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Living Organ Donation and Valuable Consideration

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Living Organ Donation and Valuable Consideration

Summary

The central issue before Congress with respect to the possibility of living organ donation is how to balance the needs of people seeking organs with one another, and with the needs of potential organ donors. While the majority of organs are harvested from deceased donors, an increasing number of donations are made by living donors each year. As new types of programs are developed to help encourage the practice of living donation, both legal and ethical issues may arise.

Two types of programs to expand the practice of living donation have recently been proposed: paired and list donation. In both types of arrangements, willing living donors who are incompatible with their intended recipients agree to donate their organs to an unknown recipient. In exchange, their intended recipient either receives an organ (paired donation), or a higher spot on the waiting list (list donation). Both systems have been implemented for kidney transplantation in limited areas, in part due to concerns that they may run afoul of the National Organ Transplantation Act (NOTA, P.L. 98-507) prohibition on the exchange of *valuable consideration* for an organ (§ 301). Both types of programs also raise or at least touch upon a range of issues, including those related to: evolving transplantation systems; the directive that physicians do no harm; risk-benefit ratios; informed consent; type O recipients; resource allocation; parity; and the possibility of paying for organs.

In February 2007, the Senate passed the Living Kidney Organ Donation Clarification Act (S. 487) by unanimous consent. In March 2007, the House passed a companion measure, H.R. 710, by a vote of 422-0. The bills would amend the National Organ Transplant Act to clarify that kidney paired donation does not involve the transfer of a human organ for valuable consideration. During the 109th Congress, S. 2306 would have done the same for both kidney paired donation and kidney list donation. In the 108th Congress, S. 573 IS would have exempted familial, emotional, psychological, or physical benefit from the definition.

This report contains background regarding how living donation is included within the larger organ donation construct, the likely impact that paired and list donation programs would have on organ supply, the legislative history and legal interpretation of the term valuable consideration as it is defined in section 301 of the National Organ Transplant Act (P.L. 98-507), and the various ethical and policy issues related to living donation, paired kidney donation, kidney list donation and legislation proposed on the topic.

This report will be updated as needed.

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Living Organ Donation and Valuable Consideration

Introduction

The issue of living organ donation is important to Congress because it represents one important set of possibilities for balancing the needs of people seeking organs with one another, and with the needs of potential organ donors. On one side of the balance, the drive to increase the supply of transplantable organs is fueled by people awaiting organ transplants. They are, in a sense, competing with one another on waiting lists for potentially life-saving scarce resources. On the other side of the balance, the drive to ensure that the transplant system is ethical and equitable precludes some mechanisms that would increase the supply of transplantable organs. Some options that have been rejected to date in the United States include paying healthy persons to donate their organs, and mandating that transplantable organs be harvested from all cadavers.

To maintain the most ideal balance for the organ transplantation system, Congress may now wish to clarify whether certain new types of living organ donation should be adopted to increase the supply of transplantable organs, or prohibited for ethical and/or equitable reasons.

Demand for Transplantable Organs

The demand for transplantable organs is outpacing the supply at an increasing rate. In the United States in 1988, there were 16,026 individuals on the waiting list for an organ transplant.[1] By 1995, the waiting list had increased almost 175%t to 43,937.[2] Since then, it has more than doubled, and as of February 13, 2007, the waiting list holds 95,075 individuals, including 69,983 people seeking kidneys.[3] Each day, on average, hospitals perform 56 organ transplants, and nearly19 people die awaiting organs that never come.[4]

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[1] Institute of Medicine, *Organ Donation: Opportunities for Action*, (Washington, DC: National Academies Press, 2006) (hereinafter referred to as IOM Report), p. 19.

[2] Id. at p. 19.

[3] Data is from the United Network of Organ Sharing (UNOS) website, at [http://www.unos.org/], visited February 13, 2007. Data on the site are continuously updated.

[4] Eric Cohen, *Organ Transplantation: Defining Ethical and Policy Issues*, President's Council on Bioethics Working Paper, June 2006 (hereinafter E.Cohen).

United States Organ Procurement System

In order to help ensure that organs are equitably distributed, Congress passed the National Organ Transplant Act of 1984 (NOTA).[5] NOTA authorized the Secretary of the Department of Health and Human Services (HHS) to establish the Organ Procurement Transplantation Network (OPTN), by contract. Currently, the OPTN is administered by the United Network for Organ Sharing (UNOS) under contract with the Health Resources and Services Administration of HHS. The OPTN and UNOS have established a national system for matching organs and individuals in need of organs. In addition OPTN and UNOS set policies for United States transplant centers and organ procurement organizations (OPOs).[6] The 1984 NOTA also prohibited the buying and selling of human organs by making it unlawful to exchange "valuable consideration" for human organs for use in transplantation.[7] The 1984 Act did, however, allow reasonable payments to be made to living donors for expenses relating to travel, housing, and lost wages in connection with the donation of an organ.[8]

Currently, The United States organ procurement system is composed of 58 OPOs which provide all the deceased and some living donor organs for the nation's 256 transplant centers.[9] Each OPO has a contiguous geographical service area designated by the federal government for recovering organs in all hospitals in that region.[10] Each OPO is required to be a member of and provide transplant candidate information to OPTN, which maintains the master waiting list of individuals seeking transplants in the United States.[11] OPOs may also implement regional organ allocation systems different from the national OPTN system for the purpose of increasing organ availability and/or organ quality, reducing or addressing an inequity

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[5] P.L. 98-507, 42 U.S.C. 274 *et seq.*

[6] § 201 of NOTA, 42 U.S.C. § 274.

