# Court of Appeals of the State of New York

ROBERT COLAVITO,

Petitioner-Plaintiff-Appellant,

- against -

NEW YORK ORGAN DONOR NETWORK, INC., ROBERT KOCHIK, SPENCER HERTZEL, GOOD SAMARITAN HOSPITAL MEDICAL CENTER, DR. DOE I, M.D. and DR. DOE II, M.D.,

Respondents-Defendants-Appellees.

AMICI CURIAE BRIEF OF AMERICAN ASSOCIATION OF TISSUE BANKS, AMERICAN SOCIETY FOR TRANSPLANT SURGEONS, AMERICAN SOCIETY FOR TRANSPLANTATION, ASSOCIATION OF ORGAN PROCUREMENT ORGANIZATIONS, NATCO – THE ORGANIZATION FOR TRANSPLANT PROFESSIONALS, NATIONAL KIDNEY FOUNDATION and UNITED NETWORK FOR ORGAN SHARING

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### INTERESTS OF AMICI CURIAE

This brief is submitted by seven non-profit organizations and associations which have prominent national roles in ensuring that organ donation and transplantation are conducted safely, efficiently, fairly and in a manner that maximizes the life-saving potential of each gift.

## American Association of Tissue Banks

The American Association of Tissue Banks ("AATB") is a national, non-profit organization dedicated to ensuring that human tissues donated for transplantation are safe and free of infectious disease, of uniform high quality and available in quantities sufficient to meet national needs. To fulfill that mission, AATB has published the only authoritative industry standards for tissue banks and initiated a mandatory Accreditation Program for its institutional members. AATB's membership currently includes more than 1,100 individual members and 92 accredited tissue banks. These accredited banks recover tissue from more than 25,000 donors and distribute in excess of 1.5 million tissue allografts for transplantation annually.

## American Society of Transplant Surgeons

The American Society of Transplant Surgeons ("ASTS") is a national, non-profit organization that promotes and encourages education and research with respect to organ and tissue transplantation to facilitate progress in the saving of lives of patients afflicted with end stage organ failure. ASTS works with existing public and private organizations to promote and encourage education and research in transplantation and participates in the coordination of efforts and formulation of programs by surgeons, physicians, scientists, agencies and health personnel to maximize efficiency in the transplant context and to optimize the benefit to transplants recipients.

## American Society of Transplantation

The American Society of Transplantation ("AST") is an international, non-profit organization of transplant professionals dedicated to advancing the field of transplantation through the promotion of research, education, advocacy and organ donation to improve patient care. AST's very diverse membership includes physicians, surgeons, scientists, nurses, coordinators, pharmacists and other allied health professionals actively engaged in the science and clinical practice of organ and tissue transplantation.

### Association of Organ Procurement Organizations

The Association of Organ Procurement Organizations

("AOPO") is a national, nonprofit membership organization

representing all 58 of the nation's federally designated organ

procurement organizations ("OPOS"), to bring their collective

voices to issues of importance to the organ and tissue

community. AOPO publishes detailed standards on organ

donation and procurement practices that are used to accredit

OPOs. AOPO represents and serves organ procurement

organizations through advocacy, support, and development of

activities that will maximize the availability of organs and

tissues and enhance the quality, effectiveness and integrity

of the donation process. OPOs serve as the vital link between

the donor and recipient and are responsible for the

identification of donors, and the retrieval, preservation and

transportation of organs for transplantation.

## NATCO, The Organization for Transplant Professionals

NATCO, The Organization for Transplant Professionals ("NATCO") is a national, non-profit organization that supports, develops and advances the knowledge and practice of its members to influence the effectiveness, quality and integrity of donation and transplantation. NATCO membership

comprises a diverse group of professionals including transplant practitioners, hospital specialists and public educators. NATCO is recognized as the preeminent provider of on-going education to transplant professionals.

## National Kidney Foundation

The National Kidney Foundation ("NKF") is a national, non-profit voluntary health organization that seeks to prevent kidney and urinary tract diseases, improve the health and well-being of individuals and families affected by these diseases and increase the availability of all organs for transplantation. NKF supports research, the continuing education of health care professionals, the expansion of patient services and community resources, fundraising and the shaping of public policy on issues related to kidney health.

## United Network for Organ Sharing

United Network for Organ Sharing ("UNOS") is a national, non-profit membership corporation that administers the nation's Organ Procurement and Transplantation Network ("OPTN"), under contract with the U.S. Department of Health and Human Services, Health Resources and Services

Administration, Division of Transplantation. As such, UNOS manages the nation's organ transplant system and oversees the

world's most comprehensive database of clinical transplant information, including the computerized organ sharing system for matching donated organs to patients who are registered on the national organ transplant waiting list. Through its role in administering the OPTN, UNOS brings together medical professionals, transplant recipients, and donor families to develop national organ transplantation policies. These policies guide the transplant community and operate in concert with the requirements of the OPTN Final Rule (42 C.F.R. pt. 121) and other Department of Health and Human Services regulations.

The seven national non-profit associations and organizations listed above address the Court as amici curiae to illuminate for the Court's consideration the gift law framework in which organ donation operates and the significant national policy implications of the issues under the Court's review. We file this brief to urge that the Court find: (a) that applicable law does not vest the intended recipient of a directed donation with rights that can be vindicated in a private party's lawsuit sounding in the common law tort of conversion; and (b) that negligent misconduct (including conduct which is grossly negligent) is immunized under New York Public Health Law consistent with the Uniform Anatomical Gift Act ("UAGA").

### PRELIMINARY STATEMENT AND SUMMARY

The first question before this Court is: Do the applicable provisions of the New York Public Health Law vest the intended recipient of a directed organ donation with rights that can be vindicated in a private party's lawsuit sounding in the common law tort of conversion or through a private right of action derived from the New York Public Health Law? To analyze this issue, we ask that the Court first consider the greater public policy context within which this question exists. The laws and regulations surrounding deceased organ donation, allocation and transplantation have purposefully established a legal infrastructure that excludes property law concepts and do not treat organs as commodities. This is not by accident or oversight. Instead, organs are donated for transplantation voluntarily (not sold or appropriated) and are regulated as a scarce national resource allocated to balance medical utility with equity in a formulation designed to avoid wastage and maximize the life saving potential of each donation. This is the policy directive established by the National Organ Transplant Act ("NOTA"), found at 42 U.S.C. §273 et seq. and reinforced through applicable regulations found at 42 C.F.R. pt. 121.

