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INTENDED RECIPIENT EXCHANGES, PAIRED EXCHANGES AND NOTA § 301

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As General Counsel to United Network for Organ Sharing (UNOS), Malcolm E. Ritsch, Jr. of our law firm has been asked to provide information and legal analysis regarding Section 301 of the National Organ Transplant Act (NOTA), 42 U.S.C. 274e. This analysis is provided as a general resource for the organ transplant community and for counsel advising organ transplant programs and organ procurement organizations.

Section 301 of the NOTA, copied verbatim below, is a federal criminal statute. It applies only to the fields of organ and tissue transplantation and must be interpreted in that specific context. In recent years, donations of kidneys by living donors have begun to involve multiple donors and/or recipients. Transplant physicians have been approached by individuals who wish to donate to a spouse or other family member, but are unable to do so because of blood type incompatibility or other immunological barriers. Thus, living donation arrangements have been initiated that permit either an intended recipient exchange or a simultaneous living donor exchange.

Intended recipient exchanges involve three individuals: a living donor, the recipient of the living donor's kidney, and the donor's intended recipient who receives an allocation priority on the kidney waiting list. The intended recipient exchange program yields additional donor sources for patients awaiting nonliving donor organs.

Paired exchanges involve two living donors and two recipients—the intended recipient of each donor is incompatible with the intended donor but compatible with the other donor in the exchange. Every paired exchange transplant avoids burdening the kidney waiting list and increases access to organs for all kidney transplant candidates.

Transplant professionals involved in these and other innovative living kidney donation arrangements have proceeded in the reasonable belief that these arrangements do not violate NOTA § 301. This position statement explains why NOTA § 301 is legally and historically inapplicable to today's living donation arrangements.

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Legal Treatment of Living Organ Donation

The donation of an organ is properly considered to be a legal gift, rather than a contractual undertaking. By definition, there is no "consideration" at all in a gift transaction.[1] The focus on organ *donation* in the legislative history of NOTA and the enactment of anatomical *gift* acts in the various states demonstrate the legal understanding that organs donated in order to confer health benefits on other individuals are legal gifts.

Like all gifts, organ donations may be made for specific purposes.[2] For example, money may be donated to a college for the specific purpose of endowing a professorship. Similarly, organs may be donated to the organ pool for the purpose of conferring a health benefit on a specific individual. In either case, the college or transplant center that accepts the gift agrees to carry out the specific purpose for which the gift was given.

History of Living Donation

When NOTA was enacted in 1984, "living-related kidney transplants" had been performed for thirty years. Living donors were usually related by blood to transplant recipients. That was not always the case, since the essential element of HLA compatibility can exist between related or unrelated individuals. In fact, unrelated living donation of kidneys began more than thirty years ago in this country, although it was often imprecisely lumped into the "living-related" category. Today, the terminology has evolved to become simply "living donation" because immunosuppressive drugs have broadened the range of donor/recipient compatibility, and the severe shortage of available kidneys has brought forth living donors motivated by the desire to make a gift to someone in need. Innovative multi-party approaches to living donation such as intended recipient exchanges and paired exchanges are today's edition of "living-related kidney transplants."

In 1984 and today, the basic attributes of the living donation arrangement remain the same. The donor intends to make a gift, is not financially benefited and assumes the lifetime health risk of having only one kidney. The donor's increased risk is acknowledged today by the award of a kidney allocation preference should the donor later need a transplant. The recipient receives a kidney and pays nothing to the donor. And the national pool of organs is one kidney better off due to the donor's generosity because

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[1] Black's Law Dictionary defines "donation" as "A gift. A transfer of title to property to one who receives it without paying for it. The act by which the owner of a thing voluntarily transfers the title and possession of the same from himself to another person, **without any consideration**." (emphasis added). Similarly, "gift" is defined as "A voluntary transfer of property to another made **gratuitously and without consideration**. Essential requisites of 'gift' are capacity of donor, intention of donor to make gift, completed delivery to or for donee, and acceptance of gift by donee." (emphasis added). A number of court cases have found that gifts cannot contain consideration. *See Liu v. T&H Machine, Inc.*, 191 F.3d 790, 797 (7th Cir. 1999) (concluding that gifts do not require consideration); *Rusk v. Rusk*, 5 S.W.3d 299, 303-05 (Tex. App. 1999) (holding that absence of consideration is key to finding a legal gift).