[7] § 301 of NOTA, 42 U.S.C. § 274e(a). The statute does not define "valuable consideration," leading to some ambiguity in the case of living donation arrangements where mutual promises are exchanged to facilitate multiple organ donations. Even though monetary payments are not involved in such arrangements, legal issues have been raised concerning application of this prohibition against the exchange of "valuable consideration." See legal discussion, *infra,* beginning on page 10.

[8] § 301(c)(2) of NOTA, 42 U.S.C. § 274e(c)(2).

[9] UNOS, Who We Are, Membership, at [http://www.unos.org/whoweare/membership.asp], visited March 3, 2007.

[10] Howard M. Nathan, et al., "Organ donation in the United States," *American Journal of Transplantation*, vol. 3, supp. 4 (2003) (hereinafter, H.M. Nathan), p. 29.

[11] All U.S. transplant centers and organ procurement organizations must be members of the OPTN to receive any funds through Medicare. § 1138 of P.L. 99-509, the Omnibus Budget Reconciliation Act of 1986, 42 U.S.C. 1320b-8. Other OPTN members include independent histocompatibility laboratories involved in organ transplantation; relevant medical, scientific, and professional organizations; relevant voluntary health and patient advocacy organizations; and members of the general public with a particular interest in donation and/or transplantation. Profile, About OPTN, at [http://www.optn.org/optn/profile.asp], visited March 3, 2007.

in organ allocation/distribution unique to a local area, and/or examining a policy variation intended to benefit the allocation/distribution system overall.[12] In 1986, in order to help increase the organ supply available for transplantation, Congress passed legislation requiring virtually all hospitals to establish protocols requiring health professionals to make organ donor requests.[13]

Living Donation

In 2004 Congress passed the Organ Donation and Recovery Improvement Act,[14] the first federal law directly applicable in part to *living donors*, i.e., living people who donate an organ they can survive without, such as one of their two kidneys. Living donation is preferable for transplant recipients, because kidneys recovered from live donors typically outlast those from deceased donors.[15] The law amended the Public Health Service Act to authorize the HHS Secretary to award grants to states, transplant centers, qualified organ procurement organizations or other public or private entities to reimburse travel, subsistence, and incidental nonmedical expenses incurred by individuals toward making living organ donations.[16] The law also authorized the Secretary to establish and maintain mechanisms to evaluate the long-term effects associated with living organ donations by individuals who have served as living donors. For all types of donations, the law created and authorized funding for donor awareness programs.[17]

Government oversight of the living donation process is limited, and some OPOs have organized non-traditional programs for living donors.[18] A typical living donor program allows individuals to receive transplants from living spouses, parents, or friends who are willing to donate and are biologically compatible.

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[12] OPTN Policy #3.1.7 (June 30, 2006), at [http://www.optn.org/PoliciesandBylaws2/policies/pdfs/policy_70.pdf], visited March 3, 2007.

[13] § 9318(a) of P.L. 99-509, the Omnibus Budget Reconciliation Act (OBRA) of 1986, 42 U.S.C. § 1320-8.

[14] P.L. 108-216, 42 U.S.C. § 273 *et seq.*

[15] Sommer E. Gentry, Dorry L. Segev, and Robert A. Montgomery, "A Comparison of Populations Served by Kidney Paired Donation," *American Journal of Transplantation*, vol. 5, no. 8 (Aug. 2005), (hereinafter, S. E. Gentry) p. 1914.

[16] § 3 of P.L. 108-216, 42 U.S.C. § 274f.

[17] § 4 of P.L. 108-216; 42 U.S.C. 274f-1. A total of $5 million was authorized to be appropriated from FY2005 through FY2009, however, the program was unfunded in FY2005.

[18] IOM Report, p. 309; H.M. Nathan, p. 39.

Two Novel Types of Living Donation: Paired Donation and List Donation

OPOs in Washington, DC, and New England have implemented two types of programs to assist those seeking organs (*intended recipients*) who have willing but incompatible donors: *list donations* and *paired donation*s.[19] To date, these programs have exclusively involved kidneys.

In a paired donation exchange, two donors whose kidneys are incompatible with their own intended recipients but compatible with each other's trade donations. Each recipient receives a compatible kidney from a living donor. In a list donation exchange, a donor who is incompatible with an intended recipient makes a donation to a stranger on the waiting list. In return, the intended recipient advances on the waiting list for a deceased donor organ. While receiving a kidney from a living donor may be preferable to receiving one from a deceased donor, recipients of organs from deceased donors still have a much greater chance of survival than those who remain on dialysis.[20] (Dialysis is a mechanical process designed to partially perform kidney functions.)[21]

The exchange element of paired and list donations has triggered questions about whether such arrangements represent the exchange of valuable consideration for an organ. If so, these arrangements would be illegal under federal law unless Congress acted to exempt these arrangements from valuable consideration. Also, questions are being raised about the entire process of living donation and the multitude of health, financial and social post-operative risks that the living donor faces.

Legislation introduced in the 110th Congress would exempt from valuable consideration paired kidney donations. The Living Kidney Organ Donation Clarification Act (H.R. 710 and S. 487) would amend NOTA to clarify that paired kidney donations do not involve the transfer of a human organ for valuable consideration. The Senate passed S. 497 by unanimous consent in February 2007. In March 2007, the House passed H.R. 710 on a motion to suspend the rules and pass the bill (a two-thirds majority was required), by a vote of 422-0. If enacted, this legislation would exempt paired kidney donation from the definition of valuable consideration, which may increase the number of kidneys available for transplantation, as discussed in the *Impact of Living Donation Arrangements on Organ Supply* section of this report.

