THE LAWS GOVERNING ORGAN DONATION

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What you get by achieving your goals is not as important as what you become by achieving your goals.

Henry David Thoreau
ABSTRACT

Organ transplantation saves lives. Once considered a last resort for critically ill patients, it is now a practical treatment for freeing kidney patients from dialysis machines and giving patients dying from heart, liver, lung and pancreatic disease a second chance for life. Unfortunately, the number of human organs available for transplant has never been sufficient to meet the need. Many transplant candidates die waiting for an organ that does not come. This research looks at the challenge of securing human organs for transplantation by examining the laws that have been enacted to attempt to alleviate this shortage.

Part I of this thesis is a review of the laws governing organ donation in the United States beginning with a historical review of early English Law moving on to Twentieth Century Law, including developing case law as well as the Uniform Anatomical Gift Act. Part II examines the 2006 Uniform Anatomical Gift Act (UAGA) more closely. Thirty-three states and the District of Columbia had adopted this model law by 2008. A quantitative analysis using a two-tailed, paired t-test compared the number of organ transplants for these Early Adopting States at the base year of 2006 and at 2012 to see if these states experienced an increase in transplants that may be attributable to the law. The 14 Late-Adopting States and the four Non-Adopting States were analyzed in the same manner.

The results revealed that the Early Adopting States experienced no statistically significant difference in the number of organ transplants between 2006 and 2012. This suggests that the 2006 UAGA has not achieved its goal of increasing the number of organ transplants. A brief discussion of reasons why this may be the case follows. This thesis also offers suggestions of other methods of organ procurement that should be considered, including those that would more fundamentally change the U.S. system of voluntary donation.
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Thesis Introduction

With absolute certainty, organ transplantation saves lives. Over the course of the past fifty years, transplantation has moved from a hopeful, experimental method that may briefly prolong life to a proven and practical treatment for freeing end-stage renal patients from dialysis machines and rehabilitating those with heart, liver, lung and pancreatic disease. Improved medical techniques and advancing clinical knowledge continue to increase the number of eligible transplant candidates that now have a second chance for life.

The number of human organs available for transplantation has historically fallen short of the need. Organ donation, more than other areas of healthcare, is limited by access. We tend to think of access in terms of the rural resident who dies on route to the nearest healthcare facility that is miles away, or the poor who die waiting for treatment in an overcrowded urban hospital emergency department. There are others, however, who die lying in a hospital bed with state-of-the art medical equipment and a knowledgeable medical team to provide care but lack access to a healthy organ to replace the one that has failed them. This is the state of transplantation today.

Three times the Uniform Law Commission (ULC) has tried to create a Uniform Anatomical Gift Act (UAGA) that would encourage donation thereby leading to an increase in transplantable organs. The ULC is a state supported organization comprised of commissioners appointed by the states. ULC drafts model laws for adoption by the states to bring clarity and uniformity in areas where this is desirable and practical. In 1968, the first UAGA was drafted and within five years adopted by all 50 states. There have been two other revisions since then. Each revision was undertaken with the intent of
bringing uniformity to the organ transplant system and increasing the number of transplants.³

The 2006 revision of UAGA is the latest model law to be presented to the states for adoption. Among other things, it strengthens the provision of first person consent. First person consent gives legal authority to organ procurement organizations, hospitals, and organ procurement personnel to proceed with organ donation without concurrence from the decedent’s family if there is a written document of donation. Most individuals assume that signing an organ donor card assures that their organs will be donated upon death. The reality is that organ donation forms are not legally binding. Past practice has allowed a family member to prohibit a donation even if the deceased consented to organ donation and documented that wish in writing. First person consent is intended to eliminate the need for family concurrence. To give backing to first person consent, the UAGA also includes immunity from prosecution for healthcare professionals who in good faith act to procure organs for transplantation.

This thesis is presented in two parts, as two separate independent articles. This format was chosen so that the background of laws, including common law, statutory law and regulations, as well as case law, could be examined separately and presented as an independent article on the background leading to the present system of organ donation. My research, which looks specifically at one law and its main provision, is presented in the second article. From this flows the natural progression of recommendations as to what policy changes should be made in the current system of organ donation and transplantation.

Part I of this thesis examines the laws governing organ donation; beginning with their historical underpinnings based on laws surrounding the disposition of cadavers,
moving through to the Constitutional question of whether there is a property interest in a corpse and if so, who holds that interest. It then looks at modern day laws directed at organ donation and transplantation as well as other acts that affect some aspect of the procurement process. Pertinent case law is also presented.

Part II focuses specifically on my research that examines the adoption of the 2006 UAGA and whether there is a relationship between early adoption of this model law with its emphasis on first person consent, and an increase in the number of organ transplants. The null hypothesis is that there is no statistical difference between the 2006 per capita rate of cadaver transplants and the 2012 per capita rate of cadaver transplants in the Early Adopting States, while the research hypothesis is that there is a difference. The Late and Non-Adopting States are examined in the same manner as the Early Adopting States. Using a quantitative approach, the 50 states and the District of Columbia (DC) are divided into two groups; those states that adopted this model law within two years after promulgation, that is, adoption by 2008, and those that adopted the model law after that time or not at all.

Using the publically available database complied and maintained by the United Network for Organ Sharing (UNOS) the number of cadaver transplants at the base year of 2006, is compared to the number at 2012, the last year for which there is complete data. This statistical analysis was first conducted on the Early Adopting States. The paired t-test is used to test for a statistical significance in the per capita rate of transplantation. This statistical analysis was also conducted on the 14 Late Adopting States both with the four Non-Adopting States and without them. There was no statistical difference in the results when the four Non-Adopting States were included in the analysis. Therefore, the four Non-Adopting States are grouped with the Late Adopters. Living donors are not
included in this study because they are only about twenty percent of total organ donations and because the focus of this study centers on an examination of the 2006 UAGA. The 2006 UAGA does not pertain to live organ donations.

The p-value obtained when the 2006 per capita cadaver transplants of the Early Adopting States were compared to the 2012 per capita cadaver transplants was greater than 0.05, the *a priori* level of statistical significance chosen. The p-value obtained when the t-test was performed comparing the 2006 per capita cadaver transplants and the 2012 per capita cadaver transplants for the Late and Non-Adopting States was also greater than 0.05.

With p-values greater than 0.05 (*p* > 0.05), the results revealed that the changes in transplant numbers in both groups likely occurred purely by chance. This suggests that Early Adoption of the 2006 UAGA has had no effect on the number of transplants. This further suggests that the 2006 UAGA has not been successful to date in increasing organ procurement. This leads to the question, where can we go from here?

Part II contains several recommendations that may aid in the goal of increasing organ procurement. These include implementation of first person consent. A decedent’s documented wish to be an organ donor does not need further consent or concurrence from family members. Also, another Organ Donation Collaborative should be initiated. There is evidence to suggest that 2003 Organ Donation Breakthrough Collaborative increased transplants during the 2003 to 2006 time period. Funding for another Collaborative as well as funding for awareness and educational programs may be enhanced by the creation of a public private partnership (PPP). With the appropriate controls in place to prevent the appearance of a conflict of interest, a PPP could increase funding and efficiencies which would benefit the PPP and the public.
This paper also suggests that the total prohibition on exchange of an organ for valuable consideration that was imposed by the National Organ Transplant Act (NOTA) should be revisited. Possible ways to incentivize altruism while maintaining safeguards against exploitation of the poor should be actively encouraged.

Lastly, this paper calls for providing more government direction to the choice of organ donation. Embracing the concept of choice architecture as espoused by the popular book *Nudge*, would lead to a system of organ donation as the default choice with the opportunity not to donate. The positive results that choice architect has had in other areas, most notably in directed retirement savings, calls for its adoption for organ donation. There is evidence to support that this will increase organ procurement. There is also precedent in that this system is already in place in many states for cornea tissue procurement.

The 2006 UAGA is the latest attempt at legislating altruism, altruism being defined as the giving of our organs and tissue simply because another needs them without acceptance of any reward. The goal of the 2006 UAGA is unanimous adoption leading to an increase in the number of organs available for transplantation. It has not achieved this goal, at least not as of yet. This research recommends revisions and alternatives to replace a system that has never resulted in supplying a sufficient number of organs to meet the need. Continued adherence to the present system of requesting organ donation as opposed to a system where it is presumed that one’s organs will be available for transplantation at the time of death has only perpetuated the historical shortage of organs for transplantation. Forty years of revisions and adjustments to a failed system calls for
more directed guidance to move society in the direction of saving the lives medical science can save.
Introduction

Organ transplantation saves lives. It saves lives, improves the quality of life, and in some cases diminishes healthcare expenditures. It is one of modern medicine’s remarkable achievements. Because human organs are in chronic, scarce supply, the medical needs of all who would benefit are not being met. A commodity in scarce supply is subject to debate as to the best policy for distribution and then subject to laws created to enforce that policy. In the case of human organs, the challenge is especially difficult since in most cases a candidate will receive the gift of a human organ only when someone else dies. Therefore, the debate surrounding this issue is fraught with emotional and ethical overtones. This project looks at the problem of lack of transplantable human organs by looking at the laws that have been enacted to attempt to alleviate this shortage. Specifically, it will look at the origin of laws governing organ donation in this country: from early English law, to common law, developing case law to modern day federal laws including the drafting of the Uniform Anatomical Gift Acts by the National Conference of Commissioners on Uniform State Laws. Then it will take a closer look at each of the three major revisions of UAGA, 1968, 1987, and 2006, along with the recent updates in 2007 and 2009. Finally, it takes a brief look at how the Patient Protection and Affordable Care Act may affect organ donation going forward.

The Challenges of Procurement

There is an ever growing, urgent need for increasing the number of human organs available for transplantation. The dramatic need for more organs is best illustrated by
statistics. In 2013, there were 19,205 transplants of organs from deceased donors in the United States. Yet, presently there are between 77,034 and 120,954 candidates on waiting lists. The reality is that in many cases waiting list candidates do not receive an organ. It takes on average, five years for a newly diagnosed kidney transplant candidate to migrate to the top of the waiting list. On an average day, 77 fortunate individuals will receive a transplanted organ. However, each week more than 100 other less fortunate individuals will die waiting for an organ.

This ever-increasing need for transplantable organs is a result, in part, of the advancements in medical science that have taken transplantation from an experimental, last hope effort to a viable, cost-effective way to prolong life and or improve its quality. With medical advances comes an increase in the number of eligible transplant candidates. Candidates once considered too sick to survive transplant surgery have been made eligible candidates through medical improvements. At the same time, medical advances have prolonged life leading to a decrease in the number of available donors. The ability to save the life of those involved in tragic accidents has left more grateful accident victims but fewer available organs. In addition to the life-saving advances in medical science, the organ shortage has been exacerbated in other ways. Laws reducing highway speed limits, increasing the legal age to obtain alcohol, enforcement of seatbelt and motorcycle helmet laws, and vigilance against drunk driving have led to decreased vehicle fatalities and decreased transplantable organs.