To fulfill this clearly articulated goal, organ allocation - even in the directed donation context - is a complicated clinical matching and coordination process that is laden with medical judgment and culminates in an intricate surgical procedure. From the time donation is authorized until a donated organ is transplanted into a recipient, there are numerous conditions and events beyond the organ donor's or potential recipient's control that determine who the actual recipient of the organ will be. An organ from a deceased donor is unlikely to be medically acceptable to a directed donee for a variety of reasons including blood or tissue type incompatibility, condition of the deceased's organ, or condition of the potential intended recipient as determined by the medical judgment of the transplant surgeon and the potential intended recipient's physician. Therefore, fluidity is critical to maintaining a national system that operates to maximize life-saving transplants and minimize wastage during coordinated clinical events and extreme time pressure.

The UAGA, as adopted in New York and all other states, establishes the gift law framework for organ donation and clearly mandates that all gifts of deceased donor organs are conditioned upon medical benefit to the intended potential recipient. In fact, the gift of an organ is neither accepted nor legally acceptable by an individual until the transplant

Surgeon actually transplants the organ into the recipient.

Until the completion of the transplant procedure, the gift is not recognized under the UAGA and, therefore, the intended potential recipient has no right in the organ. Put simply, the assertion of common law property and contract rights is misplaced in the unique context of organ donation, which is governed by the statutory gift law construct of the UAGA.

The second question before this Court is: Does New York
Public Health Law immunize either negligent or grossly
negligent misconduct? The express purpose of the good faith
immunity provisions under the UAGA is to immunize those who
coordinate the organ donation and transplantation process from
liability unless there is actual malice. The organ donation
and transplantation process is extremely time-sensitive and
highly complex. A good faith conduct standard is appropriate
to this context. We ask that the Court find that New York
Public Health Law, consistent with the holdings of courts in
New York and other states that have interpreted the UAGA,
immunizes negligent and grossly negligent misconduct.

# BACKGROUND: THE NATIONAL ORGAN DONATION AND TRANSPLANTATION SYSTEM

The facts of this case involve the directed donation of a deceased donor organ to a potential recipient. Directed

donations are made within the broader national organ procurement and transplantation system. The vast majority of transplant candidates receive transplants of deceased organs allocated through the national system. Less than 3% of total deceased organ recipients each year receive transplants resulting from directed donation. Accordingly, a potential recipient of a directed donation is also registered on the national waiting list potentially to receive a deceased donor organ and, therefore, does not rely solely on a directed donation for his or her organ transplant.

Organs for transplantation in the United States are procured and allocated through a national system designed and administered by the Organ Procurement and Transplant Network ("OPTN") pursuant to federal statute. This Network - a result of NOTA and OPTN regulations known in the organ donation and transplantation field as "the OPTN Final Rule" - seeks to maximize the use of donated organs for transplantation through an effective system of organ recovery combined with equitable organ placement. 42 U.S.C. §273 et seq. (1987); 42 C.F.R. pt. 121.

The work of recovering organs for transplantation from deceased patients in the United States is done by 58 federally-designated, non-profit, Organ Procurement Organizations ("OPOs"). Each OPO has a designated service

area for which it is responsible. Federal regulations and New York state law require hospitals to refer all deaths and imminent deaths to their area OPO to maximize all possible opportunities for donation for transplantation. 42 C.F.R. § 482.45(a)(1) (2005); N.Y. Public Health Law § 4351(1)(a) (2005); N.Y. Comp. Codes R. & Regs. tit. 10, § 405.25(b) (2005). Once an OPO receives a referral from a hospital, an initial medical suitability assessment is conducted to determine if the patient meets basic medical criteria for organ donation; if so, the OPO will send a coordinator to the hospital to obtain additional current and past medical information and to be on hand to coordinate a possible donation after the patient is declared dead.

The process of obtaining consent for donation varies slightly by state and OPO practice, but is guided by the UAGA. Generally, the UAGA sets forth the ways in which anatomical gifts of deceased donor organs may be made either by adult individuals before they die (donor card, donor registry etc.) or by next-of-kin following the death of a family member.

After consent for donation is verified (if an anatomical gift has been authorized by the donor prior to death) or obtained from the next of kin, the OPO conducts blood tests and other screening examinations, as well as an extensive medical-social history of the potential donor. Should the

donor meet the requirements of this suitability screen, then the process of allocation and recovery of the organs for transplantation can begin.

The process and policies for allocating organs are established by the OPTN through the federal contractor that operates the network, the United Network for Organ Sharing ("UNOS"). UNOS creates computerized algorithms pursuant to principles stipulated by federal regulations that take into account clinical factors such as blood type, tissue type, medical urgency, geographic location (in some cases), physical size of the donor and potential recipient (for some organs), as well as equity factors such as time waiting on the list. Organs recovered from donors are "matched" to patients awaiting transplants through the national transplantation computer system (UNetsm), which was developed and is operated by UNOS. A match list is generated for each potential donor organ at the beginning of the allocation process. This means that one single donor may generate multiple different match lists (e.g. one for the heart, one for the lungs, one for the liver, one for each of the kidneys, and so on). Each match list contains a prioritized list of potential recipient names, as well as the contact information for the listed patient's transplant program.

The local OPO uses the match lists generated through UNet<sup>sm</sup> to begin the lengthy process of contacting - in priority order - the clinicians of potential recipients to offer the donated organ for possible transplant. Depending on the donor's medical information as well as other factors such as timing, logistics, medical condition and availability of the potential recipient, a surgeon may decline or preliminarily accept a donor organ offered for the particular potential recipient. Should the organ be declined, the OPO will contact the clinicians for the next patient on that match list. If a transplant surgeon preliminarily accepts the organ for a particular potential recipient, the OPO may continue to make "back-up" offers, meaning that the organ is offered to other transplant programs that can preliminarily accept the organ for a different potential recipient as "back-up" to the higher priority potential recipient for whom his or her clinicians have preliminarily accepted the organ for transplant. Of the more than 28,000 deceased donor kidneys accepted for transplantation between 2003 and 2005, for example, only 9.2% were accepted for the first candidate (potential recipient with the highest priority) on the match list created for each donated kidney.