The version of the Living Kidney Organ Donation Clarification Act introduced during the 109th Congress (S. 2306) would have provided that not only kidney paired donation, but also kidney list donation were not proscribed by NOTA provisions that prohibit the transfer of any human organ for use in human transplantation for

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[19] H.M. Nathan, p. 39.

[20] Francis L. Delmonico, et al., "Donor Kidney Exchanges," *American Journal of Transplantation*, vol. 4, no. 10 (Oct. 2004), (hereinafter, F.L. Delmonico), p. 1632.

[21] UNOS, *definition of dialysis*, at [http://www.unos.org/resources/glossary.asp#D], visited March 3, 2007.

valuable consideration. One version of a bill introduced in the 108th Congress proposed an even broader exemption from valuable consideration. The version of the Organ Donation and Recovery Improvement Act introduced in the Senate (S. 573, IS), would have specified that the term "valuable consideration" did not include familial, emotional, psychological, or physical benefit to an organ donor or recipient. However, the version of the Act that became law (H.R.3926, P.L. 108-216) did not address the topic of valuable consideration.

Several other bills introduced during the 109th Congress were aimed at encouraging living organ donation. The Living Organ Donor Job Security Act of 2005 (H.R. 1993), would have amended the Family and Medical Leave Act of 1993 (FMLA) to entitle employees covered by FMLA to leave in order to provide a living organ donation. The Living Organ Donor Tax Credit Act of 2005 (H.R. 2472) would have amended the Internal Revenue Code to allow a nonrefundable tax credit for a donation of a qualified life-saving organ for transplantation by a living donor, and amended the Public Health Service Act to provide that any such tax credit not be deemed valuable consideration for purposes of the ban against organ purchases. The Gift of Life Congressional Medal Act of 2006 (H.R. 4753/S. 2283, 109th) would have directed the Secretary of the Treasury to design and strike a bronze medal to be awarded to organ donors and/or their families.

This report first presents information regarding the impact of living donation programs on the organ transplantation system. It presents statistics related to the current system, and estimates the impact that paired and list donation programs would have on the supply of organs for transplantation, waiting lists, and deaths. Next, the report presents a legal analysis of NOTA's prohibition on valuable consideration as it relates to novel living donation organ exchange programs. The report concludes with a presentation of ethical issues involved in living donation, with a focus on paired and list donation programs.

Impact of Living Donation Arrangements on Organ Supply

Living donation provides thousands of organs for transplantation each year. In 2005, the most recent year for which complete statistics are available, 6,904 organs were provided by living donors, which accounted for nearly a quarter of the 27,993 total organs donated (excluding hearts).[22] (See **Table 1.**) Over 95% of the organs donated by living donors were kidneys. All of the organs collected from kidney and other living donors were transplanted, while just under 86% of organs recovered from deceased donors were transplanted.

[22] United Network for Organ Sharing, based on OPTN data as of February 9, 2007, at [http://www.optn.org/latestData/rptData.asp].

Table 1. Number of Organs Recovered and Transplanted from Living and Deceased Donors in the United States, 2005

Organ Type	Living Donors		Deceased Donors		Total Donors
	# Recov. *(100% recovered were transplanted)*	% of Total # Transp.	# Recov.	# Transp.	# Transp.
Kidney	6,570	37.2%	13,313	11,102	17,672
Pancreas	2	0.1%	2,046	1,466	1,468
Liver	323	5.1%	6,691	6,042	6,365
Intestine	7	3.9%	184	171	178
Lung	2	0.1%	2,374	2,308	2,310
All Organs	6,904	24.7%	24,608*	21,089*	27,993*

Source: United Network for Organ Sharing, based on OPTN data as of February 9, 2007 [http://www.optn.org/latestData/rptData.asp]. *Totals exclude deceased heart donors: 2,220 recovered and 2,191 transplanted. Living heart transplants (*domino*)[23] have occurred in other years, but none in 2005.

The amount of living organ donation has increased over time. The overall number of living organ donors has risen steadily from 2000 to 2005. (See **Table 2.**) Each year, as in 2005, the vast majority of organs given by living donors have been kidneys. Despite the increase in organ donation, more than 6,000 individuals have died each year between 2000 and 2005 while awaiting an organ for transplant. (See **Table 3.**) More than half of those were awaiting kidneys.

Table 2. Number of Organs Recovered from Living Donors in the United States, 2000-2006

Living Organ Donors	2000	2001	2002	2003	2004	2005	2006**
Kidney	5,493	6,038	6,240	6,473	6,647	6,570	5,913
Pancreas	7	4	1	3	0	2	1
Liver	400	519	362	322	323	323	272
Intestine	3	0	1	4	6	7	4
Lung	36	49	25	29	28	2	5
Total*	5,939	6,610	6,629	6,831	7,004	6,904	6,195

Source: United Network for Organ Sharing, based on OPTN data as of February 9, 2007 [http://www.optn.org/latestData/rptData.asp]. *Totals may be less than the sums due to patients included in multiple categories. **The data for 2006 are incomplete.

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[23] A domino transplant is a procedure in which an organ is removed from one transplant candidate and immediately transplanted into a second patient, with the first patient receiving a new organ from a deceased donor. For example, lung transplants are more successful if accompanied by a donor heart as well as the lungs. A person with a healthy heart and in need of lungs might donate his or her heart if a heart/lung set became available.