Background

During the 1980’s and 1990’s, several events converged that propelled organ transplantation into the arsenal of important medical treatments: surgical techniques
improved, hospital infection rates declined, and the immunosuppressant drug, cyclosporine, came to the market. All this resulted in decreasing organ rejection thereby allowing transplant recipients’ years, or even decades, of life they would not otherwise have. As transplant techniques improved and organ rejection decreased, medical science also began making advances in treatments that served as a bridge to transplantation thereby extending the life of those waiting for an organ. Moreover, kidney transplantation became a lower cost alternative to dialysis for end-stage renal disease, one that also gave the recipient a better quality of life. Individuals once considered too sick to successfully survive a transplant became viable candidates. This resulted in longer waiting lists as candidates wait for the one ingredient that medical science has not been able to replace – human organs.\textsuperscript{16}

**Organ Procurement Laws**

**Early Law**

As in many other areas, modern day law governing organ donation has its origins in church teachings. Christians believe that the body will be resurrected at the Second Coming of Christ. Therefore, there was no property right in a corpse even for family members in early times.\textsuperscript{17} The law first granting a property interest in a corpse was the English Anatomy Act of 1832.\textsuperscript{18} This act granted medical schools the right to acquire the cadavers of the poor or unclaimed for educational purposes.\textsuperscript{19} Prior to that only the bodies of criminals, specifically murderers, were used as educational cadavers.\textsuperscript{20}

Established as a country of religious freedom, there was less church influence on laws controlling cadavers in the English Colonies. As the American settlement grew to be a federal republic of states’ rights, states retained control over areas not specifically
enumerated as belonging to the federal government. Therefore, it was and is today, the right of each state to decide how corpses are treated and who, if anyone, has a property interest in the body and body parts of the dead. To this end, the laws governing human organs can be traced back to the laws on testamentary bequests and those covering the treatment of cadavers.²¹

**Twentieth Century Laws**

The development of laws governing the disposition of dead bodies continued to be state based into the Twentieth Century. When transplantation of human organs emerged as a viable field of medicine, laws governing organ procurement were developed at the state level. What began in 1954 as an attempt to prolong the life of a dying patient by transplanting the kidney of his identical twin, transplantation moved to using cadaver organs to save the life of a stranger by the early 1960’s.²² By 1962, cadavers were found to be a suitable source for kidneys in addition to living donors, allowing, at least theoretically, for a larger pool of transplantable organs. This lead to an array of regulations to govern the procedure of extracting organs from cadavers and the need to provide direction, clarity and some uniformity to this area of medicine and law.

To this end, the National Conference of Commissioners on Uniform State Laws met in 1968 to draft the first Uniform Anatomical Gift Act (UAGA).

**National Conference of Commissioners on Uniform State Laws**

While organ donation is the purview of the individual states not the federal government, the federal government took steps to encourage organ donation as well as encourage uniformity among state laws. The first step in establishing any uniform state law is to develop a model law. To that end, the federal government turned to the National
Established in 1892, the ULC is a state supported, non-profit association comprised of state appointed volunteer practicing lawyers, judges, law professors, and legislative staff attorneys from each state, the District of Columbia, the Commonwealth of Puerto Rico, and the United States Virgin Islands. Their goal is to research, draft, and promote enactment of non-partisan, uniform state laws where uniformity is desirable. In addition to uniformity, their work is designed to bring clarity and stability to critical areas of law. The Uniform Commercial Code is probably the ULC’s most well-known work. 23

The federal government first became involved in organ donation and transplantation by commissioning the ULC to draft a model law to move the states toward establishing consistent laws to govern this emerging field. The result was the 1968 Uniform Anatomical Gift Act. As discussed below, UAGA was drafted with the goal of adoption by every state. The states are free to adopt model laws such as UAGA as they are written or modify them through the state’s legislative process.24 By 1973, the UAGA achieved its goal of adoption by every state.25

Uniform Anatomical Gift Act of 1968

In 1968, the ULC issued the Uniform Anatomical Gift Act. In drafting it, the ULC looked to the principles of self-ownership and informed consent.26 Our organs belong to us and we must give consent for them to be taken and given to another. UAGA included a suggested form for making a donation. This was the first organ donor card. If a decision to donate was not immortalized before death, then the next of kin was deemed to hold the “right” to make this decision. UAGA provided a list of relatives, with a
suggested order of contact, who could authorize donation absent a directive by the deceased.  

In the preface to the 1968 UAGA, the drafters referenced a need to end the “confusion, diversity, and inadequacy” of common law and state statutes. The preface also identified five areas of concern: the wishes of the deceased to donate an organ or organs, the desire of the surviving spouse or next of kin as to organ donation, the interest of the state in performing an autopsy to determine cause of death in cases involving crime or violence, the need for an autopsy for private matters, the need of society for organs, tissues, and corpses for transplant, medical education, and research. Unfortunately, ULC did not prioritize these interests. Their competition for priority was a key weakness of the initial UAGA.  

Within five years, UAGA was adopted by all states with no more than minor variations. It permitted an individual of sound mind who was at least 18 years old to make a gift of any or all body parts. Unless the decedent gave notice of his or her opposition to serving as an organ donor, a family member could consent to donation either immediately before or after death.  

Social Security Act Amendment of 1972  

The next federal law to affect organ transplantation came four years later when the Social Security Act Amendment of 1972 extended Medicare coverage for either dialysis or transplantation to patients with chronic renal disease through the National End Stage Renal Disease (ESRD) Program. The goal was to encourage more kidney transplants to reduce the cost of the ESRD Program. Kidney transplantation is a more cost-effective treatment than hemodialysis. This act further increased financial
accessibility by extending coverage to immunosuppressant drugs from one to three years after transplant. It was this interest in the financial aspects of kidney disease that brought greater federal government involvement to transplantation. Subsequently, transplant surgeons sought federal assistance in obtaining private insurance coverage of liver and heart transplants.\textsuperscript{32} Once the federal government recognized transplantation of these organs as medical treatment and not experimental therapy, private insurers followed to provide coverage.

The Social Security Act was further amended in 1978 to improve cost-effectiveness of the ESRD Program by encouraging kidney transplants and home dialysis. Title XVIII of the act was amended to add section 1881 to establish a statutory requirement for the Network Organization Program to coordinate services for ESRD patients.\textsuperscript{33} Presently there are 18 Networks throughout the country. Coordination of ESRD services is achieved by bringing hospitals, dialysis centers, physicians, nurses, social workers, dietitians, dialysis patients and transplant recipients into their Network Program.\textsuperscript{34}

**Uniform Determination of Death Act of 1980**

The common law standard for determining death is the cessation of all bodily functions as demonstrated by an absence of spontaneous respiratory and cardiac function. By 1970, technology enabled respiration and circulation to be maintained after brain function had ended and the common law definition was applicable in a smaller and smaller percentage of cases. In an attempt to codify a more useful definition, states began drafting their own laws. By 1975, the American Bar Association drafted a model Definition of Death Act. The ULC built upon this to promulgate the Uniform Brain
Death Act in 1978. The following year the American Medical Association developed their model Definition of Death Statute. As states began adopting one or the other of these model laws, the ULC, in keeping with its mission to promote uniformity, attempted to create a law that would encompass the salient points of each. The result was the Uniform Determination of Death Act of 1980 (UDDA). UDDA codifies the common law definition of death, total failure of the cardiorespiratory system, along with the definition of death as irreversible loss of all brain function, meaning the entire brain, consisting of the neocortex and brainstem. Because this definition has been widely adopted, patients in a persistent vegetative state (PVS) are deemed not to be dead. In PVS, there remains a small degree of brainstem function. While the preface to UDDA indicates that it applies to all situations of death, it is especially useful in determining death for the purposes of organ procurement. As of 2013, 36 states and the District of Columbia have adopted UDDA.

National Organ Transplant Act of 1984

By 1984, it was apparent that the increased demand for transplantable organs called for an organized system to regulate their procurement and distribution. Congress responded to this need by passing the National Organ Transplant Act (NOTA). The two most important contributions of NOTA have been the establishment of an independent organization to manage organ procurement and the criminalization of the buying or selling of a human organ.

NOTA grew out of the Congressional Subcommittee on Investigation and Oversight of the House Committee on Science and Technology’s concern about the difficulty in obtaining livers for transplantation into pediatric patients. There was also
concern over a proposed kidney exchange.\textsuperscript{40} Chaired by then Representative Albert Gore (D. TN), the subcommittee held hearings on how organs were allocated. Testifying before the Subcommittee was Dr. H. Barry Jacobs. Dr. Jacobs testified about his plan to establish an international kidney exchange that was to create a market for healthy individuals to sell a kidney to renal patients who needed one and were willing to pay. This plan to create an international forum to buy and sell kidneys was widely opposed by the National Kidney Foundation, the American Medical Association (AMA), and medical ethicists. The result was that a prohibition on the exchange of solid organs for “valuable consideration” was included in NOTA.\textsuperscript{41}

NOTA also called for the Department of Health and Human Services (HHS) to contract with a not-for-profit organization to establish an organ procurement transplant network (OPTN) that would maintain a national list of patients awaiting transplants and the organ(s) they needed. The OPTN was to be responsible for matching donated organs to needy patients based on medical criteria, location, and probability of transplant success.\textsuperscript{42} A National Task Force on Organ Transplantation was to be established to give recommendations and guidance on transplant policy.

The creation of a national list of transplant candidates was written into NOTA as an alternate mechanism of matching donors with candidates. The original suggestion was to create a national list of transplant donors. This idea was rejected because of the prevailing belief that the family of the donor should be involved in this very important and personal decision. Altruism became paramount to autonomy in that next of kin, even one singular family member, could override a donation decision made by the deceased.

In the intervening 30 years, the idea of providing “valuable consideration” for organs has only been slightly challenged and altered. While there is no groundswell to
establish an organ market, subtle changes are surfacing most likely due to the inability to alleviate the organ shortage by other means. The AMA has tempered its opposition to payment for organs to allow for further discussion of financial rewards for deceased donors. In 1996, Pennsylvania passed a law to create a fund to pay up to $3,000 in funeral expenses to the family of deceased donors. Upon further review, it was deemed to be a violation of NOTA’s prohibition on valuable consideration in exchange for an organ and the law was never implemented.

John Roberson, in his article on the constitutionality of NOTA, presents the notion of medical self-defense in regard to organ donation. Since an organ transplant is essential to preserve the life of a patient with organ failure, it follows that obtaining one is a form of self-defense. Looking to the Supreme Court’s interpretation of the Second Amendment as protecting an individual’s right to possess a handgun in their home for self-defense, Roberson argues that a patient in need of an organ to preserve life is acting in self-defense if they attempt to purchase an organ. Since obtaining organs is difficult, a prohibition against paying for organs makes obtaining the necessary treatment nearly impossible. Therefore, NOTA’s prohibition against purchasing an organ should be subject to strict scrutiny or perhaps intermediate or heightened scrutiny but something beyond rational basis.

NOTA’s ban on procuring organs by exchanging valuable consideration does not extend to renewable tissue such as blood, sperm, and eggs. These are explicitly exempt in NOTA. Bone marrow, which is renewable, is not listed as an exception in NOTA and is banned although that ban has recently been challenged.
Omnibus Budget Reconciliation Act of 1986

As part of the Omnibus Budget Reconciliation Act (OBRA) of 1986, Congress included the recommendations of the National Task Force on Organ Transplantation. This task force was created by NOTA. In an attempt to procure as many organs as possible from willing donors, it recommended implementing Routine Inquiry Laws. Routine Inquiry Laws initially began at the state level. By 1985, 44 states and DC had passed such laws. Under Routine Inquiry, hospital staff is required to ask each patient at the time of admission whether they have made a decision as to organ donation and if that decision has been put in writing. Absent an affirmative refusal, the hospital is to request consent for organ and tissue donation. If the patient arrives at the hospital in an incapacitated state the family is asked to consent to donate. In any case, the decision as to donation is then recorded in the patient’s medical chart. The terms Routine Inquiry and Routine Request are often used interchangeably. Initially, however, they had different meanings with Routine Request simply referring to the request as to whether a donation decision has been made, whereas Routine Inquiry took a step further and asked for a decision to be made and put in writing.

In addition to Routine Inquiry, the Task Force further recommended that the Joint Commission on the Accreditation of Healthcare Organizations (JCAHO) require procurement protocols as an accreditation requirement. JCAHO, now known simply as the Joint Commission, is an independent, not-for-profit organization that accredits and certifies more than 20,000 health care organizations and programs in the United States. It is essential that healthcare facilities are accredited or else they will not qualify for
federal and state funds without which it is not financially possible to operate. The Joint Commission did not adopt Routine Inquiry but the practice was implemented through OBRA, with OBRA tying Medicare and Medicaid funds to the establishment of Routine Inquiry protocols. The written protocols that OBRA requires include identification of potential donors and notification of their identity to the area Organ Procurement Organization (OPO). OPO personnel then come to the facility to address donation with the family if the deceased is not a registered donor or to begin coordination of the transplant process of identification of appropriate organ recipients if the deceased or his or her family agree to donation.\(^5\)\(^6\)

OBRA supersedes state law but allows for states to enact more stringent requirements. By superseding state law OBRA eliminated variation in the state laws. For example, New York’s pre-OBRA law required hospital personnel to request consent for donation absent knowledge of a contrary intension. The hospital also had to submit a certificate of request along with the death certificate, with the state health department overseeing the request process. In contrast, California in 1986 had a Routine Request Law that merely required hospitals to inform patients and their families of the option to donate an organ. The state health department was neither involved nor was there any mechanism for recording the patient’s decision.