The likelihood that a directed donation of a deceased organ will be accepted by the intended recipient is subject to

the same compatibility factors. In fact, from 2000 to 2005 in the designated service area for the New York Organ Donor Network, there were a total of 147 directed donation requests that resulted in only 28 transplants into intended recipients due to clinical compatibility factors.

Allocation is a highly complex and fluid process that must be accomplished simultaneously for each donated organ. Because the allocation process includes application of medical judgment regarding donor organ compatibility with the potential recipient within a critically short period of time, preparations for the physical recovery of the organs are often made while the allocation process is taking place in order to minimize any delay. The OPO secures operating room time for the recovery of the organs and is responsible for coordinating transportation for the recovery surgeons (usually a transplant surgeon from each of the transplant centers where the organs have been allocated).

As the procurement surgeries take place, the recovery surgeon conducts a visual inspection of each organ for possible anomalies that could not be identified in advance through standard suitability tests. Based on this examination, a recovery surgeon may request additional tests on the donor or may decline to use the organ for that particular recipient. In such event, the organ may then be

offered to a surgeon who had preliminarily accepted the organ for a "back-up" recipient. In instances where the clinicians for the back-up potential recipient decline the organ, or where there is no back-up potential recipient, further allocation offers may continue until the organ is accepted for a specific potential recipient or the match list is exhausted. It is also possible that, at the time of additional testing, at the time of recovery, or after the organ has been out of the donor's body too long (approximately, and with some variation, over six to eight hours for hearts and lungs, eighteen to twenty hours for livers and thirty-six to forty hours for kidneys) a donated organ will be determined to be unsuitable for transplantation into any recipient.

Once a transplantable organ is recovered, it is prepared for short-term preservation and transportation to the transplant center where the potential recipient is being prepared for surgery. Upon arrival at the transplant center, the transplanting surgeon will once again inspect the donor organ for suitability and evaluate the potential recipient's condition on the operating table before transplanting the organ into the recipient. Once the transplant takes place, the gift is completed.

### ARGUMENT

I. APPLYING THE COMMON LAW PROPERTY CLAIM OF CONVERSION TO THE SPECULATIVE ABILITY OF A POTENTIAL RECIPIENT TO BENEFIT FROM THE TRANSPLANT OF ANY SPECIFIC ORGAN IS ERRONEOUS FROM BOTH A LEGAL AND PUBLIC POLICY PERSPECTIVE

The issue certified from the Second Circuit Court of Appeals for this Court's consideration centers on determining when a property right in a donated organ, if any, might "vest" in a recipient. Finding such a right at any time prior to the completion of the transplant procedure is incompatible with the statutory gift law directive established by the UAGA and NOTA and would have significant negative consequences for the national system of organ donation and transplantation. It would also lead to legal conflict, confusion, and troubling public policy results.

A. Gift Laws Do Not Support A Conclusion That A
Potential Recipient Has Any Rights In A Donated
Organ Prior To Completion Of The Transplant
Procedure

Finding that a potential recipient has any right in a donated organ prior to actual transplantation of the organ into the recipient is inconsistent with the statutory UAGA gift law framework under which organ donations are regulated. No court has held that an intended recipient has any right in a donated organ or tissue prior to the completion of the gift,

which does not and cannot take place until actual transplantation into the recipient. Prior to that time, the UAGA statutory conditions placed on the anatomical gift - that it be accepted by a qualified donee - have not been met and, therefore, the gift is legally incomplete and consequently unenforceable.

#### 1. UAGA Gift Law

In 1968, the National Conference of Commissioners on Uniform State Laws drafted and approved the UAGA. Prior to the enactment of the UAGA, the organ procurement process was governed by statutory and common law principles that varied significantly from state to state. Prefatory Note, UNIF.

ANATOMICAL GIFT ACT (1968). In response to the "confusion, diversity, and inadequacy" created by the preexisting legal framework, the UAGA was drafted in order to provide "a useful and uniform legal environment throughout the country for this new frontier of modern medicine." Id. Every state in the United States has adopted the UAGA, thereby achieving a uniform legal framework for organ procurement, as intended.

The UAGA establishes the legal framework of organ donation by incorporating with modification the common law of gifts and mandating additional statutory conditions to an anatomical gift. UNIF. ANATOMICAL GIFT ACT (1987); N.Y. Public

Health Law § 4301 et. seq. (2005). Under the UAGA, an anatomical gift is defined as "a donation of all or part of a human body to take effect upon or after death." UNIF.

ANATOMICAL GIFT ACT § 1 (1987). Black's Law Dictionary defines "donation" as "a gift. . . . The act by which the owner of a thing voluntarily transfers the title and possession of the same from himself to another person without consideration."

BLACK'S LAW DICTIONARY 338 (6<sup>th</sup> ed. 1991). The UAGA incorporated this common law definition of donation by requiring that anatomical gifts be donated voluntarily without consideration.

UAGA § 10 (1987); N.Y. Public Health Law § 4307 (2005).

The essential elements of a gift under common law are:

(1) donative intent, meaning the intent to transfer

voluntarily; (2) actual delivery to a beneficiary; and (3)

acceptance by the beneficiary of the gift without paying the

donor for it. Rubenstein v. Rosenthal, 140 A.D.2d 156, 158,

528 N.Y.S.2d 539, 540 (1988). The requirement of delivery may

be relaxed if the gift is causa mortis or evidenced by a

writing. In re Goodwin's Estate, 114 Misc. 39, 44, 185 N.Y.S.

461, 464 (N.Y. Sur. 1920). These common law factors are

incorporated and modified under the UAGA to fit the unique

realities of organ donation and transplantation. An

anatomical gift under the UAGA requires: (1) donative intent

expressed through a document of gift made by the donor or made

by the donor's next of kin as authorized under the statute;

(2) recovery of the anatomical gift upon death (delivery of the document of gift is not required before death); and (3) acceptance of the anatomical gift by a qualified donee as defined by statute. See UAGA §§ 1-3, 6-8 (1987); N.Y. Public Health Law §§ 4301-4306 (2005).

