

Chapter 21

Organ Donation and Transplantation

S. Sandy Sanbar, MD, PhD, JD, FCLM

State Anatomical Gift Acts
Routine Inquiry or Required Request
Presumed or Implied Consent
Cadaver Organs: Determination of
Death
Organs and Tissues from Fetuses and
Anencephalic Infants

Living Donors: Donor Consent
Minors and Incompetent Donors
Confidentiality of Potential
Donors
Artificial and Animal
Transplants
Donor Screening

Federal Legislation
Selection of Organ Recipients
Cost and Payment Considerations
Malpractice Suits
Recent Developments

The total number of organs transplanted as of 2006 in the United States was 338,640 over a period of four decades. The majority, (201,846) were kidney transplant recipients, and the remainder included heart, liver, lung, and pancreas transplants.¹ There are about 16,000 living kidney recipients as of 2006. The number of transplants of all organs has increased over the past decade, but growth has been limited by a shortage of donors. Currently, kidneys are the most commonly harvested organs, and livers are the next most harvested. In addition, thousands of corneas and countless other tissues, such as heart valves, blood, skin, bone, and dura tissue, have been transplanted.²

The 1-year patient survival rate for kidney transplants in which the organ is donated by a living relative is now 93%, and for cadaveric kidney transplants it is 85%, up from 50% one decade before. The 1-year survival rate is 84% for heart transplants, 76% for liver transplants, and 79% for pancreas transplants.³

Transplantation centers have multiplied and no longer are limited to academic institutions. As of June 2006, there were 256 transplant centers in the United States operating one or more organ transplant programs,, including more than 248 kidney programs, 135 heart programs, 60 heart-lung programs, 126 liver programs, 68 lung programs, and 171 pancreas programs. Approximately 63 organ procurement organizations operate in 11 designated regions. The Organ Procurement and Transplantation Network (OPTN) is the unified transplant network established by the United States Congress under the National Organ Transplant Act (NOTA) of 1984 to be operated by a private, nonprofit organization under federal contract.⁴

As of May 2006, the waiting list of transplant candidates stood at 92,344. In January–February 2006, the number of transplant donors was 2360, and the number of recipients of those organs was 4508.⁵

Potential demand for vital organs is likely to increase as the indications for transplantation expand. Age limitations, for example, have become a relative contraindication. As procedures and immunosuppressives are refined and reimbursement mechanisms become better established, more potential recipients will seek transplantation. The U.S. Senate report on the National Organ Transplant

Act (NOTA) stated, “It is estimated that with recent improvements in transplantation surgery and medical management as many as 10% of our population at some time may be candidates for transplantation surgery in the future.”⁶

The traditional procurement policy of “voluntarism” has been inadequate. The potential supply of organs is limited to the estimated 20,000 patients declared brain dead in the United States each year, but organs are actually harvested from only about 15% of these.⁷ The increasing need for organs and the inadequacy of initial voluntary efforts have been the driving forces behind much of the legislation concerning transplantation. In 1968 the Uniform Anatomical Gift Act (UAGA) was promulgated to facilitate cadaver donations. Later statutes were amended to allow for donation by a signature on the back of drivers’ licenses. Brain death statutes were passed to allow removal of vital organs from artificially maintained bodies. Medicare funding and the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) standards now mandate that hospitals have protocols for routinely approaching families for organ donations. States have passed required request and routine injury laws. Implied consent for corneas from medical examiner cases has been adopted in many states. As the pressure for organs mounts, policy-makers will increasingly move away from voluntary to compulsory systems of procurement.

The major legal problems pertinent to transplantation are consent or authorization to donate, the determination of death in the case of procurement from a cadaver, and the rationing of organs and medical resources.

STATE ANATOMICAL GIFT ACTS

The foundation for the law on organ procurement in the United States is the UAGA, which provides the legal authorization for the system of voluntary donations and specifically defines the legal mechanisms for organ and tissue donations. In an effort to promote organ and tissue procurement, the National Conference of Commissioners on Uniform State Laws (NCCUSL) and the American Bar Association, after 3 years of deliberation, drafted the model

210 Organ Donation and Transplantation

act in 1968.⁸ By 1972 all 50 states, the District of Columbia, and Puerto Rico had adopted the UAGA, spurred on by the excitement over heart transplantation. Many of the states modified the UAGA during enactment or by later amendments. A substantially altered 1987 version of the UAGA, embodying new legal developments and other legislation, has been promulgated by the NCCUSL.⁹ As of August 1996 it had been adopted by 19 states (Arizona, Arkansas, California, Connecticut, Hawaii, Idaho, Iowa, Minnesota, Montana, Nevada, New Mexico, North Dakota, Oregon, Rhode Island, Utah, Vermont, Virginia, Washington, and Wisconsin), and the remaining states have all retained some version of the 1968 UAGA. However, many states that have not formally adopted the 1987 UAGA and that effectively repealed the 1968 UAGA have amended their UAGA several times over the years, blurring the distinctions. While every state has adopted some version of the 1987 UAGA, the latest revision of the UAGA is the 2006 proposed Model.¹⁰

The UAGA authorizes persons or their families to make an “anatomical gift” of all or part of his or her body to take effect upon death. The legally binding right to direct the disposition of one’s own remains after death is a new right created by the UAGA. Previously, as a carry-over from the original common law of England, one had no property rights in his or her body after death. Individuals could not clearly bequeath their bodies, and heirs could nullify or overrule bequests. Even families did not have full property rights in bodies but rather a limited right to possess the body for burial purposes. Bodies were considered “quasi-property.”^{11,12}

According to the 1968 UAGA, any person 18 years of age or older and “of sound mind” can execute an anatomical gift. Many states have substituted different age requirements. The requirement for a sound mind has been deleted from the 1987 UAGA. An anatomical part includes organs, tissues, eyes, bones, arteries, blood, other fluids, and other portions of the human body. Any condition can be imposed on the gift, but if the condition is inappropriate or unacceptable, it should be declined.

Gifts by a Decedent

The decedent’s wishes, if known, are to be carried out despite the wishes of the next of kin. Knowledge of religious beliefs may constitute knowledge of the decedent’s intentions. In *In re Moyer’s Estate* the Utah Supreme Court found that this posthumous control over one’s body was “in the public interest” as long as it was not “absurd” or “preposterous.”¹³ In *Holland v. Metalious*, the deceased willed her eyes to an eye bank and her body to one of two medical schools.¹⁴ The New Hampshire Supreme Court stated that the wishes of the decedent should usually be carried out, but because the medical schools had declined to accept the donation (because of objections of the spouse and children), the court ruled that the surviving spouse could determine the disposition of the body. No survivor has the legal right to veto a valid gift by the decedent; however, as a practical matter, if the family objects to the donation over the expressed desire of the decedent, it may be prudent to decline the decedent’s donation.

Gifts by Next of Kin

When the deceased has not indicated his or her intentions, the UAGA spells out specifically who among those available at the time of death may make an anatomical gift of the body or body parts. The UAGA first designates the spouse, and if the spouse is not available at the time of death, then an adult son or daughter, followed by either parent, then an adult sibling. If none of the aforementioned is available, a guardian of the decedent at the time of the death or any other person authorized or under an obligation to dispose of the body (e.g., the medical examiner or anatomical board) may donate the body or body parts.

Consent by one next of kin (e.g., one brother) is legally negated by the objection of another of the same class of next of kin (e.g., another brother), although inquiry of all in a class is not required to exclude the possibility that someone might object, as confirmed in *Leno v. St. Joseph Hospital*.¹⁵ New York allows any family member to veto a gift by any other family member; in Florida a spouse cannot make a donation over the objection of an adult son or daughter.

The statute does not address the status of divorced or separated spouses, stepparents, stepchildren, other dependents, designated caregivers, those appointed power of attorney, and others. The list of next of kin to be approached for organ donation in the UAGA is not necessarily the same as that for inheritance, autopsy consent, or even required request statutes. Consent by next of kin must be timely; the specified individuals must make the gift “after or immediately upon death.” This provides little guidance as to the time and diligence necessary in attempting to contact these persons before considering them “unavailable.” Time limits for the harvest of particular organs and tissues are clearly relevant.

Execution of the Gift

The gift may be executed by a will or other document. Such provisions in typical estate wills are discouraged because they are usually not immediately available at the time of death. The use of “living wills” is preferred because they are immediately available as part of the medical record. Two witnesses are necessary to validate a gift during the donor’s lifetime, but none is required in the case of a gift by next of kin. Some states have relaxed or eliminated (as in the 1987 UAGA) this witness requirement, whereas other states have statutorily specified witness requirements. The next of kin can make gifts by a signed document or by telegraphic or recorded message. The 1987 UAGA would also allow other forms of communication reduced to writing and signed by the recipient. Neither delivery nor public filing is necessary to make the gift effective. The gift can be revoked or amended by a signed statement, an oral statement in the presence of two witnesses, or a statement to an attending physician.

Any card, form, or even sticker may be carried by the donor to evidence the intention of the gift. During the mid-1970s, 44 states incorporated legislation to enable

organ and tissue donation by the mere signing of the back of a driver's license. Most organ procurement agencies and transplant surgeons do not accept such a signature by itself (so-called pocket wills) but rather require the contemporaneous consent of the next of kin. They speculate that the decedent may have changed his or her mind since the signing and that they could not afford the negative publicity that might occur in the face of objections by the family. Use of donor cards is mandated in the 1987 UAGA, which requires law enforcement officers and emergency rescue personnel to make a reasonable search for a document of gift and then requires the hospital to cooperate in the implementation of the anatomical gift. Routine inquiry further emphasizes acceptance of documents of a decedent's wishes and provides a mechanism to check the currency of the card.

Persons Accepting a Gift

Any specified person, physician, hospital, accredited medical school or university, tissue bank, or procurement agency can accept an anatomical gift for education, research, therapy, or transplantation. Several states additionally allow donation to anatomical boards, which generally receive unclaimed bodies for educational purposes. In Connecticut the state commissioner of health must approve recipients. The attending physician is the presumed donee, if a donee is not specified. The attending physician who makes a determination of death is excluded from participating in any part of the transplant procedures, although it does not prevent him or her from communicating with the transplant team. The term *hospital* is substituted for the term *attending physician* in the 1987 version of the act.

The intentions of the donor must be respected, including any condition imposed on the gift. A donee can accept or reject a gift. The donee of the entire body can authorize embalming and funeral services. One provision authorizes any postmortem examination necessary to ensure medical acceptability of the donated organ, including an autopsy. The donee of a part must remove the part without unnecessary mutilation and then relinquish custody to the next of kin or other person under obligation to dispose of the body. The drafters chose not to deal with the issue of compensation for processing the gift.

The UAGA does not qualify in any way the legal right of a physician, organ procurement organization, or transplant team who receives a donated organ to do with it what they perceive as properly carrying out the intentions of the family. It has been argued that the donee holder of an organ is the owner of the organ and thus has the absolute right, limited only by any express covenant of purpose, to choose the ultimate organ recipient. It also has been argued that the intermediary party is an agent of the donor or the donor's family and is liable for failure to comply with their wishes. It has even been espoused that the donee is a public trustee who is liable for negligence (or perhaps conversion) to a prospective recipient for an inappropriate selection.