Unfortunately, monitoring compliance with the Routine Inquiry law proved to be difficult. Another flaw that also came to light was that untrained hospital personnel were requesting donation from grieving families rather than waiting for OPO personnel to arrive. When this occurred it was unlikely that OPO personnel were able to reverse a refusal to donate, which was most often the initial donation decision.
Uniform Anatomical Gift Act 1987

UAGA was revised in 1987 to address the advances in transplant therapy that developed during the two decades since the 1968 UAGA. It had the goal of increasing the number of donated organs. UCL accepted the National Task Force on Organ Transplantation’s recommendation to incorporate Routine Request legislation into the UAGA. What was included was similar to that which was incorporated into OBRA, the requirement that all patients be asked at hospital admission if they wish to be an organ or tissue donor. If the patient is admitted in an incapacitated state and there is no written document of gift, the hospital is required to discuss organ donation with the patient’s family. Because these laws were already widely adopted prior to 1987, adding this provision to the 1987 UAGA simply brought it in line with current practices.57 This, however, did not change other practices that were identified as hindering organ procurement such as the failure of medical personnel to follow the donation wishes of the deceased, failure to convince individuals to sign a written document as to organ donation outside of hospital admission, and the inability of organ procurement organizations to quickly identify needy recipients leading to wasted organs.58

The 1987 UAGA contained a provision that medical examiners and coroners could authorize the removal of needed organs and tissue from cadavers in their control absent the knowledge that the decedent or the decedent’s next of kin objected to the removal.59 Even though the 1987 UAGA was not widely adopted, this limited presumed consent for medical examiners and coroners to remove corneal tissue was adopted by many states. It was usually limited to the extraction of corneal tissue in situations where an autopsy was required. The constitutionality of this provision was challenged in state
courts resulting in split decisions as will be discussed later. The 1987 UAGA also contained a provision allowing reliance on a document of gift that did not require a witness to sign. This was viewed as another form of presumed consent. The controversy and litigation surrounding this modest form of presumed consent was removed when the UAGA was revised in 2006 and most states have repealed it from their statutes. Perhaps, because of these provisions, the 1987 UAGA was adopted by only 26 states.

**Patient Self Determination Act of 1990**

By 1990, advances in medicine led to the ability to extend life. Often extending it beyond a point where there is any quality to that life. To attempt to address this issue, Congress passed the Patient Self-Determination Act (PSDA). PSDA was prompted, at least in part, by the Nancy Cruzan case. Nancy Cruzan was a 25-year-old woman who sustained severe head injuries in an automobile accident that left her in a persistive vegetative state in a Missouri state hospital. Her parents sought judicial action to have the feeding tube the hospital inserted removed, and all medication, nutrition, and hydration terminated. This case looked at the dilemma of when to cease providing medical care to incompetent patients and who should make that decision. In this case, the Supreme Court held that a competent person has a liberty interest in refusing unwanted medical treatment under the Due Process Clause of the Fourteenth Amendment. The Court also held, however, that the state was not require to accept the “substituted judgment” of a close family member in the absence of substantial proof of the patient’s views.
PSDA is a statutory attempt to encourage individuals to complete advance directives, healthcare proxies, or other documents that indicate the degree of advanced medical care they wish to receive. The issue most often addressed in advanced directives or by healthcare proxies is whether and when to allow the use of life support systems. PSDA requires hospitals, nursing homes, and hospices and any other health care institutions that receive Medicare and Medicaid funding, to advise patients on admission of their right to accept or refuse medical care and to execute an advance directive. Managed care organizations and home health care agencies must provide this information to each of their members at enrollment. Provider organizations are required to (1) document whether patients have advance directives, (2) implement advance directive policies, and (3) educate their staffs and communities about advance directives.\(^6^4\)

Compliance with PSDA is a condition for Medicare and Medicaid reimbursement. Since Medicare and Medicaid funding is essential for the survival of any healthcare institution, they all comply with the procedural, written requirements of the law. What is more difficult to ascertain is whether they actually follow the wishes set out in the patients’ health care directives. Since these documents cannot cover every medical situation and may be subjective in some cases, the default will be to follow the direction of a family member, regardless of whether it reflects the wishes of the incapacitated patient, a point that directly impacts organ procurement.

**Organ Allocation – Final Rule**

In keeping with NOTA’s directive to coordinate organ procurement activities,\(^6^5\) a final rule directing the organ allocation process was issued on October 18, 1999.\(^6^6\) This was a revision of the controversial rule first published in the Federal Register in April
Because the final rule allowed then Secretary of HHS, Donna Shalala, to retain the right to have final say over any organ allocation plan there was opposition from Congress. Medical groups were also opposed claiming the medical community, not the Secretary, should determine organ allocation. There was fear that community transplant centers would lose locally donated organs to larger regional centers because the final rule looked to sharing organs in broad geographic areas. There was also fear of organ waste in that transporting organs over larger geographical regions would require more time. Time is the enemy of organ transplantation in that each organ has a limited window of time in which it can be successfully transplanted.

To help evaluate the 1998 proposed final rule, Congress delayed implementation for a year while it directed the Institute of Medicine (IOM) to review the proposed rule and issues surrounding organ procurement and transplantation. IOM’s review resulted in five recommendations: 1) discontinuation of waiting time as a primary allocation criteria, 2) establishment of federal government oversight and guidance, 3) creation of a method of independent scientific review, 4) establishment of allocation criteria specific to livers, and 5) improvement in data collection and dissemination to the public.

The final rule incorporates the IOM recommendations. It advocates for a benefit analysis between the needs of the most urgent medical cases with the realities of successful transplantation. It heeds the recommendation to eliminate time on a waiting list as the main criterion and directs that waiting list time, along with medical urgency be two components of the allocation decision. It calls for the establishment of an expert advisory committee to oversee the transplant process along with federal oversight. It also calls for improved data collection and dissemination. Today, the United Network of
Organ Sharing (UNOS), the private contractor in charge of the organ allocation and procurement system, has a website containing a wealth of transplant data dating back to 1986. It is easily assessable at http://www.unos.org.

**Organ Donation and Recovery Improvement Act of 2004**

Organ Donation and Recovery Improvement Act\textsuperscript{71} amends the Public Health Service Act and authorizes the Secretary of Health and Human Services to award up to $25 million in grants to states, OPOs, transplant centers, or other public or private entities. Grants can be used to reimburse travel and incidental nonmedical expenses incurred by individuals in making living organ donations. It also allows for grants and studies on ways to increase organ donations and recovery rates. States can apply for grants to increase education and outreach leading to heightened awareness of the need for organ donations. OPOs and hospitals are eligible for matching grants to establish programs and coordinate organ donation activities designed to increase organ donation rates. The act also requires the Secretary of HHS to direct the Agency for Healthcare Research and Quality (an operating division of HHS) to support research leading to programs that will increase donation rates as well as improve recovery, preparation, and transportation of donated organs. The act also calls for support of technology and programs to enhance OPO staff skills in recovery, preservation and transport techniques.\textsuperscript{72}

**Uniform Anatomical Gift Act of 2006**

The 2006 revision of UAGA was an attempt to alleviate the ever-increasing organ shortage as well as to offer a revised version of the model law to return uniformity to state law.\textsuperscript{73} As of the end of 2013, 46 states and the District of Columbia had adopted the
2006 UAGA. An important focus of the 2006 UAGA is first-person consent. This focus stems from the disturbing finding of the 1986 Report of the Task Force on Organ Transplantation that, as suspected, there is a widespread practice of requesting family consent for organ donation even if the decedent has affirmatively taken steps to donate his or her organs. Passage of “first person consent” is an attempt to end this practice.

First person consent laws allow the documented wish of the deceased to direct whether an organ is procured for transplantation or research. There is no need for further consent or concurrence from the family. First person consent laws are usually coupled with immunity from prosecution for health professionals who act in good faith to procure organs based on the decedent’s wishes. Karan Sokohl, in her article on first person consent, argues that there are two shortcomings to this law. First is the lack of uniformity of the laws adopted by the states. Second is that the concept of first person consent must be accepted by all involved in the procurement process, including healthcare professionals and organ procurement administrators. Sokohl found that even if an individual does make an affirmative decision to donate, OPO personnel may still ask the family for consent to the donation. If the family does not agree, even if only one family member objects, that may be taken as the final decision overriding the decedent’s express wishes. First-person consent is the legal attempt to prevent this from occurring. It specifically gives legal authority to the decedent’s written document of gift (e.g. state registry, driver’s license notice, etc.) as the sole source of authority to procure an organ. Despite this, the practice of seeking family concurrence is reported to still persist.
Not long after the 2006 version of the UAGA was promulgated, it began being adopted by the states. Early adopters found concern with one particular provision that brought ethical conflict to some critical care physicians and appeared to some to be in conflict with PSDA. As previously discussed, PSDA encourages patients to execute an advance directive or other similar document to communicate their wishes for medical care in the event they become incapacitated. On admission to a hospital, all patients that do not have such a document are encouraged to sign at that time and often are provided a template they may use. The most common sentiment expressed in these documents is the desire not to be placed on life support equipment if there is little hope of regaining consciousness. However, this creates a potential conflict for medical professionals.

One of the goals of the 2006 UAGA was to increase organ procurement, specifically, to prevent those who have agreed to donate after death from having their decision reversed by an uninformed family member. To this end, the 2006 UAGA contains section 21, which was designed to prevent an advance directive with a provision not to use extraordinary measures to extend life from being interpreted as precluding organ donation. The section 21 wording that caused concern was:

“…measures necessary to ensure the medical suitability of an organ for transplantation or therapy may not be withheld or withdrawn from the prospective donor…”

For some critical care physicians and ethicists who viewed this provision as being in conflict with a patient’s advance directive, this presented a dilemma. If they followed
the advance directive that precluded extraordinary measures to sustain life, could they place the patient on a mechanical respirator to harvest the organs?\textsuperscript{76}

The problem presented is that in order to procure organs for successful transplantation both the warm and cold ischemic times must be minimized. Warm ischemic time is the time the organ remains at body temperature after the blood supply has been reduced or cut off but before it is cooled or reconnected to a blood supply. Cold ischemic time is the time between the chilling of the organ after the blood supply has been reduced or cut off and the time the organ is warmed by having its blood supply restored.\textsuperscript{77} To keep the organs as viable as possible, they need to remain in a physiological state that simulates the functioning body. To this end, the deceased donor is placed on a respirator while the suitability for donation is determined and, if applicable, the transplant teams are assembled and procurement of the organs being donated is coordinated.

The placement of a patient on a mechanical ventilator when that patient has an advance directive that contains instructions to the contrary, created a direct conflict between the document of gift and the advanced directive. If the critical care physician follows the advance directive and refuses to intubate and place the potential donor on a mechanical ventilator, it would preclude the ability to retrieve the organs, thus ignoring the dying patient’s wish to donate. On the other hand, if the physician follows the decedent’s wishes and proceeds to harvest the organs the advance directive’s prohibition against extraordinary lifesaving measures could be considered to be violated. To alleviate this conflict and clarify the process so not to discourage others from becoming donors or donating on behalf of a loved one, UCL quickly adjusted the UAGA to direct
physicians to consult with terminal patients or their health care proxy to clarify their wishes whenever possible. The 2007 revision further states that while the conflict is being resolved, measures necessary to ensure medical suitability of the organs may not be withheld or withdrawn if not contraindicated by appropriate end-of-life care, “a general statement described in a power of attorney or health care directive that the patient does not wish to have life prolonged by the administration of life-support systems should not be construed as a refusal to donate.”

Charlie W. Norwood Living Organ Donation Act of 2007

In January of 2007, a bill was introduced in the House of Representatives to amend NOTA. The bill was named after Congressman Charlie Norwood (R. GA) who received a lung transplant for idiopathic pulmonary fibrosis but died a few years later from liver cancer. The bill sought to allow human organ paired donation without violating the prohibition against acquiring a human organ in exchange for valuable consideration.