Table 3. Reported Deaths on Waiting Lists for Selected Organs in the United States, 2000-2005

Organ	2000	2001	2002	2003	2004	2005	2006**
Heart	634	671	585	534	474	417	323
Intestine	25	45	53	49	54	55	49
Kidney	3,191	3,438	3,799	3,873	4,062	4,099	3,439
Liver	1,797	2,048	1,905	1,854	1,866	1,846	1,415
Lung	500	507	497	471	489	364	220
Pancreas	36	61	38	47	59	70	65
Total*	6,148	6,713	6,787	6,716	6,858	6,688	5,356

*Totals may be less than the sums due to patients included in multiple categories.
**2006 data are not complete.

Source: UNOS, current as of February 9, 2007 [http://www.optn.org/latestData/rptData.asp].

The overall effect that proposed mechanisms for expanding the pool of potential living organ donors, such as paired and list donation, might have on the supply of available various organs is difficult to measure. This is due largely to the fact that paired and list donation systems have only been implemented and tested for kidney donation.

Research on Paired and List Kidney Donation Systems. The number of additional kidney transplants that would result from a national paired and/or list kidney donation system depends on the how the systems would operate. The number of available kidneys could be increased by numerous factors — not all of which are necessarily desirable. These factors include selecting an optimal transplant system (list, paired, or combination) for the size of the population, lowering the degree of compatibility required for a transplant, increasing donor willingness to participate in list and paired donation programs, and avoiding systemic restrictions used to achieve equitable outcomes among recipients. The studies that have examined these factors are summarized below.

One study generated data about the type of transplant system that is optimal for a given population size by comparing paired, list, and combination programs via computer model. The authors estimated that a pool of 3,584 donor/recipient pairs could generate 1,871 successful transplants (52%) using a combination paired/list exchange program, 1,730 (48%) using a paired program alone, and 1,330 (37%) using a list program alone.[24] The same study found that, for small populations of donor/recipient pairs (less than 100), list donation would generate more potential

[24] S. E. Gentry, 1917-1918.

transplants than paired donation because list donation uses the entire deceased donor pool, while paired donation is limited to the incompatible pool.[25]

A second study investigated factors that influence donors' willingness to participate in paired and list exchange programs.[26] Willingness to make a paired or list donation appeared to be directly proportional to the likely magnitude of benefit to the intended recipient. Of 174 potential donors who had been found medically incompatible with their intended recipients, 63.8% were willing to participate in paired donation (in which the intended recipient would receive a kidney immediately from a live donor), and 37.9% were willing to participate in list donation (in which the intended recipient would be moved up the list for a kidney from a deceased donor). Willingness to make a list donation was greatest when the intended recipient would be moved to the top rather than the top 20% of the waiting list (37.9% vs. 19.0%).

A third study examined the possibility of maximizing paired donations by lowering the donor/recipient compatibility requirements.[27] By doing so, authors were able to increase the percentage of possible exchanges from 57% to 91.7% of patients in their database.[28] A number of specialized centers report success with incompatible kidney transplantation using special techniques to make the kidney more compatible with the intended recipient. The results of these types of transplants are reportedly encouraging,[29] but long-term results are not yet available, and therapy is labor intensive, requires immunosuppressives, and adds an average of $28,000 to the cost of the transplant.[30]

A fourth study estimated the impact that ethical restrictions to help ensure that people of all blood types benefit equitably from list donations would have on the number of transplants performed.[31] The authors proposed certain restrictions on list donation (and others have proposed avoiding list donation altogether) because people with blood type O may be disadvantaged by such a system. Donors with blood type O may give compatible kidneys to recipients with any blood type, but

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[25] Id. at p. 1918.

[26] A.D. Waterman et al., "Incompatible Kidney Donor Candidates' Willingness to Participate in Donor-Exchange and Non-directed Donation," *American Journal of Transplantation*, vol. 6, no. 7 (Jul. 2006), p. 1631.

[27] Requirements for human leukocyte antigen matching (HLA) were lowered from four points of compatibility to three.

[28] Inessa Kaplan, et al., "A Computer Match Program for Paired and Unconventional Kidney Exchanges," *American Journal of Transplantation*, vol. 5, no. 9 (Sep. 2005), p. 2308.

[29] For example, see Robert A. Montgomery et al., Clinical Results From Transplanting Incompatible Live Kidney Donor/Recipient Pairs Using Kidney Paired Donation," *Journal of the American Medical Association*, vol. 294, no. 13 (Oct. 2005), p. 1655.

[30] S.E. Gentry, p. 1919.

[31] Lainine Friedman Ross and Stefanos Zenios, Restricting Living-Donor-Cadaver Donor Exchanges to Ensure that Standard Blood Type O Wait-List Candidates Benefit," *Transplantation*, vol. 78., no. 5 (Sep. 15, 2004), (hereinafter, L.F. Ross), pp. 641-646.

recipients with O blood type may only receive compatible kidneys from type O donors. For that reason, type O recipients, who already have the longest mean wait time on the cadaver waiting list, may have to wait an even longer time for a cadaveric kidney in a typical list donation program. The ethical dimensions of this issue are discussed further in the Ethical Issues section of this report.

Study results indicated that restrictions to benefit recipients with blood type O would decrease annually the number of additional kidneys available from list exchanges by about one-half (from a range of 844 — 2,155 additional kidneys, to a range of 414 — 1,150 additional kidneys). The study also indicated that, unless the restrictions were used, type O recipient candidates in a list exchange program would experience an increased waiting time that would translate into 15.17 deaths per year among the group.