Medical Examiners

Most vital organs are retrieved from patients who are declared brain dead because most natural deaths render organs unsuitable for transplants. Approximately 50% of brain deaths result from motor vehicle accidents or other violence and therefore fall under the jurisdiction of the coroner or medical examiner. The UAGA states that it is subject to other state laws governing autopsies; thus medical examiner and coroner laws take precedence. Comments to the original 1968 NCCUSL act state that it

is necessary to preclude the frustration of the important medical examiner's duties in cases of death by suspected crime or violence It may prove desirable in many if not most states to reexamine and amend the medical examiner statutes to authorize and direct medical examiners to expedite their autopsy procedures in cases in which the public interest will not suffer.

The 1986 National Task Force on Transplantation also recommended enactment of laws that would encourage coroners and medical examiners to give permission for organ and tissue procurement from cadavers under their jurisdiction.

Many states have "implied consent" statutes that allow harvest of corneas from medical examiner cases when no known objection to the harvest exists. The UAGA provides that the medical examiner may authorize removal of an organ or tissue for transplant purposes if it will not interfere with the postmortem investigation and if the medical examiner does not know of an objection to the donation after making a reasonable effort, and taking into account the useful life of the part, to find documentation of the decedent's intention and to contact the next of kin.

Immunity

The physician who removes an organ in good faith is protected from civil and criminal liability by the UAGA. Mississippi and Montana grant civil immunity only; South Carolina makes an exception for malpractice. In *Nicoletta v. Rochester Eye and Human Parts Bank*, parties recovering organs were protected when they relied on the good faith belief that a person consenting to donation was a surviving spouse when in fact she was not.¹⁶ This provision of immunity withstood constitutional attack in *Williams v. Hofmann*.¹⁷

The provision applies only to valid gifts. The UAGA takes effect only after death has been declared; it does not afford protection to the pronouncement of death itself. Failure to comply with the provisions of the act (e.g., no unnecessary mutilation of the body) may demonstrate bad faith. However, the act's provisions are to be construed liberally to achieve its stated goal of promoting organ and tissue donations. In *Ravenis v. Detroit General Hospital* the Michigan Court of Appeals ruled that the protection did not preclude liability for the negligent failure of a hospital to screen a donor adequately for disease that was subsequently transmitted to a recipient.¹⁸ Thus courts may interpret this provision of immunity to be inapplicable to malpractice.

212 Organ Donation and Transplantation

Most states also have protective clauses in their blood banking statutes that specifically maintain that blood transfusions, organ procurement procedures, and transplants are to be regarded as services rather than sales of products; accordingly, members of the transplant team are exempt from strict product liability.

The 2006 UAGA Update

The 1987 NCCUSL model act, among other things, added provisions for routine inquiry, required requests, presumed consent for medical examiner cases, and prohibition of the sale of organs, and the 2006 update is more encompassing.¹⁹ These substantial new provisions codify in the UAGA legislation that has to some extent been adopted elsewhere. These issues are discussed in the following sections.

ROUTINE INQUIRY OR REQUIRED REQUEST

Possible policy solutions to increase voluntary organ and tissue donations include routine inquiry, required request, and presumed or implied consent legislation. Only 1 of 25 hospital deaths provides material suitable for organ donation, although 24 of 25 deaths provide material suitable for tissue donations.²⁰ An estimated 17,000 to 26,000 potential organ donors die each year in the United States.²¹ Only 15% to 20% of potential donors become actual donors (about 2600 in 1984).^{22,23} However, approximately 70% to 75% of families were approached for permission to grant donation.²⁴ The limiting factor appears to be the inadequate request and referral by the health care team.²⁵⁻²⁸

Recognizing the problem, Arthur Caplan called for "required request" legislation, which would force providers to approach families for donation in appropriate cases.²⁹ This legislation focuses on the consent of surviving family members. "Routine inquiry," on the other hand, refers to asking a patient on hospital admission if he or she is an organ donor. This method focuses on the advance decision of the individual and his or her right to self-determinism, which is the proper priority according to the UAGA. Furthermore, it saves valuable time by preempting the need to contact the family before procurement. However, some have argued that queries during admission to the hospital are poorly timed because potential patients may feel apprehensive either that the care they receive might be substandard if they fail to comply with a request for donations or that medical providers might be less vigorous in resuscitative attempts if they do comply.³⁰

Required request is now found in the laws of most states, in federal Medicare and Medicaid conditions of participation, and in JCAHO standards of accreditation.^{31,32} Both the JCAHO and Medicare merely require that a hospital have a written protocol. Most current state legislation has been enacted in the form of amendments to state anatomical gift acts and rather closely tracks the federal law. State laws are typically more detailed and sweeping and apply to unaccredited, nonparticipating hospitals. However, state

laws are generally weak and vary greatly; few states even require documentation of the request, which would allow for enforcement, and several create institutional exemptions and wide discretionary exceptions for requests. Approximately half the states have weak versions of required request in which the sole requirement is a mere written hospital policy of routine requests of family members. In some states the request must be made by the physician, whereas in others the request must be made by a designated member of the hospital staff or of the regional organ procurement agency. Appropriate training of the requester is sometimes required. Half the states require documentation of the inquiry and its disposition; in many states this documentation is in a log book, a central registry, or a place other than the medical record.

There are numerous exceptions to the requirement of request based on considerations such as medical criteria, known objection, or religion. In Alabama the attending physician can decide that inquiry should not be made. In Massachusetts, exception is allowed when discussion would cause the family undue emotional distress. Lobbying efforts have exempted hospitals in several states.³³

Early measures requiring request have doubled and tripled overall tissue procurement, but vital organ procurement, which was the target of the legislation, has increased only modestly. Legal sanctions may be imposed if these provisions are not followed or are insufficient. The Health Care Financing Administration (HCFA) is seeking ways to assess compliance with Medicare and Medicaid required request regulations.³⁴

The UAGA has provisions for both routine inquiry and required request. Documentation is to be placed in the medical record. The hospital administrator is responsible for implementation, and the Commissioner of Health is responsible for oversight. Furthermore, the legislation mandates that donor cards be sought and respected. Law enforcement agents, emergency personnel, and hospital personnel are to make a reasonable search for a donor card or other documentation of gift at the time of death or "near" the time of death. When evidence of a desire to donate is found, the hospital is to cooperate in the implementation of the gift. Administrative (but not criminal or civil) sanctions are to be imposed.

In an effort to increase public awareness of and improve hospital participation in the donor program, Pennsylvania Act 102 amended the state's UAGA in 1994. The new law changed the way hospitals handle the identification and referral of potential donors and the request for anatomical donations, requiring hospitals to work with the organ procurement organization after every hospital death. In addition to formalizing the process of required request, the new law allows Pennsylvania drivers to indicate donor consent on the front of their driver's license; state Department of Transportation computer records are accessible 24 hours a day. The new law also created an Organ Donation Awareness Trust Fund for educational purposes and set up a contribution system tied to driver's license renewal and state income tax filings. To ensure compliance, Act 102 stipulates that a hospital can be fined up to

\$500 for every death not reported. The legislation also mandates that the state Department of Health conduct medical reviews to compare organ procurement organizations' referral records to hospitals' death records, which can be used to measure compliance rates.³⁵

Pennsylvania's routine referral law has increased referrals and donations dramatically throughout the state. Since the law was enacted, the state has experienced a 26% increase in the number of donors and a 36% increase in the number of transplants.³⁶ The legislation's success has marked an important milestone in addressing the organ shortage in Pennsylvania and has sent a message to other states that enacting similar legislation may be a key to increasing their donation rates. As of June 1997 at least eight states had enacted routine referral laws, and several more are expected to follow suit.³⁷

PRESUMED OR IMPLIED CONSENT

Presumed consent laws, in which consent is presumed in the absence of actual knowledge of objection, are common in Europe. It is a policy of "opting out" instead of "opting in." It has not been a popular notion in the United States, but as demand continues to outstrip the supply for organs and tissues, presumed consent will be increasingly favored by policymakers. Even in countries with implied consent laws, families are regularly asked permission for donations.³⁸

A number of states have enacted legislation authorizing medical examiners to have corneas removed based on presumed consent. These laws allow removal of the corneas when the death falls under the jurisdiction of the medical examiner, when removal of the corneas will not interfere with the investigation or disturb the appearance of the body, and when there is no known objection from the next of kin. Maryland passed the first such law in 1975. These presumed consent laws have been highly effective in increasing the supply of corneas.

Statutes vary remarkably in the degree of diligence required in attempting to locate family members. Some states require no effort, others require reasonable effort, some require a good faith effort, some specify attempts for a 4-hour period, and some specify attempts for a 24-hour period unless the organ or tissue would become unfit earlier. Numerous instances of families becoming outraged after corneas have been retrieved from loved ones have resulted in litigation and in Texas in a change in the law.³⁹

In *Powell v. Florida* the implied consent statute for removal of corneas by medical examiners was upheld by the Florida Supreme Court.⁴⁰ Two sets of parents sued when the corneas of their sons were removed by medical examiners without their consent or without any attempt to give them notice. The court found that the legislation was reasonable, did not violate due process or equal protection requirements, and served a public purpose. It noted that the state of Florida was spending \$138 million per year to support its blind citizenry, that corneal transplantation is in great demand, and that it is frequently successful in restoring sight.

The court determined that recovery from medical examiner autopsy cases was the most important source of quality tissue and that removal of the corneal tissue, which did not affect the decedent's appearance, was an insignificant bodily intrusion compared with the autopsy itself. The court cited California statistics that approximately 80% of the families of decedents could not be located in time for medical examiners to remove usable corneal tissue. The court further held that the next of kin has no property right in the remains of the decedent but merely a limited right to possess the body for burial purposes. Similarly, medical examiner implied consent statutes have withstood constitutional challenge in Georgia and Michigan.^{41,42}

In *Kirker v. Orange County* a mother was awarded damages for the intentional infliction of emotional distress caused by the "mutilation of her daughter's body" when the medical examiner granted permission to remove the child's eyeballs despite an expressed refusal for corneal donation in the medical record.⁴³ The medical examiner should have known of the objection. An attempted coverup was also shown.

As previously mentioned, the 1987 model act includes a provision authorizing any organ or tissue donation by a medical examiner for transplantation based on a presumed consent provided that a reasonable effort is made to discover any appropriate objection. Maryland and California have expanded presumed consent beyond medical examiner situations to include patients dying in hospitals.

CADAVER ORGANS: DETERMINATION OF DEATH

Most kidneys (80%), most livers (except those from living parental donors), and all hearts for transplantation are harvested from patients who have been declared brain dead and maintained on life support. In such cases a determination of death is necessary. Patients experiencing traumatic deaths often are not brain dead but die of cardiac arrest. An estimated five to six times more donors have no heartbeat than are brain dead.⁴⁴ Protocols for such donors have been established in several centers; rapid, timely management of the cadaver may allow organ recovery after the heart has stopped and the patient has been declared dead. The premature removal of organs may subject the physicians to civil and criminal liability.