While the UAGA follows these basic gift law principles, it also sets forth additional specific statutory conditions to making and accepting an anatomical gift. Under the UAGA, anatomical gifts may be made only for certain enumerated purposes - therapy, education and research - and may only be accepted by qualified "donees". UAGA § 6 (1987); N.Y. Public Health Law § 4302 (2005). Qualified donees of an anatomical

<sup>&</sup>lt;sup>1</sup> Under New York law, these statutory conditions to an anatomical gift include the following provisions:

<sup>&</sup>lt;u>Conditional</u> Intent

N.Y. Public Health Law § 4301(2) (2005) Persons Who May Execute an Anatomical Gift: "Any of the following persons, in order of the priority stated, may . . . give all or any part of the decedent's body for any purpose specified in [§ 4302] of this article: (a) the spouse." (emphasis added) (based on UAGA § 2(b) (1968)).

Conditional Intent - Acceptance Conditional on Medical Acceptability N.Y. Public Health Law § 4301(4) (2005) Persons Who May Execute an Anatomical Gift: "A gift of all or part of a body authorizes any examination necessary to assure medical acceptability of the gift for the purposes intended." (emphasis added) (identical to UAGA § 2(d) (1968)).

Conditional Intent - Acceptance Conditional on Qualified Donee N.Y. Public Health Law § 4302(4) (2005) Persons Who May Become Donees; Purposes for Which Anatomical Gifts May be Made: "The following persons may become donees of gifts of bodies or parts thereof for the purposes stated: (4) any specific donee, for therapy or transplantation needed by him." (emphasis added) (based on UAGA § 3(4) (1968)).

gift for the purpose of transplantation include hospitals, OPOs, physicians, surgeons and named individuals for transplantation needed by that individual. Id. Under New York's version of the UAGA, a specified individual qualifies as a donee if the anatomical gift can be used "for therapy or transplantation needed by him." N.Y. Public Health Law § 4302(4)(2005). A plain reading of this legal requirement is that a donated organ can be directed to an individual only if it can be used for therapy or for transplantation into that person. Colavito v. New York Organ Donor Network, Inc., 438 F.3d 214, 234 (2d Cir. 2006) (Jacobs, J.) (dissenting). If the named individual cannot use the anatomical gift for therapy or transplantation, the law does not recognize that individual as a qualified "donee." The donative intent to direct a donation is statutorily conditioned under the UAGA upon the organ being of benefit to the individual donee. If the organ can not benefit the intended recipient of a directed donation, the UAGA does not recognize that individual as a qualified donee and, therefore, the anatomical gift cannot be accepted by him.

The determination that a donated organ may be therapeutic or transplantable into a named potential recipient requires the exercise of significant medical professional judgment. It is a professional clinical judgment that neither the donor nor the potential recipient is qualified to make. Indeed, federal

regulations mandate that the OPTN establish allocation policies which first and foremost are based "on sound medical judgment." 42 C.F.R. § 121.8(a). Recently issued federal regulations reiterate that it is ultimately the transplant surgeon's clinical judgment to determine whether a particular donated organ is suitable for a particular potential recipient within the framework of organ allocation policy. 71 Fed. Reg. 30,982 at 31,016 (2006).

This medical judgment involves a critical analysis of many factors and begins with blood type and, in the case of kidneys, tissue type compatibility, but also includes many other clinical characteristics of both the donor and the potential recipient.<sup>2</sup> The legal requirements of the UAGA work

<sup>&</sup>lt;sup>2</sup> A representative list of those medical factors and clinical characteristics that are currently involved in determining suitability of a particular donor organ for a particular potential recipient may include but is not limited to the following:

<sup>•</sup> ABO compatibility

<sup>•</sup> Histocompatibility (HLA typing similarities, differences)

<sup>•</sup> PRA Percent Reactive Antibody (the candidate's immuno-sensitivity)

<sup>•</sup> Donor Size (Height, Weight, or BMI (Body Mass Index))

<sup>•</sup> Organ Size (usually correlates with donor body size)

<sup>•</sup> Age of donor (older organs generally more appropriate for older candidates, same for pediatrics)

<sup>•</sup> Expanded Criteria Donor vs. Standard Donor (impacts predicted viability of organ)

<sup>•</sup> Donation after Cardiac Death (DCD) Recovery vs. Donation after Brain Death (DBD) Recovery (impacts predicted viability of organ)

<sup>•</sup> Distance from the donor (Cold Ischemic Time which relates to organ viability)

<sup>•</sup> Donor Lab values (normal vs. abnormal organ specific labs)

<sup>•</sup> Urinalysis results

<sup>•</sup> Cardiac Arrest/Downtime of Donor (duration of event, whether CPR was initiated. Relates to organ viability.)

in concert with this required medical analysis by recognizing that an individual is a qualified donee only if the individual might medically benefit from the donated organ. To hold otherwise would allow a life saving organ to be diverted to an individual for whom the organ has no use, a wasteful result that would have occurred in this case had Mr. Lucia's transplantable but medically incompatible kidney been provided to Mr. Colavito.

In other words, if an anatomical gift is not medically suitable for a directed recipient, there is not a valid gift to that individual under the UAGA because the organ cannot be accepted for that individual. The medical judgment required to determine whether an organ can be accepted for a particular potential recipient is fluid throughout the donation process and does not occur with finality until the time that the transplant surgery has been completed. Prior to that time, many factors can cause the attending surgeon or physician to find a particular donor organ medically unsuitable for a particular potential recipient. Therefore, under the UAGA,

<sup>•</sup> Donor Serological testing results (Hepatitis C, Hepatitis B, CMV)

<sup>•</sup> Donor Medical/Social History (CDC High Risk Behavior Criteria or possible unidentified disease)

<sup>•</sup> Organ Specific evaluations that may be indicated at the transplant surgeon's discretion:

o Cardiac Catheterization results, Echocardiogram, EKG

o Chest X-ray, Arterial Blood Gas values, Bronchoscopy findings

any legal rights in the anatomical gift cannot pass to an intended potential recipient in advance of the completion of the transplant procedure.

This analysis under the UAGA is consistent with the common law of gifts. Where there is no delivery or acceptance of a gift, the intended beneficiary does not acquire any rights to the gift. Oman v. Yates, 422 P.2d 489, 494 (Wash. 1967). Under the UAGA, an individual does not qualify as a donee and, therefore, can not accept an anatomical gift unless it can be of benefit to that individual, which is a medical determination made at the time of transplant.

