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Human Organ Transplantation: The Role of Law

Fred H. Cate¹

I. INTRODUCTION

"It was the best of times, it was the worst of times."¹ Charles Dickens' description of revolutionary Europe in *A Tale of Two Cities* might very well be used to describe organ transplantation today. Enormous successes are paralleled by a fatal and worsening shortage of organs, discontent, and disquieting uncertainty about the future.

In 1993 there were 13,540 cadaveric, solid organ transplants in the United States.² Since 1980 almost 150,000 solid organ transplants have been performed in this country³ and, since 1985, more than one million tissue transplants.⁴ The number of transplant programs in the United States has more than doubled since 1981.⁵ The effectiveness of transplantation is demonstrated both by the long-term survival rates of transplant patients and by the quality of life transplantation restores. By 1991, the ten-year survival rate of patients with cadaveric kidney transplants was eighty percent.⁶ The five-year survival rate for more recently developed procedures was eighty percent for pancreas recipients, sixty-seven percent for heart recipients, and sixty-three percent for adult liver recipients.⁷ Although transplantation is expensive, the cost effectiveness of transplant procedures is equal to, or greater than, many other accepted medical treatments, such as those for cancer, severe burns, and dialysis for end-stage renal disease.⁸ That is real success, measured in terms of lives saved and improved, families reunited, and hope restored.

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1. CHARLES DICKENS, A TALE OF TWO CITIES 1 (1859).

2. *Facts About Transplantation in the United States—Cadaveric Donor Transplants*, UNOS UPDATE, Dec. 1993, at 35.

3. *Id.*; see also ROGER W. EVANS, EXECUTIVE SUMMARY: THE NATIONAL COOPERATIVE TRANSPLANTATION STUDY 2 (1991).

4. John Schwartz, *FDA Sets New Rules to Ensure Safety of Tissue for Transplants*, WASH. POST, Dec. 11, 1993, at A7.

5. EVANS, *supra* note 3, at 4.

6. *Id.* at 17.

7. *Id.*

8. *Id.* at 15-21, 59-62.

Despite impressive successes, transplantation is sharply curtailed by a shortage of donated organs and tissues. The number of people who either die of conditions for which transplantation is indicated or are maintained on suboptimal therapies in the absence of a transplant far exceeds the number of transplants performed.⁹ For example, in 1990, 18,592 people needed a transplanted kidney (only half received one); 40,959 needed a heart (only one in twenty received one); 14,751 needed a liver (only one in five received one); 4108 needed a pancreas (only one in eight got one); and 4618 needed a combination heart-lung (fewer than one in eighty-five received one).¹⁰

Not all people who would benefit from a transplant actually are listed on the waiting list. Nonetheless, the number of registrations on the national list far exceeds the current supply and is increasing. As of December 31, 1993, there were 24,973 registrations for a kidney, 2834 for a heart, 2997 for a liver, 1106 for a pancreas or combination kidney-pancreas, 1240 for a lung, and 202 for a combination heart-lung.¹¹ In short, the demand for organs is far outstripping the supply, and the gap is widening; more than 33,000 people are on the waiting list.¹² In the case of lifesaving organs such as hearts, this means that one-third or more of those people waiting will die before an organ is found. Every four hours a person dies while waiting.¹³

In addition, one can hardly pick up the morning paper without seeing a horror story involving transplantation. Controversies abound over racially based directed donations,¹⁴ families billed for hospital charges related to donation,¹⁵ transplant programs and surgeons under investigation for illegal drug sales and profit-making,¹⁶ public officials moving up on waiting lists,¹⁷ dramatic disparities in waiting times based on race,¹⁸ transplant programs and medical examiners fighting over dead bodies,¹⁹ wide variances in costs and charges for organ procurement and transplant procedures,²⁰ and the transmission of AIDS and other infectious diseases through transplantation.²¹

9. *Id.* at 8-9.

10. EVANS, *supra* note 3, at 9, table 5.

11. *Patients Waiting for Transplants*, UNOS UPDATE, Jan. 1994, at 38.

12. Frank P. Stuart & Diana Clark, *The Benefits of Cooperation in Organ Donation*, WASH. POST, Dec. 16, 1993 (letter to the editor), at A24.