The law has always held that a person is dead when a licensed physician pronounces him or her dead, if the determination is based on accepted medical standards. Brain death has become an accepted standard, and every court that has examined the question has held it a legally proper determination, regardless of the presence or absence of a state brain death statute. However, medical standards for determination of brain death have become rigorous in many jurisdictions, and failure to adhere to methods for determination specified by such standards may result in liability.

The physician who removes an organ in good faith may be protected from civil and criminal liability by the UAGA.

214 Organ Donation and Transplantation

This act appears to take effect only after death has been declared. However, it is to be construed liberally so that its stated goal of promoting organ and tissue donations may be achieved and conflicts of interest avoided. The act specifically states that the physician who makes the determination of death "shall not participate in the procedures for removing or transplanting a part."

In *Tucker v. Lower* the brother of an organ donor alleged that the organs had been removed before the donor was legally dead.⁴⁵ At the time, Virginia had not yet adopted a brain death standard. The jury found for the surgeon based on the instruction that death could be determined if there was complete and irreversible loss of brain function.

However, in *Strachan v. John F. Kennedy Memorial Hospital* the court ruled that the hospital was liable for delaying the release of a body while attempting to change the parent's decision not to donate. An emergency department physician had diagnosed brain death 3 days before the official pronouncement of death and disconnection of the respirator.⁴⁶

ORGANS AND TISSUES FROM FETUSES AND ANENCEPHALIC INFANTS

The national organ shortage is much more critical for pediatric organs (especially livers) than for adult organs. Less than 6% of organ donations are from donors 5 years of age and under.⁴⁷ It has been estimated that the potential demand each year for infant organs is approximately 1000 livers and 500 hearts and kidneys.⁴⁸ This is a conservative estimate because approximately 7500 infants with life-threatening congenital heart defects are born each year.⁴⁹ As of June 1997 the United Network for Organ Sharing listed 89 patients under 5 years of age who were waiting for a kidney, 355 patients waiting for a liver, 90 patients waiting for a heart, and 14 patients waiting for a heart-lung block.⁵⁰ Half the transplant candidates die before an organ becomes available. In comparison with adults, a very small number of infants and children die with transplant-suitable organs.

Anencephalic infants represent an important potential source of fetal organs. Organs from such infants could meet the bulk of the current demand for infant organs. Organs from stillborns and infants dying from other diseases generally are not suitable for procurement and transplantation.

Anencephaly is an abnormality of primary neurulation commencing within the first month of gestation and resulting in the congenital absence of a major portion of the brain, skull, and scalp. Cranial neural tissue is exposed and often protrudes from the skull defect. Both cerebral hemispheres are absent or unrecognizable. Although some rudimentary cerebral development can occur, there is no functioning cerebral cortex. Anencephalic children cannot reason and presumably cannot suffer. The term *monster* has been applied to this anomaly, which represents the most severe form of neural tube defect (spina bifida). Anencephaly is a universally fatal condition. Two-thirds of anencephalic infants die in utero. Very few survive beyond 1 week after birth. Infants provided maximal support may survive somewhat

longer, but when strict diagnostic criteria are applied, survival still does not exceed 2 months. Longer survival periods have been reported; however, the diagnostic criteria were not well documented. Cases of amniotic band syndrome, ruptured encephalocele, and iniencephaly are sometimes confused with the diagnosis of anencephaly and probably account for the rare cases of prolonged survival reported in the literature.

Between 13% and 33% of infants born with anencephaly have defects of the nonneural organs. These defects may complicate care and render their organs unsuitable for donation.

Estimates of the incidence of anencephaly have varied from 0.3 to 7 per 1000 births.⁵¹ Differences result from, among other things, different diagnostic criteria, true geographical differences, and prenatal screening programs. Prenatal detection of anencephaly usually results in early termination of pregnancy; thus screening programs can dramatically reduce the incidence of anencephaly at birth. The Centers for Disease Control and Prevention (CDC) cites an incidence of 0.3 per 1000 births (live births and stillbirths).⁵² Extrapolation of this figure would indicate that more than 1000 infants are born with anencephaly annually in the United States, but this figure would drop to less than 100 if screening and induced abortion were uniformly applied.

The first transplant of the heart of an anencephalic infant occurred in October 1987 at the Loma Linda University Medical Center in California without legal incident. Subsequently, other parents requested that their anencephalic children be used as donors to help other children. This meant that the pregnancies were carried to term rather than terminated. With parental permission, the live-born anencephalic children were then placed on respiratory support and their organs donated if brain death criteria were fulfilled within 1 week. Only 1 of 12 anencephalic newborns met brain death criteria, and no recipient could be found for his organs; consequently the program was suspended. One of the infants survived for 2 months after the respirator was removed.⁵³

The Medical Task Force on Anencephaly reported in March 1990 that it was able to identify 80 anencephalic infants who were involved in transplantation protocols.⁵⁴ Only 41 of the infants were used as sources of organs, providing 37 kidneys, two livers, and three hearts.

A major problem with organ donation from anencephalic infants is that legal criteria for brain death are not easily applied. Brain death criteria are derived from the Uniform Determination of Death Act, in which a declaration of brain death is based on irreversible cessation of all brain functions, including those of the brainstem (so-called whole brain death). Although anencephalic infants have no higher cortical function, they may have good brainstem function. Therefore they have intact circulatory and respiratory function; have good reflexes; may cry, swallow, and regurgitate; and may respond to pain, vestibular stimuli, and sometimes sound. Frequent malformations of special sense organs and facial muscles may complicate neurological evaluations or render them impossible.⁵⁵

Although technically incorrect, some have argued that anencephalic infants are "brain absent" and that the brain

death concept is not applicable. Others have argued that anencephalic infants have no capacity to reason and thus are not “persons” within the meaning of governing statutes. They may be considered nonviable fetuses. Several states have introduced bills to allow a determination of death in anencephalic infants. One approach is for states to amend their brain death acts to declare anencephalic babies brain dead. Another approach is to change the UAGA so that the term *donor* includes those diagnosed as either brain dead or anencephalic. If an anencephalic child is a person born alive, the Baby Doe handicapped-infant regulations, requiring appropriate nutrition, hydration, and medication, may apply and arguably may prevent organ procurement until natural death.

Many commentators have alluded to a “slippery slope”; that is, creating a special category of brain death for anencephalic infants may open Pandora’s box. If anencephalic babies are considered to have a marginal existence that can be sacrificed for the good of society, who else can be sacrificed? Why not extend brain death equivalence to other handicapped infants, particularly to those who are suffering from their handicap? Why limit such rationalization to neonates? What of other “brain-dead” patients, such as those in chronic persistent vegetative states? These commentators believe that the law should be consistent and that less fortunate persons should not be treated with lesser justice. If an anencephalic infant is a person and is alive, he or she is ethically worthy of respect and has legal rights.

The Medical Task Force on Anencephaly noted that anencephaly differs from a persistent vegetative state (PVS) in that (1) anencephaly is an embryological malformation, whereas PVS is an acquired condition with various etiologies; (2) in anencephaly the extent of neurological malformation is readily demonstrable by clinical examination, whereas in PVS the extent of permanent neurological damage is not always observable; (3) anencephaly can be diagnosed with certainty, whereas the diagnosis of PVS may be problematic; and (4) the prognosis for anencephaly is measured in days to weeks, whereas patients with PVS may live for months to years.⁵⁶

The Medical Task Force on Anencephaly recognized four general approaches to organ procurement from infants with anencephaly, as follows:

1. The infant is immediately placed on maximal life-support systems at birth, and the organs are removed as soon as possible without regard to presence or absence of brainstem function.
2. The infant is immediately placed on maximal life-support systems at birth, and the organs are removed after brainstem functions are observed to stop.
3. The infant is given standard (minimal) care until he or she develops hypotension, hypoxia, bradycardia, or cardiac arrest; the infant is then placed on maximal life-support systems, and the organs are removed after brainstem functions are observed to stop.
4. The infant is given standard (minimal) care until he or she dies, and then the organs are harvested.

Of 34 anencephalic infants who were on transplantation protocols and could be thus categorized, the success rate for transplantation was 100% for the first approach but

0% to 11% for the other three approaches.⁵⁷ There is a conflict of interest between the clinician’s duty to maintain the health of the donor and the duty to preserve organs for a potential recipient.

Fetal tissue has uses other than pediatric organ transplants. Fetal tissue is plastic, immunoprivileged, and available. It has been used to treat diabetes and bone marrow disorders and is a possible consideration for the treatment of Parkinson’s disease, Alzheimer’s disease, and almost any genetic metabolic disease.

The 1973 *Roe v. Wade* decision did not deprive the fetus of all legal protections, and subsequent regulations and judicial case law have furthered fetal rights. In particular, federal regulations regarding the protection of human subjects may apply. The 1975 Department of Health and Human Services (DHHS) Section 46.201 states that DHHS regulations apply to “research, development, and related activities involving... the fetus.” The 1985 Health Research Extension Act prohibits federally supported research on nonviable, living fetuses *ex utero* unless (1) that research is for the benefit or health of the fetus; (2) the research will pose no added risk of suffering, injury, or death to the fetus; and (3) the research cannot be accomplished by other means. Some states limit experimentation on aborted fetal remains, although transplantation research is arguably not research on the remains themselves, within the meaning of the statutes. The Fifth Circuit Court of Appeals has declared Louisiana’s statute prohibiting experimentation on an unborn child or a child born as a result of abortion unconstitutional.⁵⁸

Potential sources of human fetal tissue include tissue from stillbirths, ectopic pregnancies, spontaneous abortions, and elective abortions. The tissue must be viable; sufficiently differentiated for use; of sufficient quantity for extraction and implantation; free from major genetic abnormalities or diseases; and free from bacterial, fungal, and viral contamination. These requirements generally render all fetal tissue useless, except that derived from elective abortions. In other words, as a practical matter, only tissue from elective abortions is of sufficient availability and quality to serve as a significant source of fetal tissue for transplantation.

On March 22, 1988, then DHHS Secretary Robert Windom, sparked by a National Institutes of Health (NIH) proposal to implant fetal tissue into patients with Parkinson’s disease, imposed a moratorium on further NIH funding of experiments using fetal tissue pending a report from a special NIH advisory panel to examine the medical, ethical, and legal implications of using aborted fetuses for research. After several meetings, 18 of 21 panel members concluded that the use of fetal tissue from induced abortions for transplantation research would be acceptable. The panel recommended that appropriate guidelines be established and that the decision to terminate a pregnancy be kept independent from the decision to use the tissue for research. Nonetheless, on November 2, 1989, DHHS Secretary Louis Sullivan disregarded the panel’s recommendations and extended the moratorium indefinitely. He indicated that such research might provide justification for women to decide to have an abortion and would likely result in an increased incidence of abortions across the country.^{59–61}

216 Organ Donation and Transplantation

The moratorium did not affect use of fetal tissue not involving transplantation into human subjects with NIH funds. The NIH could fund research using fetal tissue from spontaneous abortions or fund transplants of human fetal tissue (even from induced abortions) into animals. Moreover, the policy letter had no legal bearing on transplantation of any fetal tissue that was not federally funded.