Legal Issues Relating to Valuable Consideration and Living Donation Arrangements

Statutory Prohibition in NOTA

The National Organ Transplant Act of 1984 (NOTA), § 301(a), prohibits buying or selling human organs "for valuable consideration for use in human transplantation."[32] This is a criminal provision with fines of up to $50,000 and imprisonment for up to 5 years, or both.[33] While the statute does not define "valuable consideration," it does state that the term "does not include the reasonable payments associated with the removal, transplantation, implantation, processing, preservation, quality control, and storage of a human organ or the expenses of travel, housing, and lost wages incurred by the donor of a human organ in connection with the donation of the organ."[34]

The legislative history of the 1984 NOTA does not discuss the meaning of the term "valuable consideration."[35] It simply expresses Congress's intent to criminalize the buying and selling of organs for profit. For example, the Senate report accompanying S. 2048 stated that "(i)t is the sense of the Committee that individuals or organizations should not profit by the sale of human organs for transplantation."[36] The House conference report for that bill reiterated that Section 301 was directed toward monetary exchanges: "This title intends to make the buying

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[32] 42 U.S.C. § 274e(a).

[33] § 301(b) of NOTA, 42 U.S.C. § 274e(b).

[34] § 301(c)(2) of NOTA, 42 U.S.C. § 274e(c)(2).

[35] According to one author, the prohibition against selling organs was enacted in part because of a Virginia physician's efforts to address the organ shortage by brokering living donors' kidneys and earning a profit. Fred H. Cate, Human Organ Transplantation: The Role of Law, 20 *Journal of Corporation Law*, 69, at 80 (1994).

[36] See S.Rept. 98-382 (1984), at 16-17, reprinted in 1984 U.S.C.C.A.N. 3975, 3982-3983.

and selling of human organs unlawful... ."[37] During congressional hearings in 2003 on incentives to increase organ donations, strong objections were proffered against the use of direct monetary incentives to procure organs.[38]

Living donations of kidneys from a single biologically compatible living donor to a recipient had taken place before NOTA was enacted in 1984. Since NOTA specifically allows certain expense payments to be provided to a living donor, it is clear that living donations are not precluded by NOTA and that single living donations do not implicate the § 301 prohibition against the exchange of valuable consideration. At the time NOTA was enacted, paired donation and list donation arrangements had not yet been developed as medical options. Thus, Congress did not consider practices involving multiple living donors and/or recipients in enacting the prohibition on giving or receiving valuable consideration for human organs. While some transplantation facilities have implemented living donation programs involving multiple recipients and/or donors,[39] apparently other transplant facilities have hesitated to implement such living donation programs because of possible legal concerns.[40] Absent indications of congressional intent, legal arguments have been advanced on both sides of this issue, with the bottom line being that legislative clarification of the applicability of the prohibition on valuable consideration to living donation arrangements such as paired donation and list donation would avoid legal ambiguities and possible lawsuits.

Valuable Consideration and Living Donation Arrangements

It is clear that living donation arrangements such as paired donation and list donation do not involve actual monetary payments to the donor or recipient. The concern that has been raised is whether the donors and recipients in multiple living donation arrangements have received "valuable consideration" for their promises to get something in return for specific acts. Such arrangements arguably involve some kind of bargain since there are mutual promises on both sides of the arrangement.[41] For example, in a paired donation where the donor trades his organ for a compatible organ for his intended beneficiary, an argument may be made that the donor receives

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[37] H.Rept. 98-1127 (1984), at 16, reprinted in 1984 U.S.C.C.A.N. 3989, 3992.

[38] Assessing Initiatives to Increase Organ Donations: Hearing Before the House Subcomm. On Oversight & Investigations of the House Comm. on Energy & Commerce, 108th Cong., at 5, 21, 64-67 (2003).

[39] Johns Hopkins Medical Center began a paired organ donation program in 2001. To date, at least twenty-two patients have benefitted from the program, and, recently, the first three-way swap involving 6 people, was completed. Sarah E. Statz, Note, Finding the Winning Combination: How Blending Organ Procurement Systems Used Internationally Can Reduce the Organ Shortage, 39 *Vanderbilt Journal of Transnational Law* 1677, 1704 (2006).

[40] Floor statement of Senator Carl Levin on introduction of the Living Kidney Organ Donation Clarification Act, S. 2306, 109th Congress, February 17, 2006, available at [http://www.govtrack.us/congress/record.xpd?id=109-s20060216-31&person=300001], visited March 3, 2007.

[41] See Michael T. Morley, Note, Increasing the Supply of Organs for Transplantation Through Paired Organ Exchanges, 21 *Yale Law and Policy Review,* 221, 255-261 (2003).

"valuable consideration" in the exchange of mutual promises to donate organs.[42] We have been unable to find any reported court cases that have ruled on the legality of this kind of organ donation arrangement.

The Associate General Counsel to UNOS recently provided a legal analysis of the applicability of § 301 of NOTA to both paired donation and list donation arrangements, concluding that "NOTA §301 is legally and historically inapplicable to today's living donation arrangements."[43] Elaborating on the applicability of the § 301 prohibition on the exchange of "valuable consideration," the UNOS legal analysis states as follows:[44]

> "Valuable consideration" under NOTA § 301 is a monetary transfer or a transfer of valuable property between donor, recipient and/or organ broker in a sale transaction. It is not familial, emotional, psychological or physical benefit to the organ donor or recipient, all of which attach equally to the "living-related kidney transplants" in yesterday's terminology and to the multi-party intended recipient donations, paired donations and similar innovative and highly beneficial living donation arrangements of today and tomorrow. There is no "valuable consideration" under NOTA § 301 in any of these living donation arrangements. The donor receives none, the recipient gives none and none is transferred to a broker. In fact, there is no "consideration" at all in a living organ donation arrangement because the donation is a "gift"....
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> A gift is different from a contract. A contract does not involve donative intent. "Consideration" and the mutual agreement of the parties are required to make the contract legally binding. A gift, on the other hand, involves a gratuitous transfer by the donor and no transfer of money, property or services or agreement not to exercise rights or to suffer material detriment ("consideration") by the beneficiary. For that reason, it is often said that no "consideration" is present in a gift. A promise to make a gift of an organ is not intended to be legally binding.
>
> The donation of an organ is properly considered to be a gift, rather than a contractual undertaking. As gifts, living donations may be made conditionally for a specific purpose. The condition can be construed as "consideration" only if the happening of the condition will be a benefit to the person who promises to give an organ. If, on the other hand, the happening of the condition will not benefit the promisor and is merely for the purpose of enabling the promisee to receive a gift, the condition is not "consideration." [footnotes omitted]