Patients in need of certain human organs such as kidneys and partial liver transplants and in rare cases segments of lung, intestine, and pancreas, can receive an organ donation from a living donor in one of three ways. First, is a Directed Donation. This is when a needy transplant candidate identifies a willing donor and the donor and recipient are biologically compatible. If, however, a willing donor is identified and the pair are not biologically compatible (that is, the blood type and antigen profile do not match) then there are two possibilities to procure an organ. There is a Living Donor/Deceased Donor Exchange (LDDD). This is where a living donor who is not biocompatible with the indented organ recipient donates his or her organ to an unknown
patient on the cadaver waiting list with whom they are compatible. The patient to whom the living donor wished to donate but was not biologically compatible then receives priority on the cadaver waiting list. The other method used for kidney transplants is Paired Exchange. This is where a willing donor who is biologically incompatible with the intended recipient is paired with another biologically incompatible donor/recipient combination. The donor from the first pair must be a match for the recipient of the second pair and the donor from the second pair must be a suitable match for the recipient of the first pair. If there are more than two pairs of willing but incompatible donor/patients they all may enter into a paired matching agreement. Organization such as the Alliance for Paired Donation, Paired Donor Network, or others that will work to find the willing donor another waiting list patient with whom they do match and who has a relative or friend who is willing to donate a kidney to them but who is also an incompatible match. The two donor/candidate pairs exchange kidneys between each other. It is possible that three or more pairs may enter into such an exchange to create appropriate matching recipients.\textsuperscript{80}

In order to ensure that such a law would be in keeping with NOTA, the General Counsel of the Department of Health and Human Services sought review by the Office of Legal Counsel of the Department of Justice (DOJ). In a memorandum to the General Counsel, DOJ clarified that both Paired Exchange and Living Donor/Deceased Donor (LDDDD) Exchange were legal.\textsuperscript{81} DOJ clarified and the Charlie Norwood Act codified that these scenarios are not considered to be an exchange of valuable consideration in violation of NOTA.
Patient Protection and Affordable Care Act of 2010

The Patient Protection and Affordable Care Act of 2010 (ACA)\textsuperscript{82} is a wide-reaching attempt to reign in the cost of health care while simultaneously expanding access to the uninsured. It is designed to expand insurance coverage to approximately 32 million previously uninsured Americans. It prohibits insurance companies from refusing coverage for those with pre-existing conditions. This will likely expand the number of patients on transplant waiting lists because it will permit coverage earlier in their illnesses. Theoretically, transplantation in the early stages of ESRD will lead to improved outcomes. Currently, Medicare covers End Stage Renal Disease (ESRD) only at the time of transplantation or after a predefined period of dialysis for those under age 65.

This possible increase in the number of newly insured patients needing organ transplants will further strain overstretched organ waiting lists. If an increased supply of transplantable organs is not correspondently found, the result will be even greater waiting list mortality than the 18 patients that currently die each day waiting for an organ to become available.\textsuperscript{83} Increased demand and decreased supply of altruistic donors could also lead to an increase in transplant tourism for those whom a living transplant is possible. Transplant tourism is when those in need of an organ, most often a kidney, visit countries that are beyond NOTA’s prohibition against paying for organs. These desperate candidates search for individuals, often very poor and disadvantaged, who are willing to “donate” a kidney – for a price. An increase in the use of marginal donors, those older than age 65, or those with comorbidities at death, may also result. These
transplant recipients often have less successful transplants or need greater treatment, which leads to greater healthcare costs.\textsuperscript{84}

**Table 1. Laws Pertaining to Organ Donation**

<table>
<thead>
<tr>
<th>Year</th>
<th>Legislation</th>
</tr>
</thead>
<tbody>
<tr>
<td>1832</td>
<td>English Anatomy Act – early regulation of cadavers, granted the right to donate a corpse for research or education. Designed to alleviate the cadaver shortage needed to train surgeons.</td>
</tr>
<tr>
<td>1968</td>
<td>Uniform Anatomical Gift Act – first model law, created the power to donate organs and tissues to someone in need.</td>
</tr>
<tr>
<td>1972</td>
<td>Social Security Act Amendment – extended Medicare coverage for dialysis or transplantation.</td>
</tr>
<tr>
<td>1980</td>
<td>Uniform Determination of Death Act – codified the common law definition of death, especially useful for organ procurement.</td>
</tr>
<tr>
<td>1984</td>
<td>National Organ Transplant Act – criminalizes the sale or purchase of a human organ, also called for the creation of an independent organization to manage organ procurement.</td>
</tr>
<tr>
<td>1986</td>
<td>Omnibus Budget Reconciliation Act – recommended states adopt Routine Request Laws requiring hospitals to request consent for donation upon admission.</td>
</tr>
<tr>
<td>1987</td>
<td>Uniform Anatomical Gift Act – included a provision allowing coroners to remove needed organs and tissue from cadavers in their control absent knowledge of an objection to the contrary.</td>
</tr>
<tr>
<td>1990</td>
<td>Patient Self-Determination Act – encourages individuals to establish advance directives, healthcare proxies, or other documents to indicate the level of advance medical care they wish to receive if they are incapacitated.</td>
</tr>
<tr>
<td>1999</td>
<td>Organ Allocation Final Rule – issued by the Department of Health and Human it provided for federal oversight of the transplant process to be managed by a private contractor as well as improved data collection and dissemination.</td>
</tr>
<tr>
<td>2004</td>
<td>Organ Donation and Recovery Improvement Act – establishes a grant program to increase organ donation through programs and research.</td>
</tr>
<tr>
<td>2006</td>
<td>Uniform Anatomical Gift Act – attempts to facilitate organ procurement via electronic registries and strengthen personal autonomy via First Person Consent.</td>
</tr>
<tr>
<td>2007</td>
<td>Uniform Anatomical Gift Act (revised) – clarifies that an advance directive prohibiting mechanical means to prolong life does not preclude donation.</td>
</tr>
</tbody>
</table>

**Case Law**

As organ transplantation grew to become the standard treatment for many end-stage organ diseases so too did litigation surrounding organ and tissue procurement. The
cases below illustrate the differing views State and District Courts have taken on the same issue.

Supreme Court of Florida v. Powell (1986)

The State of Florida was one of the first states to look at the constitutionality of its state statute authorizing medical examiners to remove corneal tissue when performing a statutorily required autopsy. The Florida statute permits corneal procurement as long as there is no known objection, specific consent is not required. Section 732.9185 of the Florida Statutes (1983) also contains a provision granting immunity to medical examiners and eye bank personnel for failure to obtain consent for corneal removal.

*Florida v. Powell* was a joint case brought by the parents of James White, a drowning victim, and Anthony Powell, who died in an auto accident. The facts in both instances are substantially the same. In both instances the corneas of the accident victims were removed while undergoing a statutorily authorized autopsy. In neither case was the family asked for consent or given notice of the tissue removal. The plaintiffs brought suit arguing that the statute was unconstitutional as it interfered with the next of kin’s right to bury the dead in the same condition as death left them. It was, in essence, “a taking” of private property, the property being the dead body. A taking of private property for public use without just compensation is a violation of the Fifth Amendment of the Constitution and therefore, unconstitutional. In a summary judgment decision, the trial court agreed. Using a strict scrutiny standard of review, the court held that the state’s objective of providing high quality corneas to those in need was commendable but not compelling. It did not outweigh the right of the families to the bodies of their deceased.

The Florida State Supreme Court disagreed with the trial court. In making its decision it looked at the financial expense Florida incurred in proving services for the blind. The
Court also considered data that showed that the small number of corneas that were procured through donation yielded only a fraction of the number of corneas needed. Not only were there few donations but the donations were often of a poorer quality.

The Florida Supreme Court spoke of the property right in dead bodies as “somewhat dubious.” The Court instead suggested that it is the personal feelings of the next of kin that are really at issue. Not seeing evidence of a religious objection to the removal of the corneas, the Court concluded that there was no protected liberty or property interest that was violated by the statute. Using the rational basis standard, the Florida Supreme Court overturned the lower court and held that the statute was constitutional because it was rationally related to the permissible state objective of restoring sight to the blind.87

**Brotherton v. Cleveland (1991)**

*Brotherton v. Cleveland* was another modern day case addressing the issue of anatomical gifts, especially statutory interpretation of a state’s Anatomical Gift Act. In this case Deborah Brotherton, the wife of the deceased, was approached at the hospital with a request for the corneas of her recently deceased husband. She refused based on what she believed would be the wishes of her husband. Her refusal was recorded in the hospital’s death report. Subsequently, the circumstances of her husband’s death called for an autopsy to be performed to determine the cause of death. At the time of the autopsy, the coroner removed her husband’s corneas. Under Ohio law, the county coroner is permitted to remove the corneas of an autopsy subject without first obtaining consent provided they have no knowledge of an objection to such removal.89

When Ms. Brotherton became aware of the removal she filed suit. The District
Court dismissed her claim of a violation of due process under Title 42 United States Code, section 1983 (42 U.S.C., section 1983) for failure to meet the burden of proof. Under section 1983, a plaintiff must show that she was deprived of a Constitutional right and that the deprivation of that right was under color of state law. The Court held that her claim of a constitutionally protected property interest in her husband’s corneas under the Fourteenth Amendment did not rise to a legitimate claim of entitlement.

The Sixth Circuit reserved the District Court. It held that Ms. Brotherton did hold a property interest in her husband’s corneas under 42 U.S.C., section 1983. Therefore she had a legitimate claim of entitlement under the Due Process Clause of the Fourteenth Amendment. The Court further stated that “The only governmental interest enhanced by the removal of the corneas is the interest in implementing the organ/tissue donation program: this interest is not substantial enough to allow the state to consciously disregard those property rights which it has granted.”

Coming to a different conclusion than Florida v. Powell, this District Court established the precedent of next of kin’s constitutionally protected property interest in the decedent’s corpse.

Flynn v. Holder (2011)

Flynn v. Holder was a recent challenge to NOTA’s ban on payment of valuable consideration or at least an attempt to contain that ban. A not-for-profit organization, More Marrow Donors (MMD), offered $3,000 for scholarships, charitable contributions or housing expenses to minorities who registered on its website to become bone marrow donors and did in fact match and donate. Minorities have an especially difficult time finding non-relative bone marrow matches. The goal of the organization is to develop a large database to help locate this difficult to match bone marrow. MMD filed suit in
federal district court in California to have NOTA’s ban on paying for bone marrow to be found unconstitutional under the Equal Protection Clause or on substantive due process grounds. The District Court dismissed for failure to state a claim but the Ninth Circuit reversed in part. The Ninth Circuit looked closely at the methods of obtaining bone marrow. There are two methods to obtain bone marrow from a donor. The first is by inserting a long needle into the hipbone of the donor and extracting the marrow through aspiration. The second, newer method is called peripheral blood stem cell (PBSC) apheresis. It involves injecting drugs into the donor for several days to stimulate stem cell production in the bone marrow. Then the stem cells are collected via apheresis, a method similar to blood donation.

Apheresis was not developed when NOTA was drafted in 1984. Relying on the fact that payment for blood was not prohibited in NOTA, the Ninth Circuit went on to conclude that the phrase “any subpart thereof” included in NOTA referred to the organ from which the material was taken and not the organ in which it was created. This led to the conclusion that apheresis of stem cells from the bloodstream is a subpart of the blood not the bone marrow. This is different from aspiration which involves direct extraction of bone marrow. Therefore, the Ninth Circuit held that NOTA’s bone marrow ban applied to extraction by aspiration. Extraction by apheresis was viewed as a blood donation and therefore permissible for payment under NOTA.

These cases are a sample of cases involving organ procurement over a 25 year time period. From the Florida State Supreme Court’s 1986 ruling that the state stature allowing procurement of corneas by coroners should be viewed under the permissive rational basis standard, to the Sixth Circuit’s ruling five years later that the next of kin did
have a property interest in the decease’s corpse, to the 2011 ruling by the Ninth Circuit that delved in-depth into the intent of NOTA, the courts have become emerged in the area of human organ donation and procurement. As medicine and technology continue to advance, this area of law will inevitably continue to evolve.