[2] *See Wilkin v. Wilkin*, 116 Ohio App. 3d 315, 318-19, 688 N.E.2d 27, 29-30 (Ohio App. 1996) (holding that the failure of the purpose attached to a gift causes the gift to fail as well); *Frame v. Shreveport Anti-Tuberculosis League*, 538 So. 2d 684, 688-89 (La. App. 1989) (noting that donor may attach any lawful condition or special purpose to gift that donor desires).

the gift removes the recipient from the waiting list. In 2001, there were 5,990 living donor kidney transplants and 8,208 nonliving donor kidney transplants.

There is no suggestion whatsoever in § 301 of NOTA (see below) that either the "living-related kidney transplants" of yesterday or the living donation arrangements of today are illegal. To the contrary, the payment of "the expenses of travel, housing, and lost wages incurred by the donor of a human organ in connection with the donation of the organ" is expressly permitted by § 301 of NOTA. Such expenses are incurred by living donors and not by nonliving donors. What NOTA's one-sentence criminal provision (§ 301(a) below) outlaws is the purchase and sale of organs for profit. That was clearly Congress' intent from the legislative history excerpted below. Certainly, Congress did not intend to endorse a payment to the living donor for expenses and lost wages in subsection 301(c)(2) of NOTA, yet render the living donation arrangement itself criminal in subsection 301(a).

"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 exchanges, paired exchanges 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. In fact, there is no "consideration" present at all. The donor receives none, the recipient gives none and none is transferred to a broker.

Section 301 of NOTA (42 U.S.C. § 274e)

§ 301. Prohibition of organ purchases

(a) **Prohibition.** It shall be unlawful for any person to knowingly acquire, receive, or otherwise transfer any human organ for valuable consideration for use in human transplantation if the transfer affects interstate commerce.

(b) **Penalties.** Any person who violates subsection (a) of this section shall be fined not more than $50,000 or imprisoned not more than five years, or both.

(c) **Definitions.** For purposes of subsection (a) of this section:

(1) The term "human organ" means the human (including fetal) kidney, liver, heart, lung, pancreas, bone marrow, cornea, eye, bone, and skin or any subpart thereof and any other human organ (or any subpart thereof, including that derived from a fetus) specified by the Secretary of Health and Human Services by regulation.

(2) The term "valuable consideration" does not include the reasonable payments associated with the removal, transportation, 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.

(3) The term "interstate commerce" has the meaning prescribed for it by section 321(b) of Title 21.

Note that the title of Section 301 is "Prohibition of organ **purchases**." Congress, in enacting

NOTA, intended to criminalize the buying and selling of organs for profit, and not the voluntary donation of organs:

> The Organ Procurement and Transplantation Act, S. 2048, amends the Public Health Service Act (PHSA) and makes additional provisions, as follows:
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> (5) Prohibits the **interstate buying and selling of human organs** for transplantation.
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> Finally, the **prohibition on the buying and selling of human organs** is directed at **preventing the for-profit marketing** of kidneys and other organs.

S. Rep. No. 382, 98th Cong., 2nd Sess. 1984, 1984 WL 37470 (Leg. Hist.). The House of Representatives agreed with the Senate's characterization of the purpose of Section 301:

> The Senate bill and the House amendment contained provisions prohibiting the sale for valuable consideration of human organs for use in human transplantation if the transfer effects [sic] interstate commerce. The Conference Agreement reflects the House provision with language clarifying this prohibition. **This title intends to make the buying and selling of human organs unlawful** with maximum penalties not to exceed $50,000 and/or imprisonment of up to five years for such violation. 'Human organ' is defined as the kidney, liver, heart, lung, pancreas, bone marrow, corneas, eyes, bone, and skin, and any other human organ included by the Secretary of Health and Human Services by regulation. The term 'human organ' is not intended to include replenishable tissues such as blood or sperm.
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> The term 'valuable consideration' does not include the reasonable payment associated with removal, transportation, implantation, processing, preservation, quality control, and storage of a human organ in connection with the donation of that organ. Reasonable payments to organizations processing human tissues, such as corneas, should not be included in the terms 'valuable consideration.'

H.R. Conf. Rep. No. 1127, 98th Cong., 2nd Sess. 1984, 1984 WL 37471 (Leg. Hist.). The Senate continued to refer to "valuable consideration" as relating to the purchase and sale of organs in the legislative history of the 1988 Amendments to NOTA:

> In addition to **prohibiting the purchase of organs**, the act provided for the establishment of grants to organ procurement agencies and a national organ-sharing system.

S. Rep. No. 310, 100th Cong., 2nd Sess. 1988, 1988 WL 169911 (Leg. Hist.)