In this case, the donative intent of the deceased's spouse was conditioned by statute upon the organ being medically acceptable for the purpose of transplantation into the potential recipient, Mr. Colavito. Neither of the kidneys was needed by Mr. Colavito unless either kidney was medically acceptable for transplantation into Mr. Colavito, which they were not; one kidney was unsuitable for transplant into any recipient and the other kidney was medically incompatible for transplant into Mr. Colavito. Appendix at A-76, 78-79, 105. There could be no acceptance of the anatomical gift by Mr. Colavito. Mr. Colavito never became a donee under the UAGA and, therefore, he never had any rights in the organs.

### 2. NOTA And The OPTN Final Rule

NOTA was enacted in 1984 to accomplish several purposes including encouragement of organ donation, development of an organ allocation system that functions on a nationwide basis, and establishment of a basis for effective federal oversight of the OPTN. S. Rep. No. 382, 98<sup>th</sup> Cong., 2<sup>nd</sup> Sess. 1984.

NOTA also established the federal criminal prohibition against acquiring, receiving or transferring organs for valuable consideration, thereby criminalizing the buying and selling of organs for profit. 42 U.S.C. § 274e. As with the UAGA, which preceded NOTA and is not preempted by NOTA, the context of NOTA is gift law, as opposed to contract or property law.

The donation of organs as permitted under NOTA involves the gift of a national resource into a system designed to preserve public trust by allocating organs based on medical utility and equity. The prohibition against buying and selling organs expresses clear legislative intent that the transfer of organs from donors to recipients be considered outside of the traditional legal principles of contract and property law. Indeed, the Task Force established by NOTA characterizes organs as "a national resource" rather than private property. Organ Transplantation: Issues and Recommendations, Report of the Task Force on Organ Transplantation, at 86 (1986).

Pursuant to NOTA, the Department of Health and Human Services promulgated a series of rules and regulations governing organ donation and transplant, most notably the OPTN Final Rule. 63 Fed. Reg. 16296 et seg. (1998) (codified at 42 C.F.R. pt. 121). The OPTN Final Rule, published in 1998, was designed "to ensure that organ allocation policies . . . meet the statutory goal of equitable national allocation of organs in accordance with medical criteria." Id. at 16298. Consistent with the position taken by the NOTA Task Force, donated organs for transplant are characterized under the OPTN Final Rule not as private property but as a national resource; "human organs that are donated for transplantation are a public trust." Id. The OPTN Final Rule neither prohibits directed donations, nor does it require allocation of an organ to an intended recipient of a directed donation. 42 C.F.R. § 121.8(h). Policies for the allocation of organs under the OPTN Final Rule must: (a) be based on sound medical judgment; (b) seek to achieve the best use of donated organs; and (c) avoid wastage. Id. at § 121.8(a). The OPTN Final Rule also mandates that, "upon receipt of an organ, the transplant hospital responsible for the potential recipient's care shall determine whether to proceed with transplant. In the event that an organ is not transplanted into the potential recipient, the OPO . . . must offer the organ for another

potential recipient in accordance with [the regulations]."

Id. at § 121.7(d) (2005). Granting a potential recipient any rights in a donated organ prior to actual transplant, therefore, also conflicts with the legal requirements of NOTA and the OPTN Final Rule because such a result would not be based on sound medical judgment, achieve the best use of a donated organ or avoid wastage.

## 3. Donor Rights To Direct An Anatomical Gift

The UAGA establishes legal principles to "preserve the personal preferences" of donors and donor families. Although not clearly discerned by the majority opinion of the Second Circuit, the preferences and rights of donors under the UAGA are distinct from those of any other individuals. The UAGA establishes the parameters of donor consent for organ donation. This includes the donor's ability to specify which organs and tissues are to be gifted, to whom, and the purpose for which the gift can be used. UAGA § 6 (1987). Conditions on the anatomical gift are legally enforceable under the UAGA. In contrast, the potential recipient has no enforceable rights under the UAGA. Until the gift of the organ is completed by the transplantation into the recipient, the potential recipient does not qualify as a donee and, therefore, has no right in the donated organ. Cf. Id. at § 8; N.Y. Public

Health Law \$4301(5)\$ (2005) (recognizing the rights of a donee created by a gift).

# 4. Intended Recipient Rights To Receive The Anatomical Gift

The Second Circuit voiced disagreement with the District Court's statement that even if a donor has enforceable rights, an intended donee would not have standing to enforce them. Colavito v. New York Organ Donor Network, Inc., 438 F.3d 214, 228 n.14 (2d Cir. 2006). The Second Circuit based its position on an analysis of the intended potential recipient as a third party beneficiary to a contract. Id. The Second Circuit, however, misconstrues the legal underpinnings of organ donation. As discussed above, organ donation is governed by the UAGA gift law. 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 a contract legally binding. See Restatement (Second) of Contracts §§ 71, 75, 81 cmt. a. A gift, on the other hand, involves a gratuitous transfer by the donor. There is no transfer of money, property or services by the donee. Likewise, the donee suffers no material detriment and makes no agreement not to exercise any of his/her rights. For that reason, courts have held that no "consideration" is

present in a gift. Signacon Controls, Inc. v. Mulroy, 69

Misc. 2d 63, 65, 329 N.Y.S.2d 175, 177 (N.Y. Sup. Ct. 1972)

("A gift by definition is a voluntary transfer of property without consideration or compensation").

Even under the contract law principles relied upon by the Second Circuit in footnote 14 of its decision, an intended recipient would not have an enforceable right to a directed organ. Section 309 of the Restatement (Second) of Contracts, cited with approval in Matter of Liquidation of Union Indem. Ins. Co. of New York, 200 A.D.2d 99, 108, 611 N.Y.S.2d 506, 512 (1994), provides that "a promise creates no duty to a beneficiary unless a contract is formed between the promisor and the promisee; and if a contract is voidable or unenforceable at the time of its formation the right of any beneficiary is subject to the infirmity." (emphasis added). The Comments to Section 309 make clear that "the right of an intended beneficiary is created by contract, and in the absence of a contract there is no such right. Moreover, where there is a contract, the beneficiary's right is subject to any limitations imposed by the law. Thus absence of mutual assent or consideration ... may be asserted by the promisor against the beneficiary." By state and federal statute, organ donation can not include the exchange of any "valuable consideration." 42 U.S.C. § 274e; UAGA § 10 (1987); N.Y.

Public Health Law § 4307 (2005). Because there can be no consideration present in the context of an organ donation, there is no contract and, therefore, no enforceable "third party beneficiary" rights on the part of the intended potential recipient of an anatomical gift. Restatement (Second) of Contracts § 309.