Conclusion

Recognizing even from its earliest stages that transplanting a functioning organ from one human to replace a non-functioning organ of another was a valuable life-saving procedure, state and federal legislatures have looked for ways to increase that practice. Unfortunately, organ donation has never been able to meet the need. Built on the premise of autonomy and individual choice, state and federal governments shy away from policies that presume an individual is willing to donate his or her organs upon death. Instead, legislatures have focused their efforts on encouraging the altruistic act of voluntary donation. The three major revisions of the UAGA have been attempts to provide a model of a law that would promote, but not require, organ donation.

Other federal laws have been enacted with the same noble goal of increasing organ procurement without offending the sensitivities of the American people. The most notable of these is NOTA. Its prohibition against the buying and selling of human organs is still believed to be favored by most people, except needy patients facing a life tied to a dialysis machine or death on a waiting list. “Transplant tourism,” the practice of traveling to less developed countries for the purpose of buying a needed organ is a growing reality indicating a desperate willingness to evade NOTA’s ban.

Indeed, another example where legislation and practice conflict is “first person consent.” The 2006 UAGA directs OPO’s to procure organs from deceased individuals who have made known their desire to be organ donors. This is to be done without
seeking concurrence from the next of kin. To ensure this end, the 2006 UAGA provides immunity from prosecution for OPO and hospital personnel who, in good faith, follow this directive. Yet, families are still routinely consulted and an objection, even by a single member, will usually preclude organ procurement regardless of the decedent’s wishes. It is the rare OPO or hospital that will go against the wishes of a decedent’s family. When asked why a patient’s wishes would be ignored for those of a family member one physician replied “because dead patients don’t sue but their family’s do.” The fear of litigation evidently weighs heavily on physicians and the desire to avoid it is paramount.

The legal history of organ donation and transplant laws shows multiple unsuccessful attempts to increase the number of organs available for transplantation, while never going beyond the bounds of altruism. It is clear that legislative attempts to promote altruistic behavior as the means of solving the organ donor shortage must be accompanied by policy and practice change. Changing human behavior is a monumental task that requires a concerted effort by federal, state and private organizations to accomplish. The need for human organs has not yet galvanized that effort.

As we enter 2014, the implementation of the Patient Protection and Affordable Care Act and its effects on organ transplantation are unclear. Now may be the opportunity to look beyond altruism as a source of organs.
Paper II

Legislating Altruism: Are the Laws Governing Organ Donation Achieving Their Goal?

Introduction

In 1967, a South African surgeon named Christian Barnard successfully transplanted the first human heart. It made news worldwide.\textsuperscript{94} Even though the first kidney transplant occurred more than a decade earlier, it was the transplantation of a human heart from a brain-dead accident victim into a dying patient that brought this procedure to the world’s attention.\textsuperscript{95} Today organ transplantation does not make news despite the fact that it has established itself as a lifesaving treatment for failing and diseased organs for young and old alike. The complication of infection that killed many of the early transplant recipients has been greatly reduce through improved surgical practices coupled with the discovery of modern pharmaceuticals that prevent the body from rejecting the foreign organ without severely compromising the immune system. Organ transplantation should serve as one of the most resounding medical achievements of the Twentieth Century. Yet, its usefulness today is limited by the most basic need, the lack of human organs to transplant.

In the United States, the need to organize and promote organ transplantation was recognized early on. In 1968, the Uniform Law Commission (ULC) drafted a model law that the states could adopt that would bring uniformity to this emerging field as well as promote the practice of organ donation and transplantation. Not achieving this goal despite widespread adoption, the 1968 Uniform Anatomical Gift Act (UAGA) was revised in 1987 and again in 2006. Other laws have also been adopted on both the federal
and state levels. Nonetheless, thousands die annually due to the lack of a transplantable organ.96

This article begins by looking at the current organ procurement process. It discusses the ULC and the drafting of model laws in general. Next it analyzes whether the most recent model law governing organ donation and transplantation, the 2006 UAGA, has achieved its goal of increasing the number of organ transplants by increasing the number of organs available for procedure. To do this analysis, the per capita organ transplantation rates among those states that adopted the model law soon after it was promulgated are compared to those states that more recently enacted it and those states that have yet to adopt the model law. Sufficient time has likely passed to determine if the law has had an impact on the transplant numbers of the early adopting states.

This article also takes a closer look at a few states that experienced large changes in the number of transplants during the past several years or those that have taken a unique approach to some aspect of organ donation. Next it explores other factors that are believed to influence organ donation and transplantation. Lastly, policy recommendations that may increase organ procurement are suggested.

**Regulatory Background and Study Data Source**

This study looks at the 2006 UAGA, the most recently promulgated model law in this area, and whether early adopters of this law have experienced an increase in the number of organ transplants for their state. The 2006 UAGA, like all model laws, was drafted by the ULC and adopted by the states at varying times. When state legislatures discuss adoption of a proposed model law they can vote to adopt it as written or they can amend or change it as each state legislature sees fit. The ULC was established in 1892 (also referred to as the National Conference of Commissioners on Uniform State Law)
and is comprised of lawyers, judges, legislatures, and law professors all of whom have been appointed by their state government. They bring together what they believe are the best practices in a particular area of state governed law for the purposes of drafting a model law that will bring uniformity to state law in that subject area. The goal is adoption of the model law by all states with minimal, if any variations. In addition to the 50 states and District of Columbia (DC), the U.S. Virgin Islands and Puerto Rico are also represented on the Commission. As of the end of 2013, 46 states and DC have adopted the 2006 UAGA. Thirty-three of which adopted it by 2008, 14 have adopted it after 2008, and four states still rely on the 1987 UAGA as their statutory authority. The breakdown of states can be seen in Table 2 below.

In order to understand organ donation laws, a discussion of the organ procurement process is needed. The United Network of Organ Sharing (UNOS) holds the contract with the federal government to operate the Organ Procurement and Transplant Network (OPTN). The need for a non-governmental organization to create a network for organ procurement came out of the 1984 National Organ Transplant Act (NOTA). NOTA directs the Secretary of the United States Department of Health and Human Services (HHS) to establish the OPTN and to provide a framework to guide it in the coordination of organ procurement activities. UNOS was awarded the first contract in 1986 and has continued to operate the OPTN since then. UNOS’ mission includes maximizing organ supply and equitable allocation of organs through education, technology and policy development. It collects and maintains data on every organ donation and transplant event that has occurred in the United States since 1986. Most of this information is
Table 2. Summary of Early, Late, and Non-adopting States of the 2006 UAGA

<table>
<thead>
<tr>
<th>Early Adopters</th>
<th></th>
<th>Late Adopters</th>
<th></th>
<th>Non-Adopters</th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>State</strong></td>
<td><strong>Year Adopted</strong></td>
<td><strong>State</strong></td>
<td><strong>Year Adopted</strong></td>
<td><strong>State</strong></td>
<td><strong>Year Adopted</strong></td>
</tr>
<tr>
<td>Arkansas</td>
<td>2007</td>
<td>Oklahoma</td>
<td>2009</td>
<td>Delaware</td>
<td>1987</td>
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<tr>
<td>Colorado</td>
<td>2007</td>
<td>Ohio</td>
<td>2009</td>
<td>Pennsylvania</td>
<td>1987</td>
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<tr>
<td>Iowa</td>
<td>2007</td>
<td>South Carolina</td>
<td>2009</td>
<td>Florida</td>
<td>1987</td>
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<tr>
<td>Idaho</td>
<td>2007</td>
<td>Wyoming</td>
<td>2009</td>
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<td>Indiana</td>
<td>2007</td>
<td>Connecticut</td>
<td>2010</td>
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<tr>
<td>Kansas</td>
<td>2007</td>
<td>Kentucky</td>
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<td>Minnesota</td>
<td>2007</td>
<td>Nebraska</td>
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<td>Montana</td>
<td>2007</td>
<td>New Hampshire</td>
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<td>North Carolina</td>
<td>2007</td>
<td>Vermont</td>
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<td>North Dakota</td>
<td>2007</td>
<td>Louisiana</td>
<td>2010</td>
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<tr>
<td>New Mexico</td>
<td>2007</td>
<td>Maryland</td>
<td>2011</td>
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<tr>
<td>Nevada</td>
<td>2007</td>
<td>Massachusetts</td>
<td>2012</td>
<td></td>
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<tr>
<td>Oregon</td>
<td>2007</td>
<td>Illinois</td>
<td>2013</td>
<td></td>
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<tr>
<td>Rhode Island</td>
<td>2007</td>
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<td>South Dakota</td>
<td>2007</td>
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<tr>
<td>Tennessee</td>
<td>2007</td>
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<tr>
<td>Utah</td>
<td>2007</td>
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<td>Virginia</td>
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<td>Alaska</td>
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<td>Alabama</td>
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<td>California</td>
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<tr>
<td>DC</td>
<td>2008</td>
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<tr>
<td>Georgia</td>
<td>2008</td>
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<td>Hawaii</td>
<td>2008</td>
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<td>Maine</td>
<td>2008</td>
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<td>Michigan</td>
<td>2008</td>
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<td>Missouri</td>
<td>2008</td>
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<td>Mississippi</td>
<td>2008</td>
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<tr>
<td>New Jersey</td>
<td>2008</td>
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<td></td>
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<tr>
<td>Washington</td>
<td>2008</td>
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<tr>
<td>Wisconsin</td>
<td>2008</td>
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<tr>
<td>West Virginia</td>
<td>2008</td>
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</table>

publically available on its website. Data are reported at the national, regional, and state levels as well as by organ procurement organizations (OPO). UNOS also issues an annual report that is publically available. The report is issued to the Health Resources and Services Administration, an operating division of HHS. The report provides data by state, region, organ type, and whether the transplant involves an adult or a child. UNOS is the data source for the number of transplants referenced in this study.  

The final rule establishing the regulatory framework for the OPTN was published in the Federal Registrar, effective March 16, 2002. The final rule was not without controversy. Initially drafted in 1998, the medical community joined with transplant specialists, as well as Congress, to lobby for the HHS Secretary to defer to their judgment as to what is best for the transplant community. Smaller transplant centers were concerned they would lose organs to larger centers in distant geographical areas if HHS had the final authority in transplant allocation rules. In deference to their concerns, the government delayed implementation and commissioned the Institute of Medicine (IOM) to conduct a review of OPTN’s policies and the proposed 1998 final rule. IOM’s review resulted in five important recommendations: 1) discontinuation of waiting time as a primary allocation criteria, 2) establishment of federal government oversight and guidance, 3) creation of a method of independent scientific review, 4) establishment of allocation criteria specific to livers, and 5) improvement in data collection and dissemination to the public.

HHS, under the direction of then Secretary Donna Shalala, adopted a final rule that attempted to incorporate the recommendations of the IOM Report as well as the medical and transplant communities. It stressed that medical factors affecting organ
viability must be considered in allocation policy. To that end, the rule moved away from time on the waiting list as the main criteria for receiving an organ and instead adopted an allocation system that encompasses both waiting list time as well as medical urgency. For organs to be used most efficiently under this system, local allocation should be considered first but if a suitable candidate was not immediately found then regional and finally national allocation was to follow. Flexibility is allowed to consider medical urgency as a reason to move ahead of others on the waiting list.\textsuperscript{102}

To create public trust in the new transplant policy, the final rule established an expert advisory committee with the members to be nominated by the transplant community and the public. This independent, multidisciplinary scientific advisory board’s role is to continue to guide UNOS in developing transplant policy. There is also a provision that directs transplant networks to ensure that hospitals fairly assess the medical urgency of their transplant candidates so that they do not classify them as more critical to obtain organs more quickly.\textsuperscript{103} This system remains in place today.