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[42] While one may find state court cases stating that "(a)ny act or promise which is of benefit to one party or disadvantage to the other is a sufficient consideration to support a contract," *Steinberg v. Chicago Med. Sch.*, 371 N.E.2d 634, 639 (Ill. 1977), one may also find cases stating that the fulfillment of a promisor's condition that is merely for the purpose of enabling the promisee to receive a gift, does not constitute consideration for a contract. See *Stelmack v. Glen Alden Coal Co.*, 14 A.2d 127, 128-129 (Pa. 1940).

[43] Malcolm E. Ritsch, Jr., Position Statement: Kidney Paired Donations, Kidney List Donations and NOTA § 301, at 2 (September 18, 2006).

[44] Id. at 3.

The Associate General Counsel's analysis concludes that, although list donation and paired donation involve more than a single set of recipients and/or donors, the condition in each case benefits the intended recipient rather than the donor. Thus, these transactions are conditional gifts and do not involve any federally prohibited exchange of valuable consideration.

Because NOTA does not specifically address living donation arrangements which have only been developed in recent years, various proposals have been offered to make clear that living donation arrangements such as paired donation and list donation are legal and do not involve the exchange of "valuable consideration" under § 301 of NOTA. As previously noted, S. 487 and H.R. 710 in the current Congress would amend § 301 of NOTA to specifically provide that "kidney paired donation shall not be considered to involve the transfer of a human organ for valuable consideration." While this language would clarify the application of § 301 to kidney paired donation, it would not provide definitive clarification for other kinds of living donation arrangements. Other approaches also could be used to clarify that the prohibition on the exchange of "valuable consideration" for human organs does not implicate newly developed living donation arrangements. For example, S. 573 in the 108th Congress would have amended § 301 to state: "Such term does not include familial, emotional, psychological, or physical benefit to an organ donor, recipient, or any other party to an organ donation event."

Ethical and Policy Issues Related Living Organ Donation, and Paired and List Kidney Donation

The central ethical question involved in organ transplantation is how to balance the needs of people seeking organs with one another, and with the needs of potential organ donors. This question has given rise to many issues, discussed below, including those related to: evolving transplantation systems; the directive that physicians do no harm; risk-benefit ratios; informed consent; type O recipients; resource allocation; parity; and the possibility of paying for organs.

In order to help address the ethical issues, two groups have made recommendations, and a third has held deliberations. First, the ACOT[45] has made a series of recommendations to the Secretary. Second, the Institute of Medicine (IOM) issued a report in 2006, *Organ Donation: Opportunities for Action.*[46] Third, the President's Council on Bioethics (PCBE), which was created in 2001 to advise the President on bioethical issues, took up the issue of organ transplantation in its June 2006 and February 2007 meetings.[47] Relevant recommendations and discussions from ACOT, IOM, PCBE and a variety of articles are summarized in the following sections.

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[45] ACOT was established under the authority of 42 U.S.C. Section 217a. See the ACOT website, at [http://www.organdonor.gov/research/acot.htm], visited March 3, 2007.

[46] IOM Report.

[47] Background materials and transcripts from the PCBE's June 2006 meeting on organ transplantation are available at the PCBE site, at [http://www.bioethics.gov/topics/organ_index.html], visited March 3, 2007.

Evolving Transplantation Systems

As new transplantation systems test the boundaries of old regulations, the primary question arises — does Congress want to maintain direct control over key components of the system to help ensure that ethical boundaries are not breached, or does Congress want to delegate more of its authority in order to make the system more flexible? This question may be sparked by several aspects of H.R. 710 and S. 487. First, the bills would only apply to the donation of kidneys, not to other organs, so they would not resolve questions related to paired transplantation systems for other organs, should they ever be developed. Second, the bills use but do not provide a definition for the term *kidney paired donation*, which could eventually lead to questions regarding the boundaries of this type of arrangement. Third, the bills only specify that paired kidney donation (not kidney list donation) is exempt from the definition of valuable consideration and, therefore, permissible. This proposal is more narrow than that of S. 2306 (109th), which would have also exempted both kidney paired and list donation, and S. 573 IS (108th), which would have exempted the even broader category of "familial, emotional, psychological, or physical benefit[s]."

ACOT proposed one possible alternative that would enable more flexibility for developing transplantation systems. The Committee recommended that the HHS Secretary seek the authority from Congress to promulgate regulations clarifying the scope of the term valuable consideration, thus allowing for the regulations' revision as transplantation technologies and methods evolve.[48] This would allow the Secretary to make modifications as new systems are developed and to develop any definitions necessary to interpret the regulations. ACOT also recommended that the Secretary support S. 573 (108th).[49]

Ethical Issues Related to Living Donation

In medical practice generally, three primary guiding principles are that a physician should, above all, do no harm to a patient, that a procedure's benefits to a patient should outweigh its risks, and that one must obtain informed consent prior to medical procedures. The practice of obtaining organs from living donors challenges all three of these principles. Because H.R. 710 and S. 487 seek to expand the practice of living organ donation, they raise issues with respect to these three principles, but not to a greater extent than such issues already raised by the current practice of living organ donation. The same was true for S. 2306 (109th) and S. 573 IS (108th).