13. *Id.*

14. *See, e.g.*, Jeff Testerman, *Should Donors Say Who Gets Organs?*, ST. PETERSBURG TIMES, Jan. 9, 1994, at 1A.

15. *See, e.g.*, Ann Landers, *Sending Organ Donor a Bill Was Mistake*, ST. LOUIS DISPATCH, Dec. 27, 1993, at 2E. This story was reported in Ann Landers' column of December 27, 1993, and was widely reported throughout the United States.

16. *See, e.g.*, Christopher Anderson, *Scandal Scars Minnesota Medical School*, SCI., Dec. 17, 1993, at 1812. The University of Minnesota and transplant surgeon John Najarian were investigated by the FDA, FBI, IRS, and U.S. Attorney's office for producing and selling the immunosuppressive drug antilymphocyte globulin (ALG) without FDA approval. *Id.*

17. *See, e.g.*, Claudia Coates, *Casey's Quick Transplant Renews Ethics Debate*, L.A. TIMES, July 25, 1993, at A3.

18. *See, e.g.*, David Bauder, *Blacks Wait Longer for Kidneys*, L.A. TIMES, Nov. 24, 1991, at A22.

19. *See, e.g.*, Sally Squires, *Two Agencies in a Grim Battle Over Bodies*, WASH. POST, Nov. 18, 1993, at C1; Sally Squires, *Transplant Tug-of-War*, WASH. POST, Nov. 23, 1993, at Z7.

20. *See, e.g.*, Roger W. Evans, *Organ Procurement Expenditures and the Role of Financial Incentives*, 269 JAMA 3113 (1993); EVANS, *supra* note 3, at 24.

21. *See, e.g.*, Lawrence Altman, *3 Die of AIDS After Getting Organs From a Man Infected With the*

Law and lawyers have proven to be a mixed blessing in human organ transplantation. Although law is in many ways responsible for the success of transplantation, most notably through the Uniform Determination of Death and Uniform Anatomical Gift Acts,²² law is also one of transplantation's greatest impediments. This Article examines the primary laws applicable to organ donation and transplantation and recommends renewed attention to three roles for law and lawyers in the future.

II. SOURCES OF TRANSPLANT LAW

A. Early Regulation by States

State legislatures adopted the earliest regulatory measures to facilitate transplantation. As advances in medical technology made the widespread transplantation of hearts and kidneys feasible, these institutions sought to encourage the donation of organs and to provide a legal framework for organ donation and transplantation.

1. The Uniform Anatomical Gift Act

In the 1960s the National Conference of Commissioners on Uniform State Laws began the process of formulating a model organ donation act. In 1968 the Conference adopted the Uniform Anatomical Gift Act (UAGA).²³ By 1972 some version of the UAGA had been adopted in every state and in the District of Columbia.²⁴

Virus, N.Y. TIMES, May 18, 1991, at 8; B.J. Pereira et al., *Liver Disease and HCV Infection After Transplantation of Organs From Hepatitis C Antibody Positive Donors*, 25 TRANSPLANTATION PROC. 1458 (1993); B.J. Pereira et al., *Transmission of Hepatitis C Virus by Organ Transplantation*, 325 NEW ENG. J. MED. 454 (1991).

22. UNIF. DETERMINATION OF DEATH ACT, 12 U.L.A. 414 (Supp. 1994) [hereinafter UDDA]; UNIF. ANATOMICAL GIFT ACT OF 1987, 8A U.L.A. 19 (1993) [hereinafter UAGA]. All UAGA cites are to UAGA OF 1987, 1993 edition unless otherwise noted.