The Organ Procurement Process – How It Works

Before we begin a closer look at whether the UAGA is working, we need to look at the organ procurement process itself. NOTA established the current OPO system. Presently there are 58 OPOs in the United States. Their two main functions are to: 1) increase the number of registered organ donors and 2) coordinate the process of organ procurement and patient matching. The procurement process begins when a hospital notifies their OPO of a potential donor in their facility. It is the OPO staff that first checks the national data base to determine if the potential donor has a documented decision as to organ donation.
OPOs are responsible for receiving referrals from hospitals, determining donor status, and obtaining family consent. OPOs receive federal reimbursement for the organs they recover. OPOs receive payment from the Medicare program at a rate determined by a diagnostic related group (DRG) prospective payment. The payment includes pre-transplant services for the recipient and all costs for the donor whether living or deceased. Annual reimbursements amount to several hundreds of millions of dollars.\textsuperscript{104}

In addition, OPOs provide educational programs and events to the public and perform quality assurance audits for association members. OPOs also develop protocols for procurement, educate hospital staff, and manage the medical aspects of organ recovery, which includes coordinating removal of donated organs. Each donated organ requires a special team for removal and for transport. These teams must all be assembled and ready to enter the operating room at the same time. This coordination is very time sensitive, driven by the warm ischemic time of the most time sensitive organ (usually the heart). Each organ has a specific period of time, known as the ischemic time, in which it remains viable after its owner’s circulatory system ceases to function. Warm ischemic time refers to the length of time that an organ can remain in the body when the natural circulatory system has stopped.

Because organ retrieval is a time sensitive process, those who die at home cannot be considered for organ donation. Certainly the home may be the most comfortable environment for a terminally ill patient, but the inability to confirm the exact time of death and thus determine the length of viability of the organ, prevents an individual who dies in this setting from being able to donate an organ. Without the exact time of death the start of the ischemic clock and thus when viability ends, is indeterminable. Most individuals do not die at home, therefore, the number of donors loss for this reason is
small; nonetheless, the loss of even one donor can equal the loss of up to eight organs (two lungs, two kidneys, one liver, heart, pancreas, and intestine). Some ethicists may argue that allowing a terminally ill patient to die in the comfort of his or her home is a greater good than salvaging those organs even in the face of the severe organ shortage that now exists. Robert Truog, who agrees that clinicians have an ethical obligation to ensure that the wishes of those who want to donate are respected, also argues that we must remember that there is a dying patient behind each source of organs. A balance needs to be found between these competing ethical principles. Yet, under the Utilitarian maximization strategy the loss of eight lives for the comfort of one is not in keeping with the principle of the greatest good for the greatest number.

**Study Methodology**

This study examines whether the 2006 UAGA has successfully lead to an increase in the number of organ transplants. The 2006 UAGA was put forth for state adoption in July 2006, with the first states adopting in 2007. Within the first two years, thirty-three states and the District of Columbia adopted this model law. Therefore, by 2012, there was four or five years of data on these 34 Early Adopters. This allowed exploration of the research question as to whether there was a statistically significant difference in the per capita number of organ transplants for the Early Adopting States between 2006 and 2012.

The UNOS website provides comprehensive data on organ transplants. The focus of this study is on the procurement of organs for transplants from deceased volunteers. The number of cadaver donors for each state and DC was obtained from the UNOS Website. Cadaver donors provide approximately 80% of organs for transplant. Live donor transplants pertain primarily to kidneys (with a very small percentage of partial
liver transplants). The number of live organ transplants was left out of this analysis because the focus of this study is to examine whether the 2006 UAGA has been successful in its goal of increasing the number of organs for transplantation. The 2006 UAGA does not pertain to live organ donations.

To test the research question presented, the 51 entities comprising the 50 states and DC were divided into two groups. Group 1, known as “Early Adopters” contains the 33 entities that adopted the 2006 UAGA in 2007 or 2008. Group 2, “Late Adopters,” is comprised of the 14 states that adopted the 2006 UAGA in 2009 or later. There are also four states that have not adopted the 2006 UAGA as of the beginning of 2014. The Non-Adopting states are Delaware, Florida, New York and Pennsylvania. These four states use either the 1987 or 1968 UAGA as the basis of their organ donation laws although revisions may have occurred during the intervening years. For statistical testing, the Non-Adopting States are included with the Late Adopting States. A t-test was run including the four Non-Adopters with the Late Adopting States and again without them. There was no statistical difference in the results with or without the Non-Adopters, therefore the Late and Non-Adopting States are grouped together.

The per capita number of cadaver organ transplants for 2006, the base year before the model law was adopted, and the number for 2012, the last year for which there is complete data, serve as the comparative points in time for the Early Adopters and the Late and Non-Adopters. Because the states vary widely in population, a per capita rate was used to standardize the data by removing the confounding effect of population. The 2006 and 2012 state population estimates were used to convert the number of transplants to per capita rates. This information was obtained from the U.S. Census Bureau Website. 

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The null hypothesis for this analysis is that there is no statistical difference in the per capita rate of transplants between the Early Adopting States in 2006 and the Early Adopting States in 2012. The alternate hypothesis is that there is a difference between the per capita rate of transplants in the Early Adopting States between 2006 and 2012. To see if the Late and Non-Adopting states had a similar or different experience, they were also tested. The null hypothesis is that there is no statistical difference in the per capita rate of transplants between the Late and Non-Adopting States in 2006 and the Late and Non-Adopting States in 2012. The alternate hypothesis is that there is a difference between the per capita rate of transplants in the Late and Non-Adopting States between 2006 and 2012. The \textit{a priori} expectation was that the 2006 UAGA would lead to an increase in the number of organs available for transplantation and thus lead to an increase in the number of transplants performed. It would follow that states that adopted this model law soon after it was promulgated would show a statistically significant increase in the number of organ transplants.

For this study, a significance level of 0.05 was chosen. The interpretation of the significance level is that if the test statistic meets this criterion, then there is a 95% level of confidence that the observed difference did not happen by chance. Because the null hypothesis states that there is no difference between the two groups, a two-tail t-test was used to allow for an increase or decrease in the per capita rate of transplants. The t-test is a parametric test used to compare small samples that are assumed to be normally distributed.\textsuperscript{110} It is the appropriate test to use for nominal or ordinal data to assess whether the means of the two groups are statistically different from each other. The two groups being the rate of organ transplants in 2006 and in 2012 for the Early Adopting
States. Similarly, the t-test was chosen for the same comparison of 2006 and 2012 transplants for the Late and Non-Adopting States.

Descriptive statistics were obtained for the two groups and appear in Table 3, below. Table 3 gives the number of states, the average number of transplants, the standard deviation, the median number of transplants, the average number of per capita transplants, and the standard deviation for the average per capita number of transplants for both the Early and Late and Non-Adopters in 2006 and 2012.

**Table 3. Descriptive Statistics for Early Adopting States and Late and Non-Adopting States**

<table>
<thead>
<tr>
<th>Statistics</th>
<th>Early Adopters (n=33)</th>
<th>Late and Non-Adopters (n=18)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>2006</td>
<td>2012</td>
</tr>
<tr>
<td>Average Number of Transplants</td>
<td>332   (657)</td>
<td>352   (488)</td>
</tr>
<tr>
<td>(standard deviation)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Median Number of Transplants</td>
<td>246</td>
<td>209</td>
</tr>
<tr>
<td>Average Per Capita Number of Transplant</td>
<td>.0000640 (0000724)</td>
<td>.0000626 (0000721)</td>
</tr>
<tr>
<td>(standard deviation)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Table 4 shows the p-value results for both the Early Adopting and Late and Non-Adopting States. The results reveal a p-value greater than 0.05 for the paired t-test. As mentioned previously, the p-value is the probability of the results occurring by chance. A p-value of 0.05 was chosen *a priori* to be the level of statistical significance. A p-value of 0.05 is commonly accepted as a statistically significant level indicating that there is at most a five percent probability that the results obtained could have occurred by chance. A p-value that is less than or equal to the chosen significance level indicates that the results obtained were not likely to have occurred by chance. In those instances, the null hypothesis is rejected. Because the p-value for the Early Adopting States equals 0.542,
which is greater than 0.05, we failed to reject the null hypothesis. There is no statistical difference in the rate of per capita organ transplants between 2006 and 2012 for the Early Adopters.

**Table 4. P-value Results for Two-Tail t-Test for Early Adopting States and for Late and Non-Adopting States**

<table>
<thead>
<tr>
<th>Test</th>
<th>P-value</th>
</tr>
</thead>
<tbody>
<tr>
<td>Two Tailed Paired t-test, Early Adopters</td>
<td>0.542</td>
</tr>
<tr>
<td>Two Tailed Paired t-test, Late and Non-Adopters</td>
<td>0.309</td>
</tr>
</tbody>
</table>

As previously discussed, the results of the t-tests show no statistical significant difference for the Early Adopters between 2006 and 2012, nor is there statistical significant for the Late and Non-Adopters. Thus, we fail to reject the null hypotheses in both instances.

Figure 1, is a graphic depiction of the mean per capita change in transplants between 2006 and 2012 for each of the Early Adopting States. From this figure, we see that there is no consistency across the states. There is, in fact, a wide range of changes that occurred during these years. A few states experienced relatively larger increases and several experienced relatively larger decreases. Had early adoption of the 2006 UAGA led to an increase in transplants as hoped, more consistent increases across the Early Adopting States would have occurred.
Figure 1. Percent Change in Transplants Among Early Adopting States Between 2006 and 2012

* Mississippi exhibited a 600% change, the bar was truncated at 100% for scaling purposes

Figure 2, depicts the mean per capita change in transplants between 2006 and 2012 for the eighteen Late and Non-Adopting States. Here too we see a wide range of changes for these states. These graphs appear to corroborate the t-test analysis that there is no statistically significant difference in the number of transplants between 2006 and 2012 for either the Early Adopting States or the Late and Non-Adopting States.

Figure 3, shows the national trend in all cadaver transplants beginning in 1988. As can be seen from this graph, after a 2006 peak in transplants the number declined until 2011. The following year, 2012, saw another decrease in transplants. This suggests that the widely adopted 2006 UAGA is not meeting its goal of increasing organ transplants. It should be noted that although there is an overall increase in the number of
Figure 2. Percent Change in Transplants Among Late and Non-Adopting States Between 2006 and 2012.

*Delaware exhibited a percent change of 244%, the bar was truncated at 100% for scaling purposes

transplants between 1988 and 2006 this increase did not match the increase in the need for transplantable organs. It was this continued need for organs that lead to the 2006 revision of the UAGA.

The increase between 2003 and 2006 may be attributable to the Organ Donation Breakthrough Collaborative (Collaborative), which was launched in 2003 with great fanfare by Tommy Thompson, then Secretary of HHS. The promoters of the Collaborative maintain that it was responsible for this positive effect on increasing the number of transplants. The Collaborative was an intense effort to facilitate breakthrough transformation in organizational performance; the Collaborative’s goal was to increase the number of transplantable organs. In a retrospective review, an increase in the consent rates was seen beginning in 2004 but it was not sustained. Further research is needed to determine how a transient increase in transplant rates that may be generated by a concerted effort such as the Collaborative, can be sustained.
Analysis

As of early 2014, complete transplant numbers for 2013, have not yet been compiled. The preliminary numbers, however, continue to present a dismal picture of organ donation and transplantation in this country. Nationally, organ transplants from cadaver donors appear to have decreased, continuing the downward trend from 2012. Few states have experienced an increase during recent years. One that did is Mississippi. In 2012, Mississippi saw an 85.73% per capita increase in the number of cadaver transplants from the base year of 2006. Mississippi is an Early Adopter, passing the 2006 UAGA in 2008. However, the large increase Mississippi experienced between 2006 and 2012 is primarily derived from a large increase seen in 2007, the year before the revised UAGA was adopted. In looking at Mississippi’s organ donation law, it is similar to the 2006 UAGA as drafted with increased protection for healthcare workers who, in good faith, procure organs without seeking concurrence from next-of-kin. In other words,
Mississippi supports first person consent. Mississippi is also one of only five states that require organ donation education in both school and driver education courses. Two others, Indiana and Louisiana, which saw a 17.28% and 18.00% increase respectively, might indicate that the educational component is key. However, the other two states that have this education requirement are Arkansas and Ohio. Both of these states experienced a decrease in transplant numbers, Arkansas had a 14.73% decrease and Ohio had a 2.89% decrease.\textsuperscript{110}

The data did not reveal a reason for the large increase in transplants in Mississippi but it was made clear by the response to an electronic query to the Mississippi Organ Recovery Agency. The number of transplants increased because access to transplants in Mississippi increased. Before 2006, there were a limited number of kidney and heart transplants occurring at the one medical facility that performs transplants in Mississippi, the University of Mississippi Medical Center (UMMC). In 2007, additional transplant surgeons were brought to UMMC, which increased the number and type of transplants that could be performed.\textsuperscript{111} The element of access to transplant facilities and transplant physicians is a component of the transplant equation that cannot be overlooked. Moreover, the increased availability of transplants may have raised awareness among physicians and patients of the value of organ donation.