Concern has also been raised over a market in fetal tissue for transplantation, which might result in conceptions and abortions for profit or in manipulation of abortion decisions at the risk of pregnant women. Hana Biologicals of Alameda, California, applied to the Food and Drug Administration (FDA) for permission to market fetal pancreatic tissue. Jeremy Rifkin petitioned the DHHS to declare such a sale prohibited by the NOTA.⁶²

The National Institutes of Health Revitalization Act of 1993, enacted to amend the Public Health Service Act and revise and extend programs of the NIH, addresses the issue of research on transplantation of fetal tissue. According to the act, the secretary may conduct or support research on the transplantation of human fetal tissue for therapeutic purposes, regardless of whether the tissue is obtained pursuant to a spontaneous or induced abortion or pursuant to a stillbirth.⁶³ Under the statute, federally funded projects require a statement in writing from the woman providing the tissue, stating that she is donating the tissue for use in research, that the donation is made without any restriction regarding the identity of any recipients, and that the woman has not been informed of the identity of any recipient. In addition, the attending physician is required to make a statement in writing that the abortion was not planned to coincide with the need for the tissue. The statute also prohibits the purchase of human fetal tissue or the use of donated tissue from a specified donor (e.g., a relative).

In a report issued by the General Accounting Office, extramural projects using fetal tissue that are funded by the NIH follow federal guidelines, including informed consent requirements, and there have been no reports of violations in the methods used to obtain fetal tissue at sites conducting transplantation research.⁶⁴

The NIH awarded more than \$6 million to five extramural research projects involving therapeutic uses of human fetal tissue between fiscal 1993 and 1996; of this, \$5.9 million supported human fetal tissue transplantation activities. Researchers have found that human fetal tissue can be used to treat a number of illnesses, including juvenile diabetes, leukemia, and Parkinson's disease.⁶⁵

The British Medical Association has promulgated guidelines on the use of fetal tissue, including the condition that tissue may be obtained only from dead fetuses resulting from therapeutic or spontaneous abortion. Death of a fetus was defined as an irreversible loss of function of the organism as a whole.⁶⁶

LIVING DONORS: DONOR CONSENT

Legal requirements for transplantation by a living donor primarily revolve around issues of consent of the donor for organ procurement. The rights of privacy and self-determination

demand that adults of legal age and sound mind must give informed consent for donation of their organs or tissues. Competent adults should give consent voluntarily, knowingly, and intelligently after being fully informed of potential risks.

In the typical case the HLA-matched sibling is asked to donate a kidney. The sibling may have considerable trepidation concerning the risk, pain, and disfigurement of the surgery, as well as the potential future compromise of his or her remaining kidney. Although consent is usually granted, the potential donor may decide to refuse. There is no legal duty to be a Good Samaritan. Family and community pressure may significantly cloud the voluntariness of this consent. The issue of living, unrelated kidney donors, which was once viewed with suspicion, has now become common practice. Spousal donation is the most common, but it has been extended to friends. Again the donor shortage has prompted attempts to increase the donor pool. Living-donor protocols include extensive education and psychological evaluation to ensure informed consent.

In the case of *McFall v. Shrimp*, Robert McFall, a victim of aplastic anemia in need of a bone marrow transplant, sued to compel his cousin, David Shrimp, the only person found on initial testing to be a compatible donor, to complete his compatibility testing and if compatible to donate a portion of his marrow.⁶⁷ The marrow harvest was described to Shrimp as consisting of inserting a curved needle into his hip at least 200 times. McFall's counsel argued that there is a duty to aid another in peril of his life; the court disagreed. McFall never received a transplant and died shortly thereafter.

In the case of a vital organ transplant, a psychiatric or psychological assessment of the donor and donee may be advisable to negate possible future allegations of duress and also because of the high rates of psychiatric morbidity and suicide in recipients.

Organ donors have failed in their suits against transplant surgeons because of the absence of a physician-patient relationship. In *Sirianni v. Anna* a mother, who donated a kidney to her son after his kidneys were negligently removed by a surgeon, was not allowed to recover against the surgeon for her impairment of health, which she sustained as a result of the loss of her kidney.⁶⁸ She undertook the operation with full knowledge of the consequences.

MINORS AND INCOMPETENT DONORS

In the case of minors and incompetent (e.g., mentally impaired) persons a court order is usually necessary for the organ transplantation. Although parents and guardians generally may consent to medical treatment of their children and wards, it is not clear that they have the same authority when surgery is not medically indicated. As a practical matter, most surgeons refuse to perform such surgery without a court order. The consent of guardians or parents is often additionally sought, but the court may overcome their refusal.

In most cases involving intrafamilial transplants, judicial approval has been granted. Judges conducting these hearings in chambers have almost always allowed the harvest

procedure and foregone the need for a written explanation of the court's findings. Even where a record is present, courts have not always articulated well the basis for their decision. This may be categorized best as simple judicial approval of parental consent.

In a 1972 Connecticut case, *Hart v. Brown*, the court approved a transplant between two identical 7-year-old twins, considered the medical ramifications, and stated that the parents' motivation and reasoning had met with approval of the guardians ad litem, physicians, clergy, and the court.⁶⁹ Courts also invoke the equitable doctrine of *parens patriae* to give consent on behalf of minors and incompetent persons. The court often appoints a guardian ad litem in such cases to argue on behalf of the incompetent person.

If the court focuses on the interests of the potential donor with a protective eye, it may find that no objective reason exists for the donor to submit to the risk and bodily intrusion of an organ harvest. It has been argued that the court has no power to authorize the surgery in the absence of specific enabling legislation.

In the 1973 Louisiana case *In re Richardson* a husband brought suit against his wife to compel her consent to the removal of a kidney from their mentally retarded son for donation to his older sister.⁷⁰ The Fourth Circuit Court held that neither the parents nor the courts could authorize surgical intrusion on a mentally retarded minor for the purpose of donating organs, that such an authorization would invade the minor's right to freedom from bodily intrusion, and that it was not shown to be in the minor's best interest.

In 1975 the Supreme Court of Wisconsin in *In re Guardianship of Pescinski* held that the court had no power to compel a 39-year-old catatonic schizophrenic patient to donate a kidney to a 38-year-old sister in the absence of any showing of benefit to the incompetent: "[The] incompetent particularly should have his own interests protected. Certainly no advantage should be taken of him."⁷¹ Medical testimony indicated that the risk to the donor at that time was one death in 4000 kidney transplants. The dissent stated that requirement of consent was inappropriate as applied to an incompetent person without lucid intervals.

Other courts have authorized donation by applying a "best interest" test and finding psychological benefit (or absence of detriment) and asserting consent.

In a 1979 Texas case, *Little v. Little*, a mother sought judicial consent for the removal of a kidney from her 14-year-old daughter with Down syndrome for her son.⁷² The guardian was opposed. The mother argued that the daughter was the only suitable donor for her brother, that there was no threat to her life, and that the daughter would have wanted this for her ill brother. Medical testimony alleged that the daughter was a perfect match (despite brother and sister not being identical twins) and that the chance of finding a suitable cadaver kidney was extremely remote. The judge authorized the transplant on the basis of "substantial psychological benefit" to the donor.

Courts have increasingly used the doctrine of "substituted judgment" to decide medical cases involving difficult ethical issues with incompetent persons. Specifically, the court must substitute itself, as nearly as possible, for

the incompetent person to act with the same motives and considerations as would have moved the individual.

In the 1969 case *Strunk v. Strunk*, the mother of a 27-year-old mentally retarded man with an IQ of 35 petitioned the court for a kidney removal to be used for his 28-year-old brother.⁷³ The court, based on psychiatric testimony that the death of the donor's brother would have an extremely traumatic effect on the donor, allowed the transplantation to avoid the detriment. The court reached this result despite testimony from the director of the renal division at the local institution; the director stated that, if something happened to the retarded donor's remaining kidney, he would not meet the selection criteria necessary for hemodialysis or transplantation. The dissent stated that "it is common knowledge that the loss of a close relative or a friend to a 6-year-old is not of major importance." Opinions concerning psychological trauma at best are nebulous.

CONFIDENTIALITY OF POTENTIAL DONORS

Potential donors are often HLA matched to find an immunocompatible host and thereby achieve a greater chance of graft survival. Modern immunosuppressive therapies generally obviate this need except in the case of bone marrow transplantation. The need for matched organs has given rise to expensive HLA registries. There is great pressure to give names of those individuals with matching phenotypes to potential recipients.

In the case of *Head v. Colloton* the plaintiff, William Head, had leukemia and sued to demand disclosure of the identity of the only potential donor in the institution's bone marrow transplant registry who had a matching HLA type.⁷⁴ The potential donor had been HLA typed as a possible platelet donor for an ill family member. She was telephoned by the registry and asked in general terms if she would be interested in being a bone marrow donor; she responded that she would be interested only if it was for a family member. The court maintained the anonymity of the potential donor and refused further inquiry but did so on narrow legal grounds relating to the interpretation of the Iowa Freedom of Information Act. The plaintiff died during the court proceedings without having had a marrow transplant.

Names of potential donors should be placed on registries only after they have given informed consent, and donors should be able to withdraw their names at any time. Disclosures should be restricted to necessarily involved medical personnel only.

ARTIFICIAL AND ANIMAL TRANSPLANTS

In the immediate future, organs from animals (xenografts), except porcine heart valves, will continue to play only a minor role in transplantation and will remain largely experimental. Important strides have been made in the understanding of xenograft rejection, but a major barrier to this technique remains. Genetically engineered animals, probably

218 Organ Donation and Transplantation

pigs, will incorporate human immunological factors. Baboon hearts and livers have always been rejected and thus have fallen from favor. Simians will not meet the need because of low numbers. An additional concern is the transmission of animal diseases (zoonoses).

Artificial hearts also have a poor overall record but are increasingly used for temporary replacement until a human transplant can be performed. Left ventricular assist devices, on the other hand, have become popular.

Failure to obtain adequate informed consent has been a major criticism of most pioneering efforts. Today, this issue is better recognized, and more appropriate consent procedures are being followed. All human experimentation must be reviewed by a medical institution's internal review board. The first artificial heart transplant precipitated a lawsuit, *Karp v. Cooley*, which remains the leading authority on the issue of informed consent for an experimental therapy.⁷⁵

Special considerations exist regarding artificial organs. The Medical Device Amendment enacted in 1976 ensures the safety of medical devices and imposes strict regulations on manufacturers of artificial organs regarding interstate commerce.⁷⁶ The DHHS and FDA have responsibility to promulgate regulations under this act. These regulations were not enforced in cases of early artificial heart transplants but have since been and will continue to be enforced. Also, strict product liability may be applied to these implants.