23. UAGA OF 1968, 8A U.L.A. 63 (1993) (superseded by UAGA OF 1987).

24. ALA. CODE §§ 22-19-40 to -47, -60 (1975 & Supp. 1994); ALASKA STAT. §§ 13.50.010-.090 (Supp. 1987); ARIZ. REV. STAT. ANN. §§ 36-841 to -849 (1993); ARK. CODE ANN. §§ 20-17-601 to -613 (Michie 1991); CAL. HEALTH & SAFETY CODE §§ 7150-7156.5 (Deering Supp. 1994); COLO. REV. STAT. §§ 12-34-101 to -109 (1991); CONN. GEN. STAT. ANN. §§ 19a-270 to -288 (West 1986); DEL. CODE ANN. tit. 16, §§ 2710-2719 (Supp. 1992); D.C. CODE ANN. §§ 2-1501 to -1511 (1994); FLA. STAT. ANN. §§ 732.910-.922 (West Supp. 1994); GA. CODE ANN. §§ 44-5-140 to -151 (1991); HAW. REV. STAT. §§ 327-1 to -9 (1985); IDAHO CODE §§ 39-3401 to -3417 (1993); ILL. REV. STAT. ch. 110½, paras. 301-3111 (1991); IND. CODE §§ 29-2-16-1 to -12 (1993); IOWA CODE §§ 142A.1-.10 (1993); KAN. STAT. ANN. §§ 65-3209 to -3217 (1992); KY. REV. STAT. ANN. §§ 311.165-.235 (Michie/Bobbs-Merrill 1990); LA. REV. STAT. ANN. §§ 17:2351-.2359 (West 1982); ME. REV. STAT. ANN. tit. 22, §§ 2901-2910 (West 1992); MD. CODE ANN. EST. & TRUSTS §§ 4-501-512 (1991); MASS. GEN. L. ch. 113, §§ 7-14 (1992); MICH. COMP. LAWS ANN. §§ 333.10101-.10109 (West 1992); MINN. STAT. §§ 525.921-.9224 (1992 & Supp. 1993); MISS. CODE ANN. §§ 41-39-11, 41-39-31 to -53 (1972 & Supp. 1994); MO. REV. STAT. §§ 194.210-.290 (1986 & Supp. 1993); MONT. CODE ANN. §§ 72-17-101 to -312 (1993); NEB. REV. STAT. §§ 71-4801 to -4818 (1990 & Supp. 1993); NEV. REV. STAT. §§ 451.500-.590 (1991); N.H. REV. STAT. ANN. §§ 291-A:1 to -A:9 (1987); N.J. STAT. ANN. §§ 26:6-57 to -65 (West 1987 & Supp. 1994); N.M. STAT. ANN. §§ 24-6-1 to -11 (Michie 1994); N.Y. PUB. HEALTH LAW §§ 4300-4308 (McKinney 1985 & Supp. 1994); N.C. GEN. STAT. §§ 130A-402 to -412.1 (1990); N.D. CENT. CODE §§ 23-06.2-01 to -12 (1991); OHIO REV. CODE ANN. §§ 2108.01-.10 (Baldwin 1987); OKLA. STAT. tit. 63, §§ 2201-2218 (1991 & Supp. 1994); OR. REV. STAT. §§ 97.250-.290 (1990); PA. STAT. ANN. tit. 20, §§ 8601-8607 (1975 & Supp. 1994); R.I. GEN. LAWS §§ 23-18.6-1 to -15

The UAGA provides that any individual who is at least eighteen years old may make or refuse to make an anatomical gift.²⁵ Where a decedent has neither executed an anatomical gift form nor indicated opposition to such a gift, the UAGA provides that certain people may authorize a gift of all or part of the decedent's body.²⁶ Those persons must fall within one of six hierarchical classes of individuals who can authorize a donation: a spouse, adult son or daughter, parent, adult sibling, grandparent, guardian,²⁷ or any other person authorized or under obligation to dispose of the body.²⁸ An individual may authorize the gift only if no member of a prior class is available at the time of death, and no actual notice of opposition by any member of the same or a prior class is evident.²⁹

According to the UAGA, "[a]n anatomical gift that is not revoked by the donor before death is irrevocable and does not require the consent or concurrence of any person after the donor's death."³⁰ The donation of a specific body part is not presumed to be a refusal to give other parts, should the next-of-kin consent to other body parts being donated.³¹ Similarly, the revocation by the donor of an anatomical gift is not presumed to be a refusal of the donor to make a subsequent anatomical gift, should the next-of-kin consent.³²

The UAGA defines who may receive human body part donations and for what purposes as:

1. a hospital, physician, surgeon, or procurement organization, for transplantation, therapy, medical or dental education, research, or advancement of medical or dental science;
2. an accredited medical or dental school, college, or university for education, research, advancement of medical or dental science; or
3. a designated individual for transplantation or therapy needed by that individual.³³

The UAGA provides that human body parts may be donated through a will or by another document.³⁴ If the gift is through a will, it becomes effective upon death and does not have to wait for probate.³⁵ If the donation is by another document, most com-