From the preliminary data, Utah appears to be one of the few states that saw an increase in cadaver transplants in 2013.\textsuperscript{112} It is an Early Adopter of the 2006 UAGA. After passage in 2007, Utah has seen a modest but consistent increase in cadaver transplant numbers in 2009, 2010, 2011, and 2013. The preliminary data through November 30, 2013, reveals a 26% increase in cadaver transplants. Utah maintains that
it follows first-person consent and will procure a donated organ even without family consent.\textsuperscript{113}

Pennsylvania, on the other hand, has not adopted the 2006 UAGA. (It has been before the Pennsylvania General Assembly since the 2013 session.\textsuperscript{114}) Pennsylvania, however, put first-person consent into practice several years ago.\textsuperscript{115} Yet, it has experienced a steady decrease in the number of cadaver transplants since 2006, with a 42% decrease between 2006 and 2012. This is perplexing because Pennsylvania is a densely populated state with premiere medical facilities and is serviced by three organ procurement organizations. It would appear that Pennsylvania has all the elements necessary for maximizing the number of transplants, yet it has not.

\textbf{Why has UAGA Failed?}

The 2006 UAGA was designed to remove barriers to organ donation and thereby increase transplantation. It has not been successful in increasing organ transplants. On its face, the 2006 UAGA recognizes the autonomy of the deceased to proactively agree to donation during his or her lifetime. Yet, Mesich-Brant and Grossback found that even when a state legally adopts this policy of first-person consent it is not always implemented by organ procurement personnel.\textsuperscript{116} The practice of engaging the family is defended on the grounds that forgoing such a practice would create a negative public opinion of organ transplantation. Not to be dismissed is the human element. Death of a loved one is an extremely emotional time. OPO personal have admitted that they do not want to add to the grief of an already grieving family. Thus, the practice of seeking family consent even when a document of gift exists, persists.\textsuperscript{117} To further compound the problem, laws in this area carry virtually no means of enforcement. Whether they are
followed or not depends on the practice of each OPO. Until first person consent is implemented, we will continue to deprive needy waiting list candidates of donated organs that could be theirs.

**Recommendations**

**Transform Laws into Policy and Practice**

Organ donation in this country cannot remain as a system based solely on altruism with laws and policies designed to encourage this practice. After more than four decades with continually increasing shortages clearly our voluntary system does not work. Moreover, to reiterate the sentiment by Troug, there is an ethical obligation to see that a decedent’s wish to be an organ donor is followed. To do this the practice of deferring to the next-of-kin despite having a documented willingness to donate needs to be replaced by first person consent. This will also restore the dignity of the dying patients by allowing them the autonomy to decide whether they wish to have their organs be given to another when they no longer need them. OPOs need to fully implement first person consent. Forty-six states and the District of Columbia have adopted the 2006 UAGA with its directive to procure organs from known donors without seeking additional consent. Three of the other four Non-Adopting States (Florida, New York, Pennsylvania) currently are operating under the 1987 UAGA that also has a first person consent provision. Even the state of Delaware, whose organ donation laws are based on their adoption of the 1968 UAGA, states that when a request for donation is made the requester will ask if there is a document of gift. If not, then the persons listed in the statute will be asked for consent. The Delaware law is silent on the exact course of action if there is a document of gift but does not require that the next of kin be consulted.
OPOs should initiate training and if necessary, sensitivity awareness, for their personnel so that they will not feel that procuring donor directed organs would add to the burden of the grieving family.

Second, another Organ Donation Collaborative, modeled after the first, should be undertaken. The first Organ Donation Breakthrough Collaborative (Collaborative) was launched in 2003 with great fanfare by Tommy Thompson, then Secretary of HHS. Defining collaboration as an intense effort to facilitate breakthrough transformation in organizational performance, the Collaborative had the goal to increase the number of transplantable organs. It was an intense effort to identify best practices of transplant hospitals and OPOs and share those practices with others. The president of the Association of OPOs, the executive director of UNOS, and the president of the Joint Commission lent their support to this effort. The Collaborative lasted for 20 months. It included six two-day learning sessions for all personnel involved in the donation and transplant process. This team approach included: social workers, pastoral care associates, critical care nurses, attending physicians, as well as OPO personnel. It challenged hospitals and OPOs to reach a goal of converting 75% of eligible donors into actual donors. It lasted from September 2003 to May 2005. As Figure 3 indicates, there was a 10.8% increase in cadaver transplants between 2004 and 2006. Twenty-one of the participating hospitals achieved the goal of a 75% conversion rate. It is time for another concerted effort such as the Collaborative to extract best practices from states that have experienced large transplant increases and to determine causes for decreases and how to avoid them. Most importantly, there should also be an added focus on sustainability of any increases achieved.
Creation of a Public –Private Partnership

The Collaborative could also look into other methods to increase funds for organ donation efforts. One recommendation could be the formation of a public-private partnership (PPP). PPPs combine the financial resources and knowledge of the government and the private sector to provide better services to the public. There is a high level of accountability in PPPs. Government regulators are aware of the scrutiny these partnerships are under by the media and the public. This scrutiny ensures less opportunity for waste or corruption. PPPs are successful because private companies use economies of scale and long-term financing to contain expenses. Coupled with the increased efficiencies from the partnership, revenue often increases. The public receives increased services without the burden of increased taxes.¹²³

A PPP could be developed by the creation of a charitable 501(c)3 foundation. Funding would be a combination of HHS/HRSA grants, contributions from other not-for-profit organizations that support organ donation and private tax-deductible contributions. (Several states currently allow private citizens to donate to state organ donation efforts. New Jersey, for example, encourages tax filers to donate one dollar to the state’s organ donation efforts by checking off a box on their state income tax return.) An independent council of overseers could ensure that contributions were not accepted from organizations or individuals that resulted in a conflict of interest or even gave the appearance of one.

Funds from a PPP could be used for education and public awareness campaigns: education to dispel the lingering myths surrounding donation and public awareness to highlight the need for organs. Most people know of the process of transplantation and support it in theory if not in action.¹²⁴ They may not be aware, however, of the severe
shortage of organs and the effectiveness of transplantation in treating end-stage organ
disease. The old notion of a transplant being a last-chance effort to save a dying patient
has not fully been replaced by the reality of transplantation as a treatment option. The old
image is reinforced by the occasional media coverage of a public plea for an organ, quite
often for a very sick child. Putting a face on a problem ignites a call for action in a far
greater way than proclaiming direr statistics. The effect, however, is ephemeral. Once
the crisis is over the memory fades and no systemic change is made to correct the
problem. In other words, it is policy by crisis management. The true crisis, however, is
that 77,000 people are actively awaiting an organ for transplant. Many of which,
perhaps up to 60%, will die waiting for the altruistic gift that will never come.

In addition, to an awareness campaign needs to come increased education about
the facts surrounding organ donation. Dispelling the myths that surround donation will
remove the fear. The most common fear about organ donation is that if you register to
become a donor and are taken to a hospital you will be left to die because your organs
will be viewed as more valuable than you. This is not the case. The primary care
physician cares for the patient. He or she is separate from the transplant surgeon.
Transplant surgeons never request organ donation from a dying patient or the patient’s
family. OPOs are the bridge between the two. Their role includes preventing any
conflict of interest, or even the appearance of one. The fear of physical mutilation of the
body is another myth. The removal of organs and even the removal of most tissues cause
no physically noticeable marks that would preclude an open casket funeral. This is
mainly a secular fear because most major religions are in favor of organ donation.
Revisit NOTA

NOTA’s ban on exchange of an organ for valuable consideration had the noble goal of preventing exploitation of the poor by incentivizing the living to sell a kidney or other body part out of desperation for a few dollars.\textsuperscript{129} It has successfully prevented that sort of exploitation in this country. There is, however, a wide area between exploitation and incentivizing. The AMA’s recent decision to reconsider their support of NOTA’s ban on all forms of compensation in exchange for an organ is an important first step to revising NOTA’s ban.\textsuperscript{130} Not that a kidney exchange such as the one that was the original impetus for the NOTA ban is an idea whose time has come, but incentives such as the Pennsylvania law to contribute up to $3,000 for the funeral expenses of a deceased donor are positive incentives that may increase organ donation without taking advantage of the poor as was the fear of outright sale.\textsuperscript{131}

A Nudge to Benefit Society

The most important recommendation, however, is that the federal government needs to do more than encourage altruism, it should direct a change in the procurement system through a change in human behavior.

Examples of the federal government protecting the public health and safety by directing a change in behavior include: mandatory speed limits, seat belt laws, and the prohibition on the sale of alcohol to those less than 21 years old. One of the more controversial areas in which the government forced a change in human behavior is that of motorcycle helmet laws. Motorcycle riding is an inherently dangerous activity. Not only are lives lost, but often the victim suffers serious head injuries leaving him or her in a persistive vegetative state. The cost to society in terms of long-term care for such victims
can be $12 billion annually.\textsuperscript{132} To ease this burden the federal government sought to require motorcycle riders to wear helmets. Since the federal government has no direct authority to impose this restriction on the citizens of the various states, it encouraged passage of such a law at the state level. This “encouragement” took the form of a policy transferring funds from highway construction accounts to highway safety accounts.\textsuperscript{133}

Seat belts laws are another method of regulating behavior. Seat belts save lives. They would not have the degree of acceptance, and therefore the efficacy, if it were not for the legal requirement to wear one while driving and the attached fine if the law is not followed. Public safety was also the goal in linking federal highway money to state adoption of 21 as the legal age for alcohol purchase and consumption. The country went from having a range of legal drinking ages between 18 and 21, to 21 years being the universally accepted drinking age. These federally “encouraged” and state enacted laws have all had a positive effect on individual safety and health, which has benefitted society as a whole.

A softer approach to directing behavior would be the one advocated by Richard Thaler and Cass Sunstein in their popular book, \textit{Nudge}.\textsuperscript{134} Based on the observation that human beings make many decisions but often their choices are not in their own best interest, they espouse what they call “choice architecture.” Known as libertarian paternalism in their academic writings, Thaler and Sunstein argue that a paternalistic nudge towards making the best decision while still allowing individuals to choose otherwise, is in the best interest of the individual and of society. The classic example of this, and the one that some companies have employed, is in the area of retirement savings. Given the choice of whether to put money into a retirement savings account, many
individuals often do not do so, even when the company provides matching funds. Driven by the perceived need for the money now, these individuals make the irrational choice to forgo matching funds in the future for the immediate benefit of money. Following the Thaler and Sunstein model, companies that automatically enroll employees in their retirement funds by directing a small percentage of their pay into the fund find that most employees stay in the fund. They do not take the step of stopping the deposit of their funds into the retirement account. This leads to Thaler and Sunstein’s other important observation that inertia is always the preferred choice. People will more often do nothing rather than make a change.

Having been successful in leading people to retirement savings, this approach should be applied to organ donation. The inertia principle along with a libertarian paternalistic nudge towards donation, will lead up to a system of presumed consent. Otherwise known as opting-out, this is the opposite of the U.S. system. Adopted by some European countries with varying degrees of success, this system presumes you are willing to donate your organs upon death. If you do not wish to do so you may opt-out by making known your wish not to donate on a registry, on your license, in a separate instrument, or other manner much the same as if you were to opt-in. While admitting that this system is not a panacea, Thaler and Sunstein present findings that it would increase the donation rate by about sixteen percent in this country. They also point to the fact that this system is used for obtaining corneas. In many states, coroners and medical examiners are permitted to remove corneas as long as there is no known objection to the removal. This is presumed consent. There have been lawsuits in this area but not to the extent that some suggest would occur if this country were to move to a system of
presumed consent. In light of the continuing organ shortage, it is time that there is further exploration of this option.