Above All, Do No Harm. The traditional first rule of medicine — above all, do no harm — would seem on its face to proscribe the practice of removing a heathy organ from a healthy person, making one a patient solely to benefit another person

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[48] ACOT, *Recommendation 36*, November 4-5, 2004, at [http://www.organdonor.gov/research/acotrecssumm36-42.htm], visited March 3, 2007.

[49] ACOT, *Recommendation 26*, May 22-23, 2003, at [http://www.organdonor.gov/research/acotrecsbrief.htm], visited March 3, 2007.

who is already a patient. Indeed, one survey of 100 liver transplant surgeons found that 77% experienced a moral dilemma in placing a living donor at risk.[50] Still, 72% also agreed that transplant centers had a duty to offer their patients the possibility of transplantation using living donors. IOM considered this point in its report, and suggested that the Health Resources and Services Administration (HRSA) conduct a long and full review of living donation.[51]

Risk-Benefit Ratios. The IOM also noted difficulties with living donation and the principle that a doctor should not perform a procedure unless the potential benefits outweigh the risks.[52] This calculation is generally made for each patient independently — it is not ethically acceptable for one patient to bear all of the risks and another to reap all of the benefits. On this point, IOM noted that a living donor may gain psychosocial benefits from donating an organ to one in need, which could arguably outweigh the risks to the donor's physical health. However, in order to help ensure that the risk is not too great for a particular donor due to a preexisting medical condition or the like, IOM recommended that an independent donor advocate be appointed to assess the risk-benefit ratio.

Even with a donor advocate to make the risk-benefit assessments, one major factor complicates the assessment of the ratio: little is known about the long term health and quality-of-life effects of being a living organ donor. This lack of information makes it difficult for professionals to ensure that they consider the full spectrum of risks to be outweighed by benefits. Therefore, IOM recommended (as ACOT had before[53]) that living donor registries be established to enable follow-up research on the long-term effects of living donation.[54] In addition, in June 2006, HHS solicited public comments from the organ transplant community for living donation after "several widely publicized living donor deaths" and an increasing trend in the number of living donations.[55]

Informed Consent. Ethically justifiable living organ donation presupposes the competent donor's voluntary informed consent. ACOT specified that living donors' informed consent must be competent, free from coercion, and fully informed of the risks and benefits as a donor, among other things.[56] As IOM noted, obtaining informed consent is confounded by the same lack of long-term health data

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[50] S.J. Colter, et al., "Adult living donor liver transplantation: Perspectives from 100 liver transplant surgeons," *Liver Transplantation*, vol 9, no. 6, pp. 637-644 (2003), in IOM Report, p. 307.

[51] IOM Report, p. 308.

[52] Id. at pp. 312-315.

[53] ACOT, *Recommendation #42*, May 9-10 2005, at [http://www.organdonor.gov/research/acotrecssumm36-42.htm], visited March 3, 2007.

[54] IOM Report, p. 276.

[55] HHS, HRSA, *Federal Register*, June 16, 2006, p. 34946.

[56] ACOT, *Recommendation #1*, November 18-19, 2002, at [http://www.organdonor.gov/research/acotrecsbrief.htm], visited March 3, 2007.

that makes assessing the risk-benefit ratios difficult.[57] It is not possible to fully inform potential living donors (a necessary component of informed consent) without information about the likely impact of the procedure on long-term health. IOM suggested that creating a living donor registry would enhance informed consent as well as inform the risk-benefit analysis.

Further problems in obtaining informed consent are related to the requirement that it be given voluntarily. Establishing a voluntary process may be complicated if donors are not legally competent to consent (e.g., children), or if situations are coercive (e.g., loved ones feel pressured to become living donors). Some potential donors have expressed relief at discovering that they were incompatible with their intended recipients. The prospect of paired and list exchanges eliminates the incompatibility excuse for potential donors, and may thus create a coercive situation. IOM's recommendation that each living donor receive an advocate is aimed at protecting voluntary informed consent as well as evaluating the risk-benefit ratio. In addition, IOM recommends that the advocates address gender disparities in living donation. Women represent 56% to 59% of living kidney donors each year, and one study suggests that this is due primarily to the fact that women are asked to donate more often than men.[58]

Ethical Issues Related to List Donation: Blood Type O

Approximately 46% of the population has the blood type O, yet they represent 51.9% of people awaiting organ transplants, and 52.5% of people awaiting kidney transplants.[59] More than half have to wait more than 5 years for an organ (53.2%) or kidney (54.8%). No other blood type comes close to rivaling these waiting times. The percentage of people who have to wait more than five years is as follows:

- for blood type A — 28.3% for organs, and 22.8% for kidneys,
- for blood type B — 16.1% for organs, and 20.2% for kidneys, and
- for blood type AB — no recipients have to wait more than five years.

As noted previously, several authors have expressed concern that individuals with the blood type O, an already disadvantaged population in the transplantation system, may be further disadvantaged by a list donation system. Implementing a system with a disparate impact, particularly one that falls on an already disadvantaged group, has caused some authors to recommend that list paired

[57] IOM Report, p. 315.

[58] Id. at p. 318.

[59] The statistics in this paragraph are from UNOS, current as of February 9, 2007 [http://www.optn.org/latestData/rptData.asp].

donation have a minimal role on a national level.[60] It has caused others to recommend that the system be modified to protect type O recipients.[61]

A different set of authors has come out in favor of the list exchange program despite the impact on people with type O blood.[62] They claim that the impact on type O recipients would be transient. Though some people would be bumped to the top of the transplant list, their absence from that list when they would have come to its top (4-5 years later) would eventually balance out the impact of the system.