(1989); S.C. CODE ANN. §§ 44-43-310 to -400 (Law. Co-op. 1985); S.D. CODIFIED LAWS ANN. §§ 34-26-20 to -41 (1994); TENN. CODE ANN. §§ 68-30-101 to -111 (1992); TEX. HEALTH & SAFETY CODE ANN. §§ 692.001-.016 (West 1992); UTAH CODE ANN. §§ 26-28-1 to -12 (Supp. 1994); VT. STAT. ANN. tit. 18, §§ 5238-5247 (Supp. 1993); VA. CODE ANN. §§ 32.1-289 to -297.1 (Michie 1992 & Supp. 1994); WASH. REV. CODE §§ 68.50.520-.630 & §§ 68.50.901-903 (Supp. 1993); W. VA. CODE §§ 16-19-1 to -9 (1991); WIS. STAT. § 157.06 (1991-92); WYO. STAT. §§ 35-5-101 to -112 (1994).

25. UAGA § 2(a), 8A U.L.A. at 33.

26. *Id.* § 3(a), at 40.

27. *Id.* § 4(a), at 43.

28. *Id.*

29. *Id.* § 3(b), at 40.

30. UAGA § 2(h), 8A U.L.A. at 34.

31. *Id.* § 2(j), at 34.

32. *Id.* § 2(k), at 34.

33. *Id.* § 6(a), at 53.

34. *Id.* § 2, at 33-34.

35. UAGA § 2(e), 8A U.L.A. at 34.

monly a donor card, the 1968 UAGA required that the document be signed in the presence of two witnesses; today, however, witnesses no longer are required unless the intent to donate is expressed orally.³⁶ Under the UAGA, a donor may, but is not obligated to, specify a recipient of the anatomical gift.³⁷ The donor may revoke a gift at any time, even if notice of the intent to donate was given to a specified donee.³⁸ Where donation does take place, the UAGA requires that the organ or tissue be taken without unnecessary mutilation and that the decedent's body be returned to the family or the person who is under obligation to dispose of the body.³⁹ Furthermore, any person who acts in good faith in accordance with the terms of the UAGA or of any state's or nation's anatomical gift laws is not liable for civil damages or subject to criminal prosecution for his or her act.⁴⁰

In 1984, the Executive Committee of the National Conference of Commissioners on Uniform State Laws began the process of drafting a new UAGA in response to the increasingly visible inadequacies of the 1968 Act. In 1987 the Conference approved the new UAGA; the American Bar Association approved the Act in 1988. The 1987 UAGA contains an entirely new section entitled "Routine Inquiry and Required Request; Search and Notification."⁴¹ This section requires that a hospital ask each patient on admission: "Are you an organ or tissue donor?"⁴² If the answer is affirmative, the hospital is to request a copy of the document of gift.⁴³ If the answer is negative, the hospital, with the consent of the attending physician, "shall discuss with the patient the option to make or refuse to make an anatomical gift."⁴⁴ If the patient is at or near death, and no medical record indicates that the patient has made or refused to make an anatomical gift, the hospital is directed to consider approaching the next-of-kin about human body part donation.⁴⁵

The section also obligates law enforcement officers, firemen, paramedics, other emergency rescuers, and hospital personnel to "make a reasonable search for a document of gift or other information identifying the bearer as a donor or as an individual who has refused to make an anatomical gift."⁴⁶ The penalty for failing to comply with the section is neither criminal nor civil liability, but rather "appropriate administrative sanctions."⁴⁷ The first two states to pass this "required request" legislation were New York and Oregon in 1985. By January of 1992, forty-six states and the District of Columbia had enacted some form of required request legislation.⁴⁸

36. *Id.* § 2, at 35 (comment).

37. *Id.* § 6(b), at 53.

38. *Id.* § 2(f)(4), at 34.

39. *Id.* § 8(a), at 55.

40. UAGA § 11(c), 8A U.L.A. at 47.

41. *Id.* § 5, at 47.

42. *Id.* § 5(a), at 47.

43. *Id.*

44. *Id.*

45. UAGA § 5(b), 8A U.L.A. at 47.

46. *Id.* § 5(c), at 47.

47. *Id.* § 5(f), at 47.