Another approach, perhaps a somewhat gentler nudge, is to adopt a system of mandated choice. Writing in the Hastings Constitutional Law Quarterly, Jonathan August presents a case for mandated choice. In 2006, Illinois passed the First-Person Consent Act. This act calls for all residents 18 or older to inform the state if they wish to be an organ donor when they receive or renew a driver’s license. A definitive choice of yes or no is required. The decision is legally binding and cannot be changed by a family member at the time of death. What makes this law especially noteworthy is that it has been endorsed by the American Medical Association. That organization’s endorsement is predicated upon exchange of information in keeping with the principle of informed consent. Hopefully, the Illinois Act will avoid the problem that Texas encountered in its attempt at mandated choice. In 1991, Texas passed a similar act. However, the “requirement” to respond was not enforced. The result was that every nonresponse was recorded as a refusal to donate. The law was repealed in 1997. The 2006 Illinois Act is now ripe for research as to the effects on transplants and donor registration.

Conclusion

The present system of organ donation has failed to produce the one thing it was designed to do, save lives by procuring organs from voluntary donors. Laws to encourage this altruistic behavior have been widely adopted but often not fully implemented. First person consent laws have been adopted by all 50 states and DC yet, implementation remains incomplete. Giving deference to the wishes of the patient’s
family is still the practice in many areas. This results in many lost organs, which translates into many lost lives. Each donor has the potential to save up to eight lives through organ donation. This is a stunning example of exponential consequences. It is time to transform first person consent into practice. First person consent will benefit society, as it will lead to procurement of more organs. It will also fulfill society’s ethical obligation to respect the wishes of the deceased who have agreed to donate.

Recognizing that full implementation of first person consent will require a challenging cultural change; a large-scale concerted effort to that end should be undertaken. It is time for another organ donation collaborative similar to the one initiated in 2003. The first Collaborative lead to an exchange of best practices and experience that contributed to a double-digit increase in transplants. A renewed collaborative effort, with monetary rewards for achieved and sustained success would be an important next step in increasing transplant rates.

To generate financial resources for a renewed collaborative a public private partnership should be created. Such a partnership would combine the knowledge and expertise from government regulators and well-run not for profit organizations. By establishing the appropriate oversight and mechanism to prevent a conflict of interest, the partnership could also generate financial resources to fund the collaborative by accepting private donations.

It is time to follow the lead of the AMA and revisit NOTA’s ban on exchange of any form of valuable consideration. Allowing limited financial incentives in the form of tax deductions or burial expends, could go a long way to encourage altruistic donation without causing such an incentive to risk exploitation of the poor.
Since 1968, the UAGA has attempted to provide more organs by simplifying the donation process and encouraging the decision of the donor to be the one that is followed. All states have organ donation laws that contain a provision giving the decedent’s wishes to donate priority over those of the family. These laws have been adopted by the states but not fully implemented. Overcoming this ingrained belief that the family should be asked for consent to donate upon death of a family member and their decision should be followed over the decedent’s own wishes remains a major obstacle to increasing the number of transplantable organs.

The next version of the UAGA needs to move away from simply reaffirming the status quo of voluntary donation, we cannot legislate altruism. Because a model law is subject to adoption based on 51 separate decisions made by the state legislatures and the DC Council, this research suggests that the UAGA may not be the best mechanism to achieve the change that is needed. A more persuasive effort to direct behavioral change in keeping with the models of directing human behavior that have been successful in other areas, needs to be implemented. The concept of choice architecture has had success in assisting in other areas of human decision making. Implementation in the area of organ donation has been the subject of much debate in legal, ethical, and policy circles. There is precedent from state policies and practices regarding cornea tissue procurement to indicate that this is a viable option that would generate many needed organs and would not cause a donor backlash as opponents suggest. As a society, we need do more than simply encourage individuals to choose organ donation. There is an ever-growing waiting list of candidates literally dying for organs. Donation should be the default choice in our society. It is most often the choice individuals want to make. A more direct nudge towards this choice is needed.
Endnotes


3. *Id.*

4. As of February 17, 2014, there have been 590,152 total transplants since 1988, 127,314 of which were from living donors, equaling 21.57%.


10. The range of transplant candidates represents the active and inactive lists. The smaller number is the active list, those candidates eligible to receive organs that become immediately available. The larger number includes the inactive candidates. These are candidates who are temporarily classified as medically unsuitable for transplantation or need to complete other eligibility requirements. United Network for Organ Sharing, www.unos.org.


16. Research in the areas of tissue engineering and regenerative medicine may someday lead to human organs transplanted from synthetic materials or regenerated from the body’s own cells. Henry Fountain, A First: Organs Tailor-Made with Body’s Own Cells. N.Y. TIMES Sept. 16, 2012 at A1.


18. English Anatomy Act of 1832 allowed doctors, teachers of anatomy, and medical students to dissect donated bodies. Prior to this only the bodies of executed murders could be used for dissection. TheFreeDictionary.Com at http://encyclopedia.thefreedictionary.com/p/Anatomy


20. The Murder Act 1752 stipulated that only the corpses of executed murderers could be used for dissection. By the early nineteenth century, the rise of medical science, occurring at the same time as a reduction in the number of executions, had caused demand to outstrip supply. http://encyclopedia.thefreedictionary.com/p/Anatomy%20Act%20of%201832

21. Id.

22. Dr. Joseph Murray preformed the first transplant in Boston on Dec. 23, 1954. The transplant recipient lived 8 years with his identical twin brother’s kidney. In 1990, Dr. Murray received the Nobel Prize for Medicine.


27. Id.


30. Social Security Act Amendment of 1972, Public Law 92-603 Section 299I


36. *Id.*, prefatory note http://www.uniformlaws.org

37. *Id.* at 35.


42. *Id.*

43. 20 PA. CONS. STAT. ANN. Sec. 8622


47. Nathan, supra note 19.


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


51. Id.

52. Id.


54. Id.

55. The Joint Commission is an independent, not for profit organization that accredits and certifies health care organizations in the U.S. Joint Commission accreditation and certification is recognized as a symbol of quality and meeting high performance standards. www.JointCommission.org


57. Center for Medicare & Medicaid Services, Fact Sheet: Medicare End-Stage Renal Disease (ESRD) Network Organization Program, supra note 34.

58. Supra note 7

59. Id.

60. Mesich-Brant, supra note 1

61. WEIMER, supra note 26.


63. Cruzan v. Director, Missouri Dept. of Health, 497 U. S. 261 (1990). The U.S. Supreme Court upheld the Missouri Supreme Court that allowed the state to require clear and convincing evidence of an incompetent’s wishes to withdraw life-sustaining treatment. Subsequently the Cruzans were able to obtain substantial evidence that their daughter would not want to live in a persistive vegetative state and her feeding tube was removed leading to her death 11 days later.

64. Section 1866(a)(1) of the Social Security Act (42 U.S.C. 1395cc(a)(1)), as amended by section 6112 of the Omnibus Budget Reconciliation Act of 1989, includes the following provisions: (Q) in the case of hospitals, skilled nursing facilities, home health agencies, and hospice programs, to maintain written policies and procedures with respect to all individuals receiving medical care by or through the provider—
(i) to inform such individuals of an individual's rights under State law (whether statutory or as recognized by the courts of the State) to make decisions concerning such medical care, including the right to accept or refuse medical or surgical treatment and the right to formulate advanced directives recognized under State law relating to the provision of care when such individuals are incapacitated (such a directive in this subparagraph referred to as an 'advanced directive'), such as through--

(I) the appointment of an agent or surrogate to make health care decisions on behalf of such an individual, and

(II) the provision of written instructions concerning the individual's health care (including instructions for the disposition of organs);

(ii) to inquire periodically (and to document in the individual's medical record) whether or not the individual has executed an advanced directive and to document in such record the individual's wishes (if any) with respect to such medical care;

(iii) not to deny the initial provision of care or otherwise discriminate against an individual based on whether or not the individual has executed an advanced directive;

(iv) to ensure that legally valid advanced directives and wishes otherwise documented under clause (ii) are implemented to the extent permissible under State law, including such provisions of State law as relate to the transfer of an individual in the case of a provider which, as a matter of conscience, cannot implement the wishes of the individual; and

(v) to provide (individually or with others) for educational programs for staff, individuals receiving medical care by or through the provider, and the community on ethical issues concerning patient self-determination and concerning advance directives respecting such care.'


68. Id.

70. *Id.*


72. *Id.*


75. WEIMER, supra note 26.


85. Florida v. Powell, 497 So.2d. 1188

86. Id.


88. Brotherton v. Cleveland, 923 F.2d. 477, 481-482 (6th Cir. Ohio 1991)

89. Ohio Anatomical Gift Act, Human Bodies or Parts There of, section 2108.60


91. Flynn v. Holder 684 F. 3d 852 (9th Cir. 2011).


94. The first heart transplant was performed on Louis Washkansky. He lived only 18 days before succumbing to pneumonia, a complication of the surgery. http://www.nytimes.com/2001/09/03/world/christiaan-barnard-78-surgeon-for-first-hearttransplant-dies.html

95. The first successful transplant of a human organ occurred in 1954 when Dr. Murphy transplanted a healthy kidney to replace the two failing kidneys of the donor’s identical twin brother. The transplant was a success with the recipient living several years with his brother’s kidney, a success that was rarely achievable in non-twins until the development of modern day anti-rejection drugs.


97. Supra note 10

98. www.federalregister.gov

99. This did not happen. The general distribution system that was established offers an organ to a matching waiting list candidate in the local area, then regionally, then nationally.

100. Hussong, supra note 67.

101. Childress, supra note 69.
102. Hussong, supra note 67.

103. Id.

104. WEIMER, supra note 26.


107. Supra note 10.

108. Using data available at optn.transplant.hrsa.gov/latestData/rptData.asp, an overall calculation revealed 78.4% cadaver transplants.

109. www.census.gov

110. MICHEAL HARRIS & GORDON TAYLOR, MEDICAL STATISTICS MADE EASY (2004).

111. Supra note 10.


113. Id.

114. Supra note 10.


119. Howard M. Nathan, President & CEO of Gift of Life, the PA OPO, in a telephone conversation with the author in 2008.
120. Mesich-Brant, supra note 1.
121. Id.
122. Troug, supra note 104.
124. Shafer, supra note 5.
125. The Joint Commission is an independent, not for profit organization that accredits and certifies health care organizations in the U.S. Joint Commission accreditation and certification is recognized as a symbol of quality and meeting high performance standards. www.JointCommission.org last viewed March 10, 2014.
126. Shafer, supra note 5.
127. National Council for Public Private Partnerships, www.neppp.org,
129. The active waiting list contains only the names of those ready to receive an organ. HRSA maintains larger waiting lists that also include candidates that may periodically be remove if, for some reason such as illness, but are not permanently removed.
130. Supra note 10.
131. Id.
132. Id.
133. Supra note 38.
135. Supra note 43.
138. THALER, supra note 6.

140. THALER, *supra* note 6.

141. This is the basis for the seminal case organ donation case, Brotherton v. Cleveland, 923 F. 2d 477-9 (6th Cir. Ohio 1991).

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NOTIFICATION OF IRB ACTION

Date: July 18, 2013

IRB #: CPS13-07-04

Principal Investigator:
Eric Kupperberg
Laurie Lenkel

Department:
Doctor of Law and Policy
College of Professional Studies

Address:
20 Belvidere
Northeastern University

Title of Project:
Increasing Organ Procurement: An
Examination of U.S. Organ Donation Laws and Policies

Participating Sites:
N/A

Approval Status:
Approved

DHHS Review Category:
EXEMPT, CATEGORY #4

This approval applies to the protection of human subjects only. It does not apply to any other university approvals that may be necessary.

No further action or IRB oversight is required, as long as the project remains the same. However, you must inform this office of any changes in procedures involving human subjects. Changes to the current research protocol could result in a reclassification of the study and further review by the IRB.

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