## B. Common Law Does Not Support Extending Property Rights In A Donated Organ To Potential Recipients Prior To Transplant

The Second Circuit starts with the premise that there is clearly established case law finding a "'quasi' property right belonging to the spouse or next of kin to possess the body for the purposes of ensuring proper burial." Colavito v. New York Organ Donor Network, Inc., 438 F.3d 214, 223 (2d Cir. 2006).

The lower court concluded from these cases that the "narrow rights in a deceased's body are reserved exclusively for the next of kin and only for the purposes of ensuring proper disposition of the deceased's body." Colavito v. New York Organ Donor Network, Inc., 356 F. Supp. 2d 237, 246 (E.D.N.Y. 2005). The Second Circuit disagreed, opining that lawsuits involving a decedent's relatives about the disposition of remains or mishandling of a corpse are distinguishable because they are based on emotional distress rather than property loss. "But a lawsuit based on the loss of a donated organ

typically seeks more than compensation for injured feelings. The intended recipient of a human organ ... sues for the loss of a functioning organ." Colavito, 438 F.3d at 225. However, without the ability to use the organ, the intended recipient does not qualify as a donee and cannot receive the organ under the UAGA. For this reason, the emotional distress vindicated through quasi-property right claims in cases of burial rights may constitute more, not less, than any possible harm experienced by the potential recipient of an organ that cannot actually be used to the potential recipient's benefit.

There are at least two cases where the courts have found a fundamental right, protected by the Fourteenth Amendment, to control the final disposition of one's body that extended to property interests of possession and transfer. Brotherton v.

Cleveland, 923 F.2d 477, 482 (6th Cir. 1991); Newman v.

Sathyavaglswaran, 287 F.3d 786, 796 (9th Cir. 2002). Both the Brotherton and Newman cases involved state interference with the rights of the next-of-kin by statutorily authorizing coroners to remove a deceased's corneas without consent or even providing notice to the next-of-kin. Id. at 795-96.

Thus, these holdings simply find that the state cannot violate the next-of-kin's property interest in a deceased's body for

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With no other reported cases on point, there is no "typical" lawsuit by potential recipients over the loss of a donated organ.

burial by taking a body part without obtaining consent.

Framed this way, the protected right is a negative right to be free from interference with possession of the decedent's body, not a positive right of ownership to demand possession of a donated organ.

There is no existing support in common law to find that an individual has any right in the donated deceased body parts of another individual. See Moore v. Reg. of the Univ. of California, 51 Cal. 3d 120, 137, 793 P.2d 479, 497, 271 Cal. Rptr. 146, 156 (1990) (stating that no court has held that a person retains sufficient interest in removed cells to support a conversion claim and holding that an unprecedented extension of the common law conversion theory to impose liability for use of human cells in research was inappropriate and unnecessary); Greenberg v. Miami Children's Hospital Research Institute, Inc., 264 F. Supp. 2d 1064, 1074-75 (S.D. Fla. 2003) (holding that statutory and common law "do not provide a remedy for Plaintiff's donations of body tissue and blood samples under a theory of conversion."). In fact, the Court in Moore commented that it was not surprising to find no support in common law for a conversion theory "since the laws governing such things as human tissues [and] transplantable organs . . . deal with human biological materials as objects sui generis, regulating their disposition to achieve policy

goals rather than abandoning them to the general law of personal property. It is these specialized statutes, not the law of conversion, to which courts ordinarily should and do look for guidance on the disposition of human biological materials." Moore, 51 Cal.3d at 137, 793 P.2d at 489, 271 Cal. Rptr. at 156 (emphasis added). As set forth above, NOTA, the OPTN Final Rule and the UAGA cannot be used to support a claim for conversion or to support a claim that a potential recipient has any right in a donated organ prior to transplant.

C. Finding That A Potential Recipient Has Any Right To A Donated Organ Prior to Transplant Would Have Significant Negative Consequences To The National System Of Organ Donation And Transplantation

This Court need look no further than the present case for a glaring example of the potential consequences of holding that a potential recipient of a directed donation has a right in the donated organ prior to transplantation. In this case, the donor's kidneys were medically unsuitable for transplant into the directed recipient, but one of the kidneys was medically suitable for transplant into a different recipient (Appendix at A-76, 78-79, 105, 217-218). Accordingly, finding that the potential recipient had a right to possess the donor's kidneys, which could be of no medical benefit to the

potential recipient, not only conflicts with the UAGA gift law context under which the organ donation was made, it also results in wastage to the significant detriment of other individuals awaiting transplant who might have benefited from the organ. There are currently 92,300 people listed with UNOS awaiting organ transplantation and 17 people die every day while waiting for an organ transplant. Finding that the potential recipient had a right to possess the donor's kidneys could further result in OPOs and transplant centers declining to coordinate or participate in directed donations in order to avoid such wastage, litigation and potential liability.

Indeed, the primacy of the articulated policy goals of the UAGA, NOTA and the OPTN Final Rule to increase organ donation for life-saving transplants, as recognized in the Second Circuit's opinion, will actually be subverted by finding that potential recipients have enforceable property rights in donated organs. Colavito v. New York Organ Donor Network, Inc., 438 F.3d 214, 223, 227 (2006). The goal is to save lives and to allocate donated organs in a manner that maximizes medical utility and equity. None of these measures is served by permitting potential recipients whose ability to benefit from a specific organ is undetermined and speculative to sue for conversion of organs conditionally directed or allocated to them. The public policy is to allocate organs to

recipients who can actually use them and benefit from them and to do so within very narrow time constraints.

Moreover, if the Court were to overlook the gift law basis of organ donation and find that a potential recipient has a right in an organ prior to transplant in the case of directed donation, there could be unavoidable legal implications in the standard allocation context. Unlike a directed donation, a standard allocation - as described above - involves an extremely complex set of coordinated interactions. This complexity would result in catastrophic confusion if potential recipients could assert rights to a donated organ prior to the completed transplant procedure. It could even result in dozens of potential recipients asserting rights over one single organ since only a small percentage of organs are accepted for the first potential recipient named on the match run list.