48. ALA. CODE § 22-19-142 (1975); ALASKA STAT. § 13.50.014 (Supp. 1991); ARIZ. REV. STAT. ANN. § 36-849 (1993); ARK. CODE ANN. § 20-17-605 (Michie 1991); CAL. HEALTH & SAFETY CODE § 7151.5

The 1987 UAGA also forbids the purchase or sale of a body part for transplantation or therapy for "valuable consideration . . . if removal of the part is intended to occur after the death of the decedent."⁴⁹ The Act defines "valuable consideration" consistent with the National Organ Transplant Act, discussed below,⁵⁰ to exclude "reasonable payment for the removal, processing, disposal, preservation, quality control, storage, transportation, or implantation of a part."⁵¹

2. Determination of Death

A second area for early state regulation of transplantation involved the definition of "death." In order for organs to be viable for transplantation, both circulation and respiration must be maintained in the host body. Death must therefore be determined by the absence of all brain activity. Prior to 1970, no state statute permitted such a determination of death. Doctors and hospitals risked liability if they removed artificial life support systems from a body based on the absence of brain activity and lack of response to stimuli. The UAGA contained no definition of "brain death" because of the drafters' concern that the controversy surrounding the issue of brain death in the 1960s would delay states' passage of the Act. Instead, the UAGA merely provided that death shall be determined by a physician who will not participate in the removal or transplantation of any of the decedent's body parts.⁵²

In 1980, however, the National Conference of Commissioners on Uniform State Laws promulgated its Uniform Determination of Death Act (UDDA),⁵³ and both the ABA and the AMA approved it the following year. Recommended by the President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research, the UDDA provides: "An individual who has sustained either (1) irre-

(Deering Supp. 1994); COLO. REV. STAT. § 12-34-108.5 (Supp. 1994); CONN. GEN. STAT. ANN. § 19a-279e (West Supp. 1994); DEL. CODE ANN. tit. 16, § 2721 (Supp. 1992); D.C. CODE ANN. §§ 2-1509 to 2-1511 (1994); FLA. STAT. ANN. § 732.922 (West Supp. 1994); GA. CODE ANN. § 44-5-143 (Supp. 1994); HAW. REV. STAT. §§ 327-5 to 327-51 (Supp. 1992); IDAHO CODE § 39-3406 (1993); ILL. ANN. STAT. ch. 755, para. 60/2 (Smith-Hurd 1992); IND. CODE § 29-2-16-10 (1993); KAN. STAT. ANN. § 65-3218 (1992); KY. REV. STAT. ANN. § 311.241 (Michie/Bobbs-Merrill Supp. 1992); LA. REV. STAT. ANN. § 17:2354.4(B) (West Supp. 1994); ME. REV. STAT. ANN. tit. 22, § 2910 (West 1992); MASS. GEN. L. ch. 113, § 8 (1992); MICH. COMP. LAWS § 333.10102a (1992); MINN. STAT. § 525.9214 (1992); MISS. CODE ANN. § 41-39-15 (1993); MO. REV. STAT. § 194.233 (1986); MONT. CODE ANN. § 50-5-212 (1993); NEB. REV. STAT. § 71-4817 (1990); NEV. REV. STAT. § 451.577 (1991); N.H. REV. STAT. ANN. § 291-A:2-a (1987); N.J. STAT. ANN. § 26:6-58.1 (West Supp. 1994); N.M. STAT. ANN. § 24-6-10 (Michie 1994); N.Y. PUB. HEALTH LAW § 4351 (McKinney Supp. 1994); N.C. GEN. STAT. § 130A-412.1 (1990); N.D. CENT. CODE §§ 23-06.2-05 (Supp. 1993); OHIO REV. CODE ANN. § 2108.021 (Baldwin 1987); OKLA. STAT. tit. 63, § 2214 (1991); OR. REV. STAT. § 97.268 (1990); PA. STAT. ANN. tit. 20, § 8608 (Supp. 1994); R.I. GEN. LAWS § 23-18.6-5 (1989); TENN. CODE ANN. § 68-31-10 (Supp. 1991); TEX. HEALTH & SAFETY CODE ANN. § 692.013 (West 1992); UTAH CODE ANN. § 26-28-6 (Supp. 1994); VT. STAT. ANN. tit. 18, § 5241 (Supp. 1993); VA. CODE ANN. § 32.1-292.1 (Michie Supp. 1994); WASH. REV. CODE ANN. § 68.50.500 (West 1994); W. VA. CODE § 16-19-4a (1991); WIS. STAT. § 157.06 (1992); WYO. STAT. ANN. § 35-5-114 (Michie 1994).