DONOR SCREENING

Donors must be screened to determine suitability of donation. Transmission of disease from an organ or tissue donation is an important concern. Transplantation personnel must maintain constant vigilance against bacterial and fungal infections resulting from organs and tissue derived from septic patients and from contamination during handling. The implant may act as a nidus for infection. Cytomegalovirus (CMV) is the most common problem and can be clinically significant. Other serious diseases that can be transmitted via transplantation include cancer and infections with the human immunodeficiency virus (HIV), hepatitis B, tuberculosis, toxoplasmosis, and Jakob-Creutzfeldt disease. Cancer, except low-grade brain malignancies, obviates a patient as a donor. The organ may be impaired by nontransmissible disease, such as atherosclerosis; however, the donor shortage has led to expanded donor criteria, including older donors (over age 60); treated, controlled hypertensive patients; and even diabetic persons without evidence of renal disease.

Screening for transmissible disease involves chart review, specific laboratory tests, and examination of the donor. The United Network for Organ Sharing, discussed later in this chapter, requires documentation of certain tests and evaluations as minimal acceptable standards for an independent organ procurement agency.

Inadequate screening can give rise to litigation. Ordinary negligence liability results if the disease or defect is discoverable by standard medical practices. Failure to test for HIV antibody would be a breach of standard medical practice in cases of heart transplantation, but it would result in

liability only if the donee subsequently developed an HIV infection. If no results were available by the time transplantation would need to proceed, liability might not attach because a court might find that a surgeon acted reasonably. However, a court may find that the brain-dead cadaver should have been maintained until a result could have been obtained or that, if a risk factor were present in the donor's record, the donation ought to have been declined. Liability should not attach if, as can happen, HIV is transmitted despite a negative HIV antibody test; donor screening is imperfect. Faulty testing or specimen mix-ups may result in incompatible organs being transplanted, in which case liability is likely. The immunity statutes previously mentioned may protect an organ procurement agency or a transplantation team.

In *Ravenis v. Detroit General Hospital* the hospital was found negligent in two cases in which patients lost the sight remaining in an eye after transplantation of an infected cornea.⁷⁷ No hospital official was responsible for selection; slit-lamp examinations were not performed despite availability of equipment; and the appropriate information for the surgeon to determine the unsuitability of the tissue for transplantation was missing from the patient's chart.

In *Good v. Presbyterian Hospital* a medical malpractice action was brought under the informed consent theory against a transplant surgeon who performed a heart and lung transplant on a 5-year-old patient.⁷⁸ The plaintiff, the patient's mother, alleged that the surgeon failed to advise her that the organs to be transplanted had tested positive for CMV and that the virus caused the 5-year-old child's death. The court found that the transplant surgeon did not violate the New York informed consent standards, since the universal practice of reasonable medical practitioners in 1990 under similar circumstances was not to discuss specifically the CMV status of organs with the patient or the patient's representatives.⁷⁹

FEDERAL LEGISLATION

Health matters are generally the province of state law. Because of ongoing developments in the field, the need for centralized national allocation of organs, and funding issues, however, the federal government has become increasingly involved in transplantation and has attempted to enhance and coordinate private and local government initiatives. For example, the federal government sponsored the establishment in 1983 of the American Council on Transplantation, a group of private sector organizations and individuals to promote organ donation (dissolved in the early 1990s).

The National Organ Transplant Act (NOTA) was enacted in 1984.⁸⁰ It called for the creation of a national Organ Procurement and Transplantation Network (OPTN) to match prospective donors to prospective recipients, the creation of a special advisory task force, and the prohibition of the sale of organs. The OPTN was to create a fair and equitable system of organ allocation that could optimize matches between organs and patients throughout the United States by facilitating regional independent organ procurement agencies (IOPAs). Grants for the establishment of new agencies

and the improvement of existing IOPAs were authorized to form an adequate base of a truly national network. This network was then to “assist organ procurement organizations in the distribution of organs which cannot be placed locally, to develop organ procurement standards, and to help coordinate transport.”

The United Network for Organ Sharing (UNOS), a private, nonprofit entity solely devoted to organ procurement and transplantation, was awarded the federal contract to run the OPTN in September 1986. Federal oversight of UNOS is provided by the Division of Organ Transplantation under the Health Resources and Services Administration, within the Public Health Service and the DHHS.

The Task Force on Organ Transplantation was created by DHHS Secretary Heckler in January 1985. It rendered its final report in April 1986 and was dissolved. The 78 recommendations largely define federal policy.

The Omnibus Budget and Reconciliation Act (OBRA) of 1986 built on the 1984 legislation and the task force’s recommendations by amending the Social Security Act.⁸¹ First, it mandated as Medicare and Medicaid conditions of participation that hospitals institutionalize a required request policy (as previously explained) to increase the voluntary supply of organs. Second, also as Medicare and Medicaid funding requirements, it stated that hospitals performing transplantations must be members and must abide by the rules and policies of the OPTN (i.e., UNOS).

The statutory requirement that transplantation centers must be members and abide by the OPTN gives UNOS great regulatory power. Many consider UNOS as a unique experiment in self-regulation within the health care field. UNOS requirements are more stringent than DHHS regulations. The policies of UNOS, equivalent to conditions of participation, are subject to review and approval by the DHHS and are subjected to public “notice and comment” in the *Federal Register*. Despite lip service to the contrary, the system appears to operate in a very centralized manner, rather than the flexible, pluralistic decentralized system originally envisioned in the 1984 NOTA.⁸²

Membership in UNOS as a qualified IOPA was a great organizational challenge. The task force recommended that competition between organ procurement organizations be discouraged. IOPAs were required to have defined and exclusive service areas. The response was for all IOPAs in given areas to merge into single entities. A regional system of IOPAs is now in place. Anticipated litigation never materialized.

Membership in UNOS as a transplantation center qualified by procedure will continue to be problematic. To become members, new programs must already have performed a particular procedure many times, which is almost impossible without federal funding. Thus the UNOS membership guidelines tend to entrench existing members who helped establish the guidelines. The governmental umbrella over UNOS might shield its members from antitrust considerations.

Sale of Organs

The NOTA of 1984 prohibited the transfer of “any human organ for valuable consideration if the transfer affects

interstate commerce.”⁸³ The term *human organ* is defined as the human kidney, liver, heart, lung, pancreas, bone marrow, cornea, eye, bone, skin, and any other organ included by the secretary of the DHHS for regulation. It is not intended to include replenishable tissues, such as blood or semen. The term *valuable consideration* does not include the “reasonable payment associated with removal, transportation, implantation, processing, preservation, quality control, and storage, or the expenses of travel, housing, or lost wages in connection with donation of the organ.”

The commerce clause reflects an attempt to fit the regulation into the federal constitutional commerce powers. In other situations this language has been interpreted so broadly as to include almost any interstate or intrastate transaction. Nonetheless, several states have also passed such prohibitions.

A 38-year-old leukemia patient needed a bone marrow transplant but could not find a suitable donor. His older brother was homeless and earned money by serving as a subject in medical experiments. He initially refused to be tested for compatibility. An anonymous donor offered him \$1000 to undergo testing and \$2000 to donate. He was tested and was found not to be an HLA match. If he had matched, the prohibition against “the transfer of any human organ for valuable consideration” arguably would have been applicable and would have barred his marrow donation to his brother.⁸⁴

Food and Drug Administration

The FDA has jurisdiction over tissue banking and has maintained a task force on transplantation since 1983. The regulation of the safety and efficacy of human tissue is analogous to regulation of manufactured materials for use in therapy. The agency is developing proposals for regulating cryopreserved semen, dura mater, and heart valves. The FDA is not concerned with solid organs except possibly for disease transmission by improper screening of donors. The FDA is also concerned with organ perfusion solutions.⁸⁵

In October 1993 the U.S. House of Representatives passed H.R. 2659, the Organ and Bone Marrow Transplantation Amendments of 1993, to revise and extend programs relating to the transplantation of organs and bone marrow. The proposals amended 42 U.S.C., Sections 273 and 274. The amendments extended for 3 fiscal years the authorization of appropriations for the NOTA. In November 1995 the Senate favorably reported the proposed Solid Organ and Bone Marrow Transplant Reauthorization Act of 1995 to revise and reauthorize funding for transplantation programs.⁸⁶ This legislation, which is administered by the Health Resources and Services Administration of the DHHS, would provide for continued operation of the transplant network and scientific registries and provide rules for transplant network governance and administration. In addition, appropriations would establish a patient advocacy and case management office for the bone marrow transplantation program.

The secretary of the DHHS is required to issue regulations establishing enforceable procedures for the procurement,

220 Organ Donation and Transplantation

allocation, and transplantation of solid organs and bone marrow. Such regulations also would establish the criteria that must be satisfied for membership in OPTN. In issuing such regulations, the secretary is directed to consider existing policies and guidelines issued by UNOS and the National Bone Marrow Registry.

The secretary is required to review and approve any changes in the amount of patient registration fees imposed by the private contractor administering the system of solid organ procurement. Organ allocation policies of the OPTN and the member organ procurement organizations (OPOs) require maintenance of a single list of patients referred for transplants for each solid organ and give preference to patients who are U.S. citizens or permanent resident aliens.

Expansion of the system of patient advocacy for bone marrow transplant patients is provided with an inclusion for case management services. The General Accounting Office is required to perform studies of the National Marrow Donor Program.

Last, the secretary of the DHHS is required to study the feasibility, fairness, and enforceability of allocating solid organs to patients based solely on the clinical need of the patient involved and the viability of organs involved.

Legislation and administrative rule-making in the areas of organ donation and transplantation are undergoing continual revisions. The reader should consult the appropriate federal and state reference source materials, in addition to current medicolegal periodicals, to keep apprised of these revisions and updates.

SELECTION OF ORGAN RECIPIENTS

The scarce supply of organs and tissues relative to demand and the economic considerations of transplantation force the medical community to confront ethical issues on rationing. The public must perceive the allocation of organs as fair and equitable, or the national organ and tissue supply (which depends on voluntary contributions) will be jeopardized.

Regulation of recipient selection for organs is now imposed nationally through funding requirements. The NOTA of 1984 created the OPTN for the equitable distribution of all available organs in the United States.⁸⁷ The OBRA of 1986 requires all hospitals to abide by the policies of the OPTN as conditions of Medicare and Medicaid payment.⁸⁸ The federal OPTN contract was awarded to UNOS.

The basis of the UNOS system is a computerized point system for allocation. The point system is an objective method of patient selection determined primarily by probability of success, time on the waiting list, logistic factors, and medical need, modified from the proposal by Starzl.⁸⁹ Variances can be granted for fair patient selection criteria to accommodate local concerns.