This is not an exercise in theoretical bioethics. If the Court finds that a potential recipient has a right in a directed organ prior to transplantation, then it is foreseeable that these issues may be litigated at the intolerable expense of grinding the life saving national organ donation and transplantation system to a halt. The pressure of private lawsuits based on property law principles should not be brought to bear upon the medical decisions surrounding

organ donation, allocation and transplantation. Private lawsuits sounding in property would eviscerate the statutory and regulatory mandate of the UAGA, NOTA, and the OPTN Final Rule that organ donations be made under the principles of gift law commensurate with medical judgment.

Like the court in the Moore case, this Court should recognize at least three compelling reasons which weigh against conversion as a viable legal theory in organ donation cases. Moore, 51 Cal.3d at 142-43, 793 P.2d at 493, 271 Cal. Rptr. at 160. First, the issue of how organ donation, allocation, and transplantation are legally regulated is better resolved under the existing statutory and regulatory authorities establishing the primacy of UAGA gift law. Second, extending the potential for conversion claims in this context is not necessary to protect the donor's right to direct a donation as permitted under the UAGA and as recognized in NOTA and the OPTN Final Rule. Third, appropriate consideration of donated organs for transplant as "objects sui generis" and the fair balancing of policy considerations weigh clearly against extending the claim of conversion to this context. For these reasons, the Court should find that applicable law and public policy do not support extending any rights in a donated organ to potential recipients prior to transplant.

# II. NY PUBLIC HEALTH LAW SHOULD BE READ TO PRESERVE THE GOOD FAITH IMMUNITY PROTECTION UNDER THE UAGA WHICH IMMUNIZES AGAINST NEGLIGENCE

One of the "principal legal questions" identified by the drafters of the UAGA concerned "what protection from legal liability should be afforded to [persons] involved in carrying out anatomical gifts." Prefatory Note, Unif. ANATOMICAL GIFT ACT (1968). To address this area of concern for those involved in the organ procurement process, Section 7(c) of the UAGA provides as follows: "A person who acts in good faith in accord with the terms of this Act or with the anatomical gift laws of another state [or a foreign country] is not liable for damages in any civil action or subject to prosecution in any criminal proceeding for his act." UAGA § 7(c) (1968). It was the drafters' stated intention that the preceding good faith immunity provision merits "genuinely liberal interpretation to effectuate the purpose and intent of the Uniform Act, that is, to encourage and facilitate the important and ever increasing need for human tissue and organs for medical research, education and therapy, including transplantation." UAGA \$7(c), cmt.(1968).

New York adopted the "good faith" immunity from liability provision which, like the model UAGA, provides qualified immunity from suit, stating: "A person who acts in good faith

in accord with the terms of this article or with the anatomical gift laws of another state is not liable for damages in any civil action or subject to prosecution in any criminal proceeding for his act." N.Y. Public Health Law § 4306(3) (2005).

The New York Courts interpreted this provision in Nicoletta v. Rochester Eye and Human Parts Bank, Inc., 136 Misc.2d 1065, 519 N.Y.S.2d 928 (N.Y. Sup. Ct. 1987). In fact, Nicoletta is considered the seminal case on the UAGA good faith immunity provision, and every other jurisdiction interpreting this provision has adopted the view set forth in the Nicoletta case: "Good faith is defined as an 'honest belief, the absence of malice and the absence of design to defraud or to seek an unconscionable advantage." Nicoletta, 136 Misc.2d at 1067-68, 519 N.Y.S.2d at 930, citing Black's Law Dictionary 623 [ $6^{th}$  ed. 1981]. See the cases collected in Schembre v. Mid America Transplant Ass'n, 135 S.W.3d 527, 532 (Mo. App. 2004); Ramirez v. Health Partners of Southern Arizona, 972 P.2d 658, 662-663 (Ariz. App. 1999); and Kelly-Nevils v. Detroit Receiving Hosp., 526 N.W.2d 15, 18-19 (Mich. App. 1995). See also Carey v. New England Organ Bank, 446 Mass. 270, 282 (2006).

Based on this standard, courts have held that establishing lack of good faith under the UAGA requires more

than a showing of mere negligence "lest the Legislature's intent to protect organizations enabling organ donation and transplantation, be frustrated." Carey v. New England Organ Bank, 2004 WL 875623 at \*6 (Mass. Super. 2004). "A negligence standard is not used to determine whether good faith immunity will attach." Sattler v. Northwest Tissue Center, 42 P.3d 440, 444 (Wash. Ct. App. 2002).

Notwithstanding the desire for a uniformly broad reading of the good faith immunity provision, as set forth in the UAGA and subsequently in <a href="Nicoletta">Nicoletta</a> and the decisions cited above, the Second Circuit expressed uncertainty over the scope of the good faith immunity under the New York Public Health Law. The Court's uncertainty was based upon N.Y. Public Health Law § 4351(7), which provides that, to the extent permissible under \$ 4306(3), "any person or organization acting pursuant to this section shall be legally responsible for any negligent or intentional act or omission."

To construe Article 43 of the New York Public Health Law in such a manner as to leave those involved in the organ procurement process exposed to liability for negligent conduct would conflict with the expressed intent of the framers of the UAGA. Specifically, as set forth above, the UAGA was enacted to promote uniformity among the states. Further, the drafters' stated intention was that the good faith immunity

provision merit "genuinely liberal interpretation to effectuate the purpose and intent of the Uniform Act."

Consistent with the drafters' intention, the courts have uniformly held that the good faith immunity provision provides qualified immunity for negligent conduct. <u>Sattler</u>, 42 P.3d at 444. See also Carey, 446 Mass. at 284.

Indeed, uniformity remains an affirmed goal of UAGA. The Uniform Commissioners, in drafting a 2006 model UAGA have commented that "transplantation occurs across state boundaries and requires speed and efficiency. Thus, uniformity of state law is highly desirable." Prefatory Note, UAGA (Proposed Draft 2006). For this reason we urge the Court to interpret New York Public Health Law in a manner that enforces the good faith immunity provision of the UAGA and furthers the express legislative goal of national uniformity.

#### CONCLUSION

We urge this Court to find that potential recipients of an organ donation -- whether directed to an individual or allocated through the national system -- do not and should not, as a matter of statutory gift law and significant public policy, have a property right or any other right in a donated

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www.law.upenn.edu//bll/ulc/uaga/2006annualmeeting.htm

organ prior to completion of the transplant procedure. We also urge the Court to interpret the New York Public Health

Law in a manner that is consistent with the clear legislative intent behind the good faith immunity provision of the UAGA to provide uniform liability protection against negligence or even gross negligence claims.