49. UAGA § 10(a), 8A U.L.A. at 58.

50. See *infra* note 67 and accompanying text.

51. UAGA § 10(b), 8A U.L.A. at 58.

52. *Id.* § 8(b), at 56.

53. UDDA, 12 U.L.A. 414 (Supp. 1994).

versible cessation of circulatory and respiratory functions, or (2) irreversible cessation of all functions of the entire brain, including the brain stem, is dead. A determination of death must be made in accordance with accepted medical standards."⁵⁴

Forty-four states and the District of Columbia have enacted statutes recognizing irreversible cessation of all brain functions as an acceptable method of determining death for legal as well as medical purposes.⁵⁵ Six states—Arizona,⁵⁶ Massachusetts,⁵⁷ Nebraska,⁵⁸ New Jersey,⁵⁹ New York,⁶⁰ and Washington⁶¹—recognize "brain death" by judicial determination rather than by statute. For instance, in *State v. Watson*,⁶² the New Jersey high court held that evidence that the victim had no brain activity prior to removal from life support systems was sufficient to sustain the defendant's conviction for homicide. The New York State Court of Appeals followed this reasoning in *People v. Eulo* and *People v. Bonilla*.⁶³ In both cases, the victims were organ donors and the court directly addressed the need to develop a brain-death standard in order to facilitate organ procurement. The appellate court reviewing the cases rejected the idea that its recognition of the need "to ease and make more efficient the transfer of donated organs,"⁶⁴ rendered its brain-death criteria theoretically impure.⁶⁵

54. *Id.* § 1, at 414.

55. ALA. CODE § 22-31-1 (1975); ALASKA STAT. § 09.65.120 (Supp. 1993); ARK. CODE ANN. § 20-17-101 (Michie 1991); CAL. HEALTH & SAFETY CODE § 7180 (Deering Supp. 1994); COLO. REV. STAT. § 12-36-136 (1991); CONN. GEN. STAT. ANN. § 19a-504a (West 1986); DEL. CODE ANN. tit. 24, § 1760 (1987); D.C. CODE ANN. § 6-2401 (1989); FLA. STAT. ANN. § 382.009 (West 1993); GA. CODE ANN. § 31-10-16 (1991); HAW. REV. STAT. § 327C-1 (1985); IDAHO CODE § 54-1819 (1994); ILL. ANN. STAT. ch. 755, para. 50/2 (Smith-Hurd 1992); IND. CODE § 1-1-4-3 (1993); IOWA CODE § 702.8 (1993); KAN. STAT. ANN. § 77-202 (1977); KY. REV. STAT. ANN. § 446.400 (Michie/Bobbs-Merrill Supp. 1992); LA. REV. STAT. ANN. § 9:111 (West 1991); ME. REV. STAT. ANN. tit. 22, § 2811 (West 1992); MD. CODE ANN. HEALTH-GEN. § 5-202 (1994); MICH. COMP. LAWS ANN. § 333.1033 (West 1992); MINN. STAT. § 145.135 (1993); MISS. CODE ANN. § 41-36-3 (1993); MO. REV. STAT. § 194.005 (1986); MONT. CODE ANN. § 50-22-101 (1993); NEV. REV. STAT. § 451.007 (1991); N.H. REV. STAT. ANN. § 141-D:2 (1990); N.M. STAT. ANN. § 12-2-4 (Michie Supp. 1994); N.C. GEN. STAT. § 90-323 (1993); N.D. CENT. CODE § 23-06.3-01 (1993); OHIO REV. CODE ANN. § 2108.30 (Baldwin 1987); OKLA. STAT. ANN. tit. 63, § 1-301(g) (West 1991); OR. REV. STAT. § 432.300 (1992); PA. STAT. ANN. tit. 35, § 10203 (1993); R.I. GEN. LAWS § 23-4-16 (1989); S.C. CODE ANN. § 44-43-460 (Law. Co-op. 1985); S.D. CODIFIED LAWS § 55.55.34-25-18.1 (1994); TENN. CODE ANN. § 68-3-501 (1992); TEX. HEALTH & SAFETY CODE ANN. § 671.001(b) (West 1994); UTAH CODE ANN. § 26-34-2 (1994); VT. STAT. ANN. tit. 18, § 5218 (1987); VA. CODE ANN. § 54-325.7 (Michie Supp. 1987); W. VA. CODE § 16-10-1 (1991); WIS. STAT. ANN. § 146.71 (West 1989); WYO. STAT. ANN. § 35-19-101 (Michie 1994).