Kidneys require more stringent testing than other solid organs because potential donees can be maintained on dialysis while awaiting an optimal kidney. Difficult choices must be made for nonpaired vital organs. Kidneys will be offered first to the recipient located anywhere in the country who has a perfect antigenic match. Only 15% to 25%

of kidneys will have such a match. Otherwise, cadaveric kidneys will be allocated on a point system based on time of waiting, quality of antigen match, and panel-reactive antibody screen (a measure of sensitization). Medical urgency is not considered for kidney allocation.

Extrarenal organs will be allocated based on organ size, ABO typing, time of waiting, degree of medical urgency, and logistic factors. Pancreata will be offered solely on the basis of distance to a potential recipient and time on a waiting list.

Pediatric organs and patients are given special consideration. Dual transplants (e.g., simultaneous kidney-pancreas) are also handled outside the usual schema.

Patients on local waiting lists are offered organs in descending sequence, with the highest number of points receiving the highest priority. Only if an organ is not accepted locally will it be offered regionally, and then nationally. Organ sharing arrangements between interregional and intraregional OPOs may be entered into on approval of UNOS. The OPTN (UNOS) patient waiting list is open only to direct UNOS-member OPOs, and such members cannot offer organs to non-UNOS-member transplantation centers. A potential recipient may be placed on multiple listings, even though this confers some advantage.

The final decision to accept an offered organ remains the prerogative of the transplantation surgeon, the physician responsible for the care of the patient, or both. A transplantation center has 1 hour to accept an offered organ, or the offering procurement agency will be free to offer the organ to another recipient.

The issue of whether the patient with the greatest chance of survival or the one with the greatest urgency should receive an organ has been a source of continuing debate. A potential heart recipient deteriorates and becomes suddenly much more ill, so he or she is at once more critically in need of a new heart and less likely to survive the transplantation. This question is largely moot with respect to kidneys because patients can be placed on dialysis (except in the rare case of exhaustion of vascular access sites). However, the issue of deterioration is paramount with respect to hearts and livers. Medical urgency determines the status for liver and heart recipients in the UNOS system. The potential for manipulating the system as a result of its subjectivity has led to extensive efforts to develop listing criteria for liver transplantation. Criteria for all organs are being considered by UNOS and its membership.

Highly sensitized patients, or "responders," have antibodies against most histocompatibility antigens. A negative crossmatch may give a responder his or her only chance to receive a surviving transplantation. However, the chance of organ acceptance is lower than that for similarly matched nonresponders. The transplantation community generally feels an obligation to offer to this patient his or her last small chance at a tolerable organ.

Matching is a significant criterion based on sound immunological principles. HLA compatibility is unavoidably discriminatory against African-Americans and Hispanics (who have a several times higher rate of ESRD) because most available kidneys have been donated by whites. On the

basis of histocompatibility alone, most kidneys from large urban centers would go to white suburban areas. HLA compatibility is of debatable significance to other organs.

Other criteria, such as age and lifestyle, although not a part of the UNOS point system, may be locally operative. Valid medical justifications for these gray areas exist; for instance, is a young patient a better surgical risk than an older alcoholic patient who continues to drink and is likely to damage the new liver and unlikely to take medications regularly? However, discrimination based on age or social position raises issues of fairness. Such subjective criteria are also prone to capriciousness. These do not seem to be primary selection criteria.

After a patient receives a transplant, he or she is usually given greater consideration for a subsequent organ, but the chances for long-term success fall as a patient receives more transplants.

Persons from other countries may not come to the United States and pay for a transplant and deplete national organ resources. Payment for organs is now prohibited. Currently, aliens are held to about 5% of current waiting lists, but those on the lists are to be treated as American citizens and not to be discriminated against based on political influence, national origin, race, gender, religion, or financial status. UNOS members are not to enter into contractual arrangements with foreign agencies or governments or perform transplants on nonresident aliens for financial advantage. Exportation and importation of organs are to be strictly arranged and coordinated through UNOS. Although thousands are maintained on the United States waiting lists, several hundred kidneys are shipped abroad because they are unacceptably old by rigorous U.S. standards.

Lawsuits can be filed against hospitals, transplant surgeons, and committees on behalf of patients who fail to obtain vital organs because others have received the organs first. This is increasingly likely because criteria might be attacked as arbitrary, capricious, or otherwise unreasonable. The implication that one recipient is chosen over another for financial reasons might be argued as an illegal sale of an organ and thus a basis of liability. Another problem area involves cases in which a sudden decline in health precipitates a recipient's "jumping the queue" (being ranked higher priority) and receiving an organ that would have gone to another. Although the sudden deterioration may suggest a poorer prognosis, others in the queue are at increasing risk for sudden death. The potential liability for choosing between who lives and dies is enormous, and the absence of suits to date is surprising.

COST AND PAYMENT CONSIDERATIONS

Vital organ transplantation is extremely expensive. As of 2004, the approximate range for a typical kidney transplant is \$25,000 to \$130,000; for a heart transplant procedure, \$50,000 to \$287,000; for a heart-lung transplant, \$135,000 to \$250,000; for a liver transplant, \$66,000 to \$367,000; and for a pancreas transplant, \$51,000 to \$135,000.⁹⁰

Transplantation failures and ancillary costs (e.g., transportation and lodging for the patient and family when the patient does not live near the transplantation center) greatly elevate these figures. Almost all vital organ transplant patients require lifelong maintenance on immunosuppressant therapy, although this may be changing. The cost of conventional immunosuppression maintenance (steroids and azathioprine) averages \$1000 to \$2000 per year and \$5000 to \$7000 per year for cyclosporine. However, because cyclosporine decreases overall complications, it does not raise overall costs. The OBRA of 1986 enabled Medicare and Medicaid to cover outpatient immunosuppressive therapy, particularly cyclosporine, for 3 years after transplant.⁹¹

The cost of transplantation is generally prohibitive, and individuals must rely on third-party reimbursement. Furthermore, many if not most of those in need of a solid organ transplant are incapable of employment. Thus transplants can be viewed as treatment for a catastrophic life-threatening illness.

Established in 1972, the Medicare End-Stage Renal Disease Program (ESRDP) provides treatment to patients with kidney failure regardless of their ability to pay.⁹² ESRD was the first disease targeted for funding through a special program by the federal government. This program established the standard acquisition charge for transplantable kidneys, allowing each transplant center to predict its organ charges regardless of the location of origin of the organ or complicating expenses attributable to an individual donor. Over the years the method of payment for transplantable kidneys has been extrapolated to all solid organ transplants.

The cost of the ESRDP, primarily for long-term dialysis, continues to escalate as the number of beneficiaries, now 275,000, increases.⁹³ Transplantation costs in the United States in 1994 were approximately \$4 billion, or 0.04% of total health care expenditures.⁹⁴ This amount is much greater than anticipated, and the ESRDP is often cited as an expensive program run amok.^{95,96}

Kidney transplants are cost-effective (with the initial large investment generally being paid back in 3 years) compared with the alternative, hemodialysis. The long-term costs of maintaining patients with functioning grafts are only one-third of those for dialysis patients.^{97,98} Furthermore, the quality of life is improved, allowing more people to become productive citizens again. No alternative exists for heart or liver transplants.

In this era of cost containment, many find it difficult to justify the expense of transplantation for the few while sacrificing more widespread financing of health care. The juggernaut is not easily stopped because U.S. society typically responds to individual pleas for a specific and lifesaving treatment. Increasingly the federal government is asked to subsidize transplants, but federal fiscal restraints make this difficult.

At present the costs of transplantation are high but not higher than the costs of taking care of the typical AIDS patient or cancer patient, and the results are much better. As a result of the organ shortage, the total costs to the government are now relatively low and predictable. However, the government's ability to pay for organ transplants may not

222 Organ Donation and Transplantation

continue, particularly because of a growth in the supply of organs, increase in demand, and technological innovations, such as usable artificial organs. Over time, pressures will grow to relax the standards for patient reimbursement. The history of the ESRDP demonstrates this process of ever more lenient selection standards tending toward universal access.

Medicare coverage of services furnished to individuals with ESRD who require dialysis or kidney transplantation is authorized under Section 1881 of the Social Security Act. Medicare also covers other organ transplants that the HCFA has determined are "reasonable and necessary" and pays for those transplant and related organ procurement services.⁹⁹ Based on a report by the Office of Health Technology Assessment that liver transplants are no longer experimental, the HCFA reported that it will cover the cost of some adult liver transplants, including those needed because of alcoholic cirrhosis.¹⁰⁰ As of February 2, 1995, lung transplants and heart-lung transplants were added to the list of medically reasonable and necessary services covered under Medicare, when specific established criteria were met.¹⁰¹ Medicare considers pancreas transplantation experimental but will fund the kidney portion of a combined kidney-pancreas transplantation, whereas private insurers cover the entire procedure.

States pay for transplantation procedures for low-income persons through Medicaid (subsidized by the federal government). The states vary greatly in their coverage and payment policies. In 1990, of the 50 states and the District of Columbia, only 12 states reimbursed pancreas transplants, 15 provided for lung transplants, and 23 paid for heart-lung transplants but 40 provided reimbursement for heart transplants, 48 for liver transplants, and 50 for kidney transplants. Only Wyoming offered no transplantation reimbursement.¹⁰²

For Medicare and Medicaid (and most private health insurance plans) the funding eligibility trigger is "medical necessity" for the treatment. Thus the government will pay for transplantation if, like other medical therapy, it can be shown that the procedure is reasonable and necessary for the illness and that such treatment is not experimental.

Patients have successfully sued for reimbursement from state agencies when policies or administrative regulations have unfairly denied coverage. In *Brillo v. Arizona*, Mrs. Brillo successfully sued the state to provide coverage for her liver transplantation.¹⁰³ The service director's policy determination was that the state would not pay for adult liver transplants because they were experimental, although they would pay for pediatric liver transplants. The court found the policy to be arbitrary, capricious, and a denial of equal protection of the law.

In *Allen v. Mansour* the Michigan court ordered Medicaid funding for an alcoholic with cirrhosis, holding that the recipient selection criterion of a 2-year abstinence from alcohol in cases of cirrhosis caused by alcoholism was arbitrary and unreasonable as formulated and applied.¹⁰⁴ The court noted that this criterion was developed on meager experience and that "medical necessity" of the procedure is the touchstone for evaluating the reasonableness of standards in state Medicaid plans.

