be closely enough related to confer standing to raise the issue.

originalists and textualists, as well as those more sympathetic to a “living constitution” approach might be willing to take that step when safety, efficacy, and widespread acceptance of the treatment exists. While there is no certainty about how much lifting the bar on payment will increase organ supply, there is good reason for thinking that it will—that some donors will come forward who might not otherwise have done so and additional lives will be saved.

Legislatures have expertise in judging the ill effects of the payment schemes proposed. But their judgment should receive less deference when the harmful impact on patients’ lives becomes more pronounced and they have the burden of showing that their restrictions serve compelling interests without less restrictive ways of achieving them. Moral and philosophical objections to money alone, a mainstay of opposition to paid organ donation, are not compelling interests under strict scrutiny. Nor are concerns about harming or exploiting donors or crowding out altruism well enough established that they shield NOTA’s broad ban from all as-applied attacks.

Eventually a court might find that a carefully designed private program to protect donors and limit exploitation cannot constitutionally be banned by NOTA. Such a decision might awaken the legislative process. It will comport with the growing weight of opinion that some use of financial incentives to increase the supply of lifesaving organs is desirable.

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