56. *State v. Fierro*, 603 P.2d 74 (Ariz. 1979).

57. *Commonwealth v. Golston*, 366 N.E.2d 744 (Mass. 1977), *cert. denied*, 434 U.S. 1039 (1978).

58. *State v. Meints*, 322 N.W.2d 809 (Neb. 1982).

59. *State v. Watson*, 467 A.2d 590 (N.J. Super. Ct. App. Div. 1983).

60. *People v. Eulo*, 472 N.E.2d 286 (N.Y. 1984).

61. *In re Bowman*, 617 P.2d 731 (Wash. 1980).

62. 467 A.2d at 590-91.

63. 472 N.E.2d at 294. *Eulo* and *Bonilla* were decided together on appeal.

64. *Id.* at 292

65. *Id.* at 295 n.28.

B. The Growth of Federal Regulation
1. The National Organ Transplant Act

Raymond Cotton and Andrew Sandler observed in 1986 that “[t]he most striking aspect of the legal environment surrounding the procurement and transplantation of human organs is the virtual absence of federal regulation.”⁶⁶ The primary federal regulation stems from the National Organ Transplant Act (NOTA or the Act),⁶⁷ which Congress passed and President Reagan signed in 1984.

NOTA was the product of a series of hearings conducted by House and Senate committees of the 98th Congress. In June 1983, Surgeon General Koop convened a workshop entitled “Solid Organ Procurement for Transplantation: Educating the Physician and the Public.” Legislation regulating organ procurement and transplantation subsequently was introduced in both the House and Senate. House and Senate Conferees met in October of 1984 and produced a compromise measure that was enacted as NOTA.

NOTA has six principal provisions. The Act:

1. established a 25-member task force on Organ Procurement and Transplantation responsible for examining a broad range of “medical, legal, ethical, economic, and social issues presented by human organ procurement and transplantation;”⁶⁸
2. required the Secretary of Health and Human Services to convene a conference on the feasibility of establishing a national registry of voluntary bone marrow donors;⁶⁹
3. created the Division of Organ Transplantation;⁷⁰
4. empowered the Secretary to make grants for the planning, creation, initial operation, and expansion of organ procurement organizations (OPOs);⁷¹
5. required the Secretary to contract for an Organ Procurement and Transplantation Network (OPTN) and a Scientific Registry;⁷² and
6. prohibited the purchase and sale of human organs for “valuable consideration.”⁷³

The latter four requirements have had the most lasting consequences.

66. Raymond Cotton & Andrew Sandler, *The Regulation of Organ Procurement and Transplantation in the United States*, 7 J. LEGAL MED. 55, 57 (1986).

67. See National Organ Transplant Act, Pub. L. No. 98-507, 98 Stat. 2339 (codified as amended in scattered sections of 42 U.S.C.) [hereinafter NOTA].

68. *Id.* § 101(b)(1)(A). The Task Force’s report was published in 1986. TASK FORCE ON ORGAN TRANSPLANTATION, U.S. DEP’T OF HEALTH & HUMAN SERVS., ORGAN TRANSPLANTATION: ISSUES AND RECOMMENDATIONS (1986) [hereinafter TASK FORCE].

69. NOTA § 401(a).

70. 42 U.S.C. § 274c (1988).

71. *Id.* § 273a.

72. 42 U.S.C. § 274-274a (Supp. V 1993).