In *Lee v. Page* the Florida Medicaid program refused to fund a liver transplant to be performed at the University of Nebraska for a medically qualified 26-year-old woman with a fatal liver disease. The state's position was that the high cost of the liver transplant procedure, which would divert substantial funds from other needy persons, and the minimal benefit to the population of all eligible recipients made the refusal to pay reasonable. The court indicated that states have considerable leeway to implement federally backed Medicaid programs. States must adopt "reasonable standards," but they cannot exclude coverage for "medically necessary treatments." A state can legitimately argue in support of its refusal to fund a treatment as unnecessary either because the treatment is experimental or because it is inappropriate. The court held that liver transplantation is no longer experimental. The court also held that an unfavorable cost-benefit determination is not a medical appropriateness criterion and thus is not a reasonable standard from which to refuse funding:

This is not a question of the limits on the amount Medicaid will pay for a procedure, but rather a case where Medicaid refuses to pay the entire amount based on the cost of the procedure.... [Medicaid] cannot eliminate one health-related service while leaving others intact.... It does not appear that federal law permits Florida to refuse to fund all liver transplants.... Florida voluntarily entered the federal Medicaid cooperative program and must comply with the standards.¹⁰⁵

In *Todd v. Sorrell*, a Virginia child was determined to be a suitable candidate for a liver transplantation by the Children's Hospital of Pittsburgh.¹⁰⁶ Because of cancer, 85% of the child's liver had been removed, and secondary biliary cirrhosis had developed. The hospital required an advance payment (\$162,000). The Virginia Medicaid program refused to pay because its policy was to pay for pediatric liver transplants only in cases caused by biliary atresia. The U.S. Court of Appeals for the Fourth Circuit overturned a district court's holding and granted an injunction ordering the state to pay for the transplantation pending a final three-judge panel review. Nonetheless, citing the high costs of liver transplants (\$250,000), other priorities, and the poor outcomes of liver transplants, Virginia decided to stop Medicaid funding of all liver transplants (May 1988).

Oregon decided not to spend Medicaid monies on transplantations except for kidneys and corneas. It reversed its controversial stand after public protest.^{107,108}

MALPRACTICE SUITS

For a number of reasons, malpractice suits involving transplantation of vital organs have been almost nonexistent. First, in the past, transplantations were considered largely experimental, and thus customary standards were not well established. Second, failure was a well-recognized risk. Third, the careful attention by physicians in these cases resulted in generally good relationships and good communication

with patients and their families. Fourth, the surgeons and institutions involved were of high stature and esteem. Fifth, transplant physicians were few and closely knit, making opposition testimony difficult to find. Sixth, damages were difficult to prove, given the ill health of the patients. However, a marked increase in suits may be anticipated in the future because these conditions will no longer hold true as vital organ transplants become commonplace.

In *McDermott v. Manhattan Eye, Ear & Throat Hospital* the appellate court reversed a lower court's finding of negligent corneal transplant, holding that evidence was insufficient to support a malpractice claim that the surgeon lacked the skill or experience to perform the operation, that the operation was of extreme delicacy with a high incidence of failure, and that the situation was one of desperation.¹⁰⁹

The degree to which courts are reluctant to find liability in favor of transplant efforts can be found in *State of Missouri ex rel. Wichita Falls General Hospital v. Adolph*.^{110,111} A Missouri transplant team flew to Wichita Falls, Texas, to harvest a heart from a donor and then returned to Missouri to transplant the heart into a recipient. During the transplant they discovered that the Texas hospital had incorrectly typed the donor as type A rather than type B. The patient died shortly thereafter, despite a second transplant. A Missouri appeals court refused to allow a Missouri trial court assert jurisdiction over a Texas hospital because of the potential adverse effect on future transplants.

Several problem areas are likely to be litigated in the future, especially the issues of informed consent and suitability of the organ for transplant.

Theoretically, *strict liability* (in which the court may award damages without a finding of fault by the defendant) might apply to injuries sustained from implants of diseased or defective organs as an unreasonably dangerous defective product or from an implied warranty. Plaintiffs in early cases of hepatitis and adverse reactions to transfusions of blood and blood products successfully argued theories of strict liability. Later decisions rejected the notion, holding that provision of blood is a service and not the sale of a product.

Most states now have statutes that specifically protect hospitals and blood banks from strict liability. Such laws hold that transfusions of blood and blood products are not sales, so no warranties attach, and that liability may be imposed only for negligence or willful misconduct. Many statutes further include transplantations of other tissues and organs in these provisions. The states that specifically mention blood but fail to mention other tissues and organs might risk the interpretation that their legislatures intended to exclude organ transplantations from such protection. Otherwise, strict liability is unlikely to be applied to organ transplantation because transplantation will be construed to be a hospital and physician service instead of the sale of a product, in light of the blood banking court decisions and the federal and state proscriptions against sales of organs. Statutory immunity conferred by the UAGA also might apply to negligent procedures, as discussed earlier.

RECENT DEVELOPMENTS

On December 7, 1993, the House of Delegates of the American Medical Association (AMA) adopted a report from the Council on Ethical and Judicial Affairs that was subsequently revised in response to comments received from peer reviewers.¹¹² This report recommended that mandated choice, in which individuals would be required to state their preferences regarding organ donation when they renew their driver's licenses, file their income tax return, or perform some other task mandated by the state, should be pursued by the AMA in working with state medical societies to draft model legislation for adoption by state legislatures. The report raised ethical objections to the alternative of presumed consent, in which it is assumed that an individual would consent to be an organ donor at death unless an objection from the individual before death or from his or her next of kin after death is known to the health care provider. A federal circuit court has adopted this approach.¹¹³ In this case the circuit court of appeals, in reversing the district court's ruling, determined that a widow could maintain a civil rights action filed against the coroner based on his removal of the decedent husband's corneas for use in transplantation without the widow's consent. The court held that consent was presumed when the coroner claimed a lack of knowledge as to any objection to such removal of organs for transplantation before performing the procedure.

Medical examiners and transplant coordinators are cooperating to maximize the lawful retrieval of organs and tissues for transplantation.^{114,115} Representatives from the Association of Organ Procurement Organizations, the North American Transplant Coordinators Organization, the American Society of Transplant Surgeons, and the National Association of Medical Examiners have met to agree on guidelines for their respective members. This need for cooperative efforts is underscored by the estimate that currently approximately one suitable transplant candidate in the United States is dying every 4 hours because of lack of a suitable organ for recommended transplantation. These guidelines are needed to protect concerns that forensic evidence will not be lost or affected by the subsequent transplantation surgery. The results of a retrospective study (from 1990 to 1992) of information received from responding organ procurement organizations indicated that as many as 2979 individuals may have been denied transplants because of medical examiner denials.¹¹⁶ Such denials were generally the result of a perceived need by the medical examiner to preserve forensic evidence that could be necessary later in documenting the cause of an individual's death.

Multiple efforts to increase organ donation are underway. Virginia has become the latest in a growing number of states to offer an organ donation license plate. In the spring of 1997, Ohio residents were encouraged to discuss their decision to donate over breakfast. As part of a National Organ and Tissue Donor Awareness Week milk cartons carried the donation message. Organ donor networks across the country sponsor a variety of activities from relay races to formalized

224 Organ Donation and Transplantation

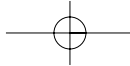
studies designed to identify and standardize effective strategies that improve donation.¹¹⁷ The 104th Congress passed the Organ Donation Incentive Act as part of the health insurance portability law enacted in 1996. The new law required the Treasury Department to include information on organ and tissue donation with each refund check. In addition, the campaign included print ads and radio public service announcements recorded by members of Congress. The new law was enacted with the goal of increasing the number of potential organ donors and encouraging potential donors to discuss their decisions with family members.¹¹⁸

In the current managed care environment, with intensified scrutiny of health care costs, questions surround the possible surplus of transplantation centers, as discussed at the first joint annual meeting of UNOS and the DHHS Division of Organ Transplantation.¹¹⁹ Statistics indicated that 40% of kidney transplant centers were performing fewer than 25 transplants a year and that 40% of liver transplant centers were performing fewer than 15 transplants per year, accounting for only 8% of livers transplanted in the United States. In contrast, the 20 largest liver transplant centers were performing 76% of the liver transplants. Since centers with a higher volume of cases seemed to have better outcomes, performance criteria were suggested as a basis for determining whether a new transplant program should be approved and whether an existing program should be allowed to continue with government support. Evidence also indicated that the cost of a transplant generally decreases as the volume of cases increases at a center. For many U.S. citizens, availability of transplant centers will be determined by these considerations.

Endnotes

1. United Network of Organ Sharing (UNOS) (2006), <http://www.unos.org/>.
2. Tissue Banking Data. Information was provided to TransWeb by the Washington Regional Transplant Consortium 2/98, updated 3/2003, <http://www.wrtc.org/>.
3. *UNOS 2005 Annual Report on The Scientific Registry of Transplant Recipients and The Organ Procurement and Transplantation Network* (Richmond, Va.), <http://www.ustransplant.org/>.
4. UNOS Membership Data, <http://www.unos.org/members/committeeEvents.asp>. See also <http://www.unos.org/whoWeAre/theOPTN.asp> (last visited June 2006).
5. UNOS (2006), <http://www.unos.org/>.
6. National Task Force on Organ Transplantation, *Organ Transplantation: Issues and Recommendations* (DHHS, Washington, D.C., GPO # 1986-O-160-709, 1986).
7. *Id.*
8. Uniform Anatomical Gift Act (1968), National Conference of Commissioners.
9. Uniform Anatomical Gift Act (1987), National Conference of Commissioners on Uniform State Laws (Chicago 1987); §8A U.L.A. 16 (Supp. 1989).
10. §8A U.L.A. 2 (Supp. 1996); §8A U.L.A. 9 (Supp. 1996); <http://www.law.upenn.edu/bll/ulc/uaga/2006annualmeeting.htm>.
11. *New Developments in Biotechnology: Ownership of Human Tissues and Cells—Special Report* (Office of Technology Assessment, U.S. Government Printing Office, Washington, D.C. 1987).
12. P. Matthews, *Whose Property?: People as Property*, Current Legal Problems 193–239 (1983).
13. *In re Moyer's Estate*, 577 P. 2d 108 (1978).
14. *Holland v. Metalious*, 198 A. 2d 654 (1964).
15. *Leno v. St. Joseph Hospital*, 302 N.E. 2d 58 (1973).
16. *Nicoletta v. Rochester Eye and Human Parts Bank*, 519 N.Y.S. 2d 928 (1987).
17. *Williams v. Hofmann*, 223 N.W. 2d 844 (1974).
18. *Ravenis v. Detroit General Hospital*, 234 N.W. 2d 411 (1976).
19. *Supra* notes 9 and 10.
20. Maximus, Inc., *Assessment of the Potential Organ Donor Pool: Report to Health Resources and Services Agency* (DHHS, Washington, D.C. 1985).
21. *Organ Transplantation Q & A* (DHHS, Division of Organ Transplantation, Washington, D.C., DHHS Pub. No. [HRS-M-SP] 89-1, 1988).
22. K.J. Bart et al., *Increasing the Supply of Cadaveric Kidneys for Transplantation*, 31 *Transplantation* 383–387 (1981).
23. S.W. Tolle et al., *Responsibilities of Primary Physicians in Organ Donation*, 106 *Ann. Int. Med.* 740–744 (1987).
24. J. Prottas, *The Structure and Effectiveness of the U.S. Organ Procurement System*, 22 *Inquiry* 365–376 (1985).
25. J.M. Prottas, *The Organization of Organ Procurement*, 14 *J. Health Politics, Pol. & L.* 41–55 (1989).
26. A.L. Caplan, *Professional Arrogance and Public Misunderstanding*, 18 *Hastings Center Report* 34–37 (1988).
27. S.J. Youngner et al., *Brain Death and Organ Retrieval*, 261 *J.A.M.A.* 2205–2210 (1989).
28. J. Prottas & H.L. Batten, *Health Professionals and Hospital Administrators in Organ Procurement: Attitudes, Reservations, and Their Resolution*, 78 *Am. J. Pub. Health* 642–645 (1988).
29. A. Caplan, *Ethical and Policy Issues in the Procurement of Cadaver Organs for Transplantation*, 314 *N. Engl. J. Med.* 981–983 (1984).
30. J.F. Childress, *Ethical Criteria for Procuring and Distributing Organs for Transplantation*, 14 *J. Health Politics, Pol. & L.* 87–113 (1989).
31. Omnibus Budget and Reconciliation Act (OBRA) of 1986, Pub. L. 99-509, §9318 amending Title XI of the Social Security Act adding §1138, *Hospital protocols for organ procurement and standards for organ procurement agencies; further clarification* in 53(40) *Federal Register* 6526–6551 (Mar. 1, 1988).
32. *Joint Commission on Accreditation of Healthcare Organizations Standards*, R.I.2 (1995).
33. V.W. Weedn & B. Leveque, *Routine Inquiry for Organ and Tissue Donations*, 84 *Tex. Med.* 30–37 (1988).
34. *Transplant Action* (American Council on Transplantation, Alexandria, Va., July/August 1989).
35. *Pennsylvania Governor Signs Legislation to Increase Voluntary Organ Donation*, *Health Care Daily* (BNA, Dec. 5, 1994); available in WESTLAW, BNA-HCD.
36. United Network of Organ sharing (UNOS) Updated (Richmond, Va., Summer 1997).
37. *Id.*
38. A. Caplan, *Organ Procurement: It's Not in the Cards*, 14 *Hastings Center Report* 9–12 (1984).
39. *Supra* note 33.
40. *Powell v. Florida*, 497 So. 2d 1188, 1986, *cert. denied*, 107 S.C. 2202 (1986).
41. *Georgia Lions Eye Bank v. Lavant*, 335 S.E. 2d 127, 1985, *cert. denied*, 475 U.S. 1084 (1986).
42. *Tillman v. Detroit Receiving Hospital*, 360 N.W. 2d 275 (1984).
43. *Kirker v. Orange County*, 519 So. 2d 682 (1988).