Respectfully Submitted,

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Richmond, VA 23219

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### Court of Appeals

State of New York

ROBERT COLAVITO,

Petitioner-Plaintiff-Appellant,

against

NEW YORK ORGAN DONOR NETWORK, INC., ROBERT KOCHIK, SPENCER HERTZEL, GOOD SAMARITAN HOSPITAL MEDICAL CENTER, DR. DOE I, M.D. and DR. DOE II, M.D.

Respondents-Defendants-Appellees.

AMICI CURIAE BRIEF OF AMERICAN ASSOCIATION OF TISSUE BANKS,
AMERICAN SOCIETY FOR TRANSPLANT SURGEONS, AMERICAN SOCIETY FOR
TRANSPLANTATION, ASSOCIATION OF ORGAN PROCUREMENT ORGANIZATIONS,
NATCO - THE ORGANIZATION FOR TRANSPLANT PROFESSIONALS, NATIONAL
KIDNEY FOUNDATION and UNITED NETWORK FOR ORGAN SHARING

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Attorneys for Amici Curiae

Dated: June 16, 2006

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Proposed Amici Curiae Brief

## STATE OF NEW YORK COURT OF APPEALS

#### ROBERT COLAVITO,

Plaintiff-Appellant,

- against -

NEW YORK ORGAN DONOR NETWORK, INC., ROBERT KOCHIK, SPENCER HERTZEL, GOOD SAMARITAN HOSPITAL MEDICAL CENTER, DR. DOE I, M.D. and DR. DOE II, M.D., Defendant-Respondents.

# Notice of Motion for Leave to File Amici Curiae Brief

Please take notice that upon the annexed affirmation of Alexandra K. Glazier, Esq., dated June 16, 2006, the undersigned will move this Court at the Court of Appeals Hall, Albany, New York, on the 26th day of June, 2006, for an order, pursuant to 22 NYCRR § 500.23(a)(1), granting leave to file an amici curiae brief on behalf of American Association of Tissue Banks ("AATB"), American Society for Transplant Surgeons ("ASTS"), American Society for Transplantation ("AST"), Association of Organ Procurement Organizations ("AOPO"), NATCO – The Organization for Transplant Professionals ("NATCO"), National Kidney Foundation ("NKF") and United Network for Organ Sharing ("UNOS").

Dated:

TO:

New York, New York

June 16, 2006

Respectfully submitted,

Alexandra K. Glazier, Esq. (appearing pro hac vice)

General Counsel

New England Organ Bank (as a member of AOPO and

UNOS)

One Gateway Center Newton, MA 02458 phone: 617-558-6615 fax: 617-558-1094

Victor Serby, Esq. Counsel for plaintiff-appellant

Richard E. Lerner, Esq.

Counsel for defendants-respondents

## STATE OF NEW YORK COURT OF APPEALS

ROBERT COLAVITO,

Plaintiff-Appellant,

- against -

NEW YORK ORGAN DONOR NETWORK, INC., ROBERT KOCHIK, SPENCER HERTZEL, GOOD SAMARITAN HOSPITAL MEDICAL CENTER, DR. DOE I, M.D. and DR. DOE II, M.D.,

Defendant-Respondents.

# Affirmation in Support of Motion for Leave to File Amici Curiae Brief

I, Alexandra K. Glazier, an attorney for whom a request pursuant to NYCRR 500.4 for *pro hac vice* admission to practice in the New York State courts has been duly made to this Court, affirm that the following is true, subject to the penalties of perjury as provided in CPLR 2106:

1. I am general counsel of the New England Organ Bank (a member of Association of Organ Procurement Organizations and United Network for Organ Sharing) and am seeking leave to file a brief as amici curiae in this appeal on behalf of American Association of Tissue Banks ("AATB"), American Society for Transplant Surgeons ("ASTS"), American Society for Transplantation ("AST"), Association of Organ Procurement Organizations ("AOPO"), NATCO – The

Organization for Transplant Professionals ("NATCO"), National Kidney Foundation ("NKF") and United Network for Organ Sharing ("UNOS").

- 2. The participation of these organizations as amici curiae would "be of assistance to the court," as provided in 22 NYCRR § 500.23(a)(4)(iii).
- AATB is a national, non-profit organization dedicated to ensuring that 3. human tissues donated for transplantation are safe and available to meet the national need. ASTS is a national, non-profit professional organization of physicians for the advancement of organ and tissue donation and transplantation. AST is an international, non-profit organization of transplant professionals dedicated to advancing the field of transplantation through the promotion of research, education, advocacy and organ donation. AOPO is a national, non-profit membership organization representing all 58 of the nation's federally designated organ procurement organizations. NATCO is a national, non-profit professional organization committed to the advancement of organ and tissue donation and transplantation. NKF is a national, nonprofit, major voluntary health organization that seeks to prevent kidney and urinary tract diseases, improve the health and well-being of individuals and families affected by these diseases, and increase the availability of all organs for transplantation. UNOS is a non-profit, scientific and educational organization that administers the nation's Organ Procurement and Transplantation Network established by the United States Congress in 1984, and is

responsible for maintaining the national waiting list and developing organ allocation policies for transplant.

- 4. These seven national, non-profit organizations, collectively and individually, have an overwhelming interest in the issue of whether an enforceable property interest is vested in potential organ recipients prior to actual transplantation. This question has far-reaching national implications. Indeed, the Court's holding in the case at bar upon the questions certified by the Second Circuit could significantly impact the complex national organ donation, procurement and allocation system that has been established by Congress, adopted by the legislatures of all fifty states, and has hitherto resulted in countless life-saving transplants.
- 5. A copy of the proposed brief of the amici curiae is enclosed. If this motion is granted, the above-described organizations will serve and file the requisite number of copies of the brief within the time set by the Court after receiving permission to do so.
- 6. Also pending before this Court is an application made by the signatories to the amici curiae brief to be admitted pro hac vice.
- 7. Accordingly, it is respectfully requested that the proposed brief of the amici curiae be accepted.

Dated: New York, New York

June 16, 2006

By:

Alexandra K. Glazie

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COUNTY OF NEW YORK	)	SS.		<ul><li></li></ul>	
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Names of attorneys served, together within the addresses.	e names of the clients represented and the attorney's designated			
VIA PRIORITY OVERNIGHT				
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Sworn to before me this 16th day of June, 2006				