H.R. 710 and S. 487 avoid the type O issue by focusing only on paired, and not list, donation. S. 2306 (109th) and S. 573 IS (108th) would have raised the type O issue, as each would have permitted list exchange systems, but neither bill addressed the issue directly.

Ethical Issues Related to Directed Donation (Paired and List)

Directed donation, which allows an organ donor to specify the recipient, creates issues related to the equitable allocation of organs. Paired and list donation (both of which are types of directed donation) create parity issues regarding what the intended recipient should be entitled to receive in lieu of the donation. H.R. 710 and S. 487 would support a form of directed donation (paired donation), and thus raise the issues discussed below. The same was true for S. 2306 (109th), and S. 573 IS (108th).

Allocation. People on waiting lists for organs may wait years for a transplant, and may die before an organ becomes available. The rules governing who gets an organ are, therefore, quite important. In general, the ranking on the waiting list depends on biological matching, medical status, patient location, age of the patient, and length of time the patient has been on the waiting list for a transplant.[63] By contrast, directed donation allows the donor to choose who receives their organ (or, in the case of list donation, who is to advance on the waiting list). The PCBE noted that this raises the question of whether it is ethical for one person to receive an organ before another more needy person, simply because someone cares for them enough to make a donation.[64] PCBE also noted that prohibiting such acts of love as living donation in the name of justice would be perverse.

Parity. Some have suggested that in paired and list donations, the donated and received organs must be of equal value to ensure an equitable exchange.[65] While

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[60] S. E. Gentry, p. 1920.

[61] L.F. Ross, pp. 641-646.

[62] F.L. Delmonico, p. 1632.

[63] For a description of the process, see, *UNOS, Fact Sheets*, Prioritizing patients for transplantation [http://www.unos.org/resources/FactSheets.asp], March 3, 2007.

[64] E. Cohen, p. 15.

[65] See, for example, Douglas J. Norman, "Commentary" *Nature Clinical Practice-*

(continued...)

this might be possible with a paired exchange, it is almost certainly not the case with a list donation, because the intended recipient will receive a kidney from a deceased donor instead of a living one. (Deceased donor organs do not typically last as long as living donor organs). Other issues related to parity have been raised, such as whether one donor in a paired exchange may change his or her mind if the other donor has already undergone surgery. To prevent these scenarios, it has been suggested that both donors should undergo surgery at the same time.[66] Other authors have suggested that outcome parity cannot be guaranteed in list and paired exchange programs.[67] If one organ fails, the recipient is not necessarily entitled to receive another.

Ethical Issues Related to Proposals for Expanding the Organ Supply: Exchanging Valuable Consideration for an Organ

The demand for transplantable organs has inspired a wide variety of proposals to increase the supply, including some that would allow or encourage forms of payment for organs. Congress has considered several proposals to give donors honorific or tax incentives for donating organs.[68] The use of financial incentives has been studied, proposed and debated in the general literature. Various organizations, including the American Medical Association and UNOS have supported the study of financial options to encourage organ donations.[69] Arguments have been made that donors of organs should be treated no differently than donors of tissues[70] (such as human hair, blood plasma, sperm, and eggs). It has also been argued that because the practice of transplanting organs is profitable for the professional parties involved, those from whose bodies the organs are harvested should be able to share in some of the profits.[71]

There has been resistance to proposals that encourage commodification of human organs. The IOM conducted an extensive analysis of various types of

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[65] (...continued)
Nephrology, vol. 2, no. 6 (June 2006), p. 303.

[66] Id. at p. 303.

[67] F.L. Delmonico, p. 1633.

[68] The 107th Congress considered S. 325 and H.R. 708 (which would have given donors a Congressional medal), and H.R. 1872 and H.R. 2090 (which would have provided tax credits for donation).

[69] See testimony of Dr. Robert M. Sade, 2003 House Hearing, supra, available at [http://energycommerce.house.gov/reparchives/108/Hearings/06032003hearing946/Sade1500.htm], visited March 3, 2007; and UNOS press release, OPTN/UNOS Board Endorses Studies of Incentives to Increase Donation (June 28, 2002), available at [http:www.unos.org/news/newsDetail.asp?=1], visited March 3, 2007.

[70] Tissues, such as corneas, plasma, and gametes, are distinct from and regulated under an entirely different system than organs.

[71] See, for example, President's Council on Bioethics, "On the Body and Transplantation: Philosophical and Legal Context, Appendix: 'Organs' and 'Tissues' in the Therapeutic Transplantation Context," *Staff Discussion Paper*, Feb. 15-16, 2007, pp. 2-3.

financial incentives to encourage donation, such as payment through regulated futures markets, payment of funeral expenses, providing bereavement counseling, tax incentives, and providing health insurance.[72] IOM concluded that none should be promoted at this time because of a lack of evidence that these incentives would improve donation rates, because once put in motion a system of financial incentives would be difficult to reverse, and because of fears that such systems might disproportionately affect the poor. This recommendation came as a disappointment to some who seek to increase the supply of transplantable organs.[73]

While both H.R. 710 and S. 487 would clarify a limitation on NOTA's definition of valuable consideration, neither would permit the payment of money in exchange for organ donation. The same was true for S. 2306 (109th), and S. 573 IS (108th).

[72] IOM Report, pp. 269-302.

[73] See, for example, Richard Epstein, "Kidney Beancounters," *The Wall Street Journal,* May 15, 2006, p. A5.