44. J.A. Light et al., *A Rapid Organ Recovery Program for Non-Heartbeating Donors* (Washington Hospital Center and Medlantic Research Institute [abstract presented at Congress], Summer 1997).
45. *Tucker v. Lower*, No. 2831, Law & Eq. Ct. (Richmond, Va., May 23, 1972).
46. *Strachan v. John F. Kennedy Memorial Hospital*, 538 A. 2d 346 (1988).
47. UNOS 1996 Annual Report (Richmond, Va., 1996).
48. J.R. Botkin, *Anencephalic Infants as Organ Donors*, 82 Pediatrics 250–256 (1988).
49. J.W. Walters, *Anencephalic Organ Procurement: Should the Law Be Changed?*, 2 BioLaw 583–589 (1987).
50. 2 The UNOS Bulletin (July 1997).
51. D.A. Stumpf et al. (The Medical Task Force on Anencephaly), *The Infant with Anencephaly*, 322 N. Engl. J. Med. 669–674 (1990).
52. Centers for Disease Control, *Congenital Malformations Surveillance, January 1982–December 1985* (DHHS, Washington, D.C. 1988).
53. *Loma Linda Stops Program to Retrieve Transplantable Organs from Anencephalic Newborns*, BioLaw §13-1, U:1127 (1988).
54. *Supra* note 51.
55. H.H. Kaufman, *Pediatric Brain Death and Organ/Tissue Retrieval* (Plenum Medical Books, New York 1989).
56. *Supra* note 51.
57. *Id.*
58. P. King & J. Areen, *Legal Regulation of Fetal Tissue Transplantation*, 36 Clin. Res. 187–222 (1988).
59. J. Palca, *Fetal Tissue Transplants Remain Off Limits*, 246 Science 752 (1989).
60. M.W. Danis, *Fetal Tissue Transplants: Restricting Recipient Designation*, 39 Hastings L. J. 1079–1152 (1988).
61. C. Marwick, *Committee to Be Named to Advise Government about Fetal Tissue Transplantation Experiments*, 259 J.A.M.A. 3099 (1988).
62. *Committee on Fetal Tissue Transplantation Established*, BioLaw §13-1, U:965 (1988).
63. National Institutes of Health Revitalization Act of 1993, Pub. L. No. 103-43, 107 Stat. 122 (1993).
64. United States General Accounting Office, *NIH-Funded Research: Therapeutic Human Fetal Tissue Transplantation Projects Meet Federal Requirement* (GAO HEHS-97-61, March 1997).
65. *Id.*
66. *BMA Guidelines on the Use of Fetal Tissue*, The Lancet 1119 (May 14, 1988).
67. *McFall v. Shrimp*, Allegheny Cnty Ct. Common Pleas, 10 Pa.D.& C. 3d 90 (1980).
68. *Sirianni v. Anna*, 285 N.Y.S. 2d 709 (1967).
69. *Hart v. Brown*, 289 A. 2d 386 (1972).
70. *In re Richardson*, 284 So. 2d 185 (1975).
71. *In re Guardianship of Pescinski*, 226 N.W. 2d 180 (1975).
72. *Little v. Little*, 576 S.W. 2d 493 (1979).
73. *Strunk v. Strunk*, 445 S.W. 2d 145 (1969).
74. *Head v. Colloton*, 331 N.W. 2d 870 (1983).
75. *Karp v. Cooley*, 349 F. Supp. 827 (1972), *aff'd*, 493 F. 2d 408 (1974).
76. Medical Device Amendment, Pub. L. 94-295 (1980).
77. *Supra* note 18.
78. *Good v. Presbyterian Hospital*, 934 F. Supp. 107 (1996).
79. *Id.*
80. National Organ Transplant Act, Pub. L. 98-507, 98 Stat 2339, 42 U.S.C. 201 (Oct. 1984).
81. *Supra* note 31.
82. J.F. Blumstein, *Government's Role in Organ Transplantation Policy*, 14 J. Health Politics, Pol. & L. 5–39 (1989).
83. *Supra* note 80.
84. *Payment to Homeless Man to Donate Bone Marrow to Brother*, BioLaw §13-3, U:881 (1988).
85. *Transplant Action 2* (American Council on Transplantation, Alexandria, Va., Sept./Oct./Nov. 1989).
86. *Senate Labor Panel Reports Out Bill Reauthorizing Funding for Programs*, Health Care Daily (BNA, Nov. 15, 1995); available in WESTLAW, BNA-HCD.
87. *Supra* note 80.
88. *Supra* note 31.
89. T.E. Starzl et al., *A Multifactorial System for Equitable Selection of Cadaver Kidney Recipients*, 257 J.A.M.A. 3073–3075 (1987).
90. <http://www.chfpatients.com/tx/transplant.htm> (last updated January 13, 2004), last visited June 7, 2006. See also [http://www.milliman.com/pubs/Healthcare/content/research_reports/US-2 Organ-Tissue-Transplant-2005-RR.pdf](http://www.milliman.com/pubs/Healthcare/content/research_reports/US-2%20Organ-Tissue-Transplant-2005-RR.pdf).
91. *Supra* note 31.
92. End-Stage Renal Disease Program (ESRDP), Pub. L. No. 603, §86 Stat. 1329 (1972).
93. United States Renal Data Systems (DHHS/PHS, Washington, D.C. 1995).
94. J.S. Wolf, *Financial Support of Organ Procurement in the United States*, 29 Transplantation Proceedings 1631–1632 (1997).
95. M. Angell, *Cost Containment and the Physician*, 254 J.A.M.A. 1203–1207 (1985).
96. J. Aroesty & R. Rettis, *The Cost Effects of Improved Kidney Transplantation*, Rand Rep. No. R-3099-NIH/RC (1984).
97. *Id.*
98. P.E. Eggers, *Effect of Transplantation on the Medicare End-Stage Renal Disease Program*, 318 N. Engl. J. Med. 223–229 (1988).
99. 42 C.F.R. §405 (1996).
100. HCEA Notice, 55 Fed. Reg. 8547 (Mar. 8, 1990).
101. 60 F.R. §6537 (1995).
102. Congressional Research Services, 103rd Cong., 1st Sess., *Medicaid Source Book: Background Data and Analysis (A 1993 Update)* 605 at 292–295.
103. *Brillo v. Arizona*, cited in ACT, *Transplant Action* (July/Aug. 1986).
104. *Allen v. Mansour*, 681 F. Supp. 1232 (D.Ct. E.D. Mich., 1986).
105. *Lee v. Page*, No. 86-1081-Civ-J-14, U.S. Dist. Ct. (Middle Dist. of Florida, Jacksonville Division, Dec. 19, 1986).
106. *Todd v. Sorrell*, No. 87-3806, U.S. Ct. of App. (4th Cir., Mar. 4, 1988).
107. H.G. Welch & E.B. Larson, *Dealing with Limited Resources: The Oregon Decision to Curtail Funding for Organ Transplantation*, 319 N. Engl. J. Med. 171–173 (1988).
108. R. Crawshaw et al., *Organ Transplants: A Search for Health Policy at the State Level*, 150 West. J. Med. 361–363 (1989).
109. *McDermott v. Manhattan Eye, Ear & Throat Hospital*, 270 N.Y.S. 2d 955, *aff'd without opinion* 224 N.E. 2d 717 (1966).
110. *State of Missouri ex rel. Wichita Falls General Hospital v. Adolph*, 728 S.W. 2d 604 (1987).
111. R.M. Baron, *Asserting Jurisdiction Over the Providers of Human Donor Organs: State of Missouri ex rel. Wichita Falls General Hospital v. Adolph*, 92 Dick. L. Rev. 393 (Winter 1988).
112. Council on Ethical and Judicial Affairs (AMA), *Strategies for Cadaveric Organ Procurement Mandated Choice and Presumed Consent*, 272 J.A.M.A. 809–812 (1994).
113. *Brotherton v. Cleveland*, 923 F. 2d 477 (6th Cir., 1991).



226 Organ Donation and Transplantation

114. D. Jason, *The Role of the Medical Examiner/Coroner in Organ and Tissue Procurement for Transplantation*, 15 Am. J. Forensic Med. & Path. 192-202 (1994).
115. R. Voelker, *Can Forensic Medical and Organ Donation Co-exist for Public Good?*, 271 J.A.M.A. 891-892 (1994).
116. T. Shafer et al., *Impact of Medical Examiner/Coroner Practices on Organ Recovery in the United States*, 272 J.A.M.A. 1607-1613 (1994).
117. *Supra* note 36.
118. UNOS Update (Richmond, Va., Spring 1997).
119. A. Skolnick, *Are There Too Many US Transplantation Centers? Some Experts Suggest Fewer, Cheaper, Better*, 271 J.A.M.A. 1062-1064 (1994).