73. *Id.* § 274e.

a. Division of Organ Transplantation

NOTA mandated the creation of “an identifiable administrative unit in the Public Health Service” to administer the Act, coordinate organ procurement activities, encourage organ donation, and report to Congress about the status of organ procurement and transplantation.⁷⁴ The Secretary of Health and Human Services responded by creating the Division of Organ Transplantation (DOT). Today the DOT is responsible for the OPTN and Scientific Registry contracts and grants to OPOs.⁷⁵ The DOT’s two branches—the Operations and Analysis Branch and the Public and Professional Education Branch—also have expanded their public, media, and professional education activities, oversight of both the OPTN and the Scientific Registry, and exploration of current issues in transplantation, such as participation by minority communities and better coordination among organ and tissue organizations. The DOT’s responsibilities relating to OPOs, the OPTN, and the Scientific Registry are discussed in greater detail below.⁷⁶

b. Organ Procurement Organizations

NOTA enshrined OPOs as the backbone of the organ procurement and distribution system. First established in a 1968 pilot program in Boston and Los Angeles, OPOs flourished with the creation of the federal government’s End-Stage Renal Disease Program through which federal funds became available for kidney procurement and distribution.⁷⁷ NOTA authorized twenty-five million dollars for grants to “qualified” OPOs.⁷⁸ The DOT has awarded grants each year, beginning in 1986.⁷⁹ Between the End-Stage Renal Disease Program and the OPO grant program, OPOs, although they are private organizations, receive significant federal funding. This level of funding naturally has led to OPOs increasingly becoming subject to federal regulations. In the Omnibus Budget Reconciliation Act of 1986,⁸⁰ Congress expanded federal regulation of OPOs by subjecting all OPOs to the authority of the Secretary of Health and Human Services and requiring all OPOs, as a condition of participating in Medicare, to be members of and agree to abide by the rules of the OPTN.

74. *Id.* § 274c.

75. *See* Transplant Amendments Act of 1990, Pub. L. No. 101-616, 104 Stat. 3283 (codified as amended in scattered sections of 42 U.S.C.).

76. *See infra* part II.B.1.b-c.

77. Social Security Amendments of 1972, Pub. L. No. 92-603, § 299I, 86 Stat. 1329, 1463-64 (codified as amended in scattered sections of 42 U.S.C.).

78. NOTA § 201.

79. Grants To Increase Organ Donation, 58 Fed. Reg. 19,673 (1993); National Organ Transplant Act; Grants To Increase Organ Donation, 57 Fed. Reg. 18,158 (1992); National Organ Transplant Act; Grants To Increase Organ Donation, 56 Fed. Reg. 25,433 (1991); National Organ Transplant Act; Grants for Organ Procurement, 55 Fed. Reg. 24,935 (1990); National Organ Transplant Act; Grants for Organ Procurement, 54 Fed. Reg. 20,438 (1989); National Organ Transplant Act; Grants for Organ Procurement, 53 Fed. Reg. 15,601 (1988); National Organ Transplant Act; Grants for Organ Procurement, 52 Fed. Reg. 19,406 (1987); National Organ Transplant Act; Grants for Organ Procurement, 51 Fed. Reg. 18,509 (1986).

80. Omnibus Budget Reconciliation Act of 1986, Pub. L. No. 99-509, 100 Stat. 1874, 2009-10 (codified in scattered sections of 42 U.S.C.).

c. *Organ Procurement and Transplantation Network and Scientific Registry*

In a compromise provision of NOTA, Congress opted for the creation of a private organization to maintain the list of people waiting for organs. While delegating that task to a government entity likely would have guaranteed federal oversight of organ procurement and distribution generally, the Reagan Administration objected to any measure that might create more government bureaucracy. Congress therefore created the OPTN as a private monopoly, funded by taxpayer dollars and user fees, and required that it be operated only by organizations working exclusively in transplantation.

According to the Act, the OPTN is designed to establish a national list of individuals who need organs and a national computer system to match available organs with individuals on that list. The Network must also maintain a twenty-four-hour telephone service to assist with the matching process, to adopt standards of quality for the acquisition and transportation of donated organs, and to collect and distribute information on organ donation and transplantation.⁸¹ NOTA provided that no more than two million dollars per fiscal year may be spent to support the Network.⁸²

On September 30, 1986, the Secretary awarded a \$379,000, one-year contract for the Network to the United Network for Organ Sharing (UNOS). On September 30, 1987, the Secretary renewed the contract for three years in the amount of \$1.1 million for fiscal year 1987, \$1.2 million for fiscal year 1988, and approximately \$1.5 million for fiscal year 1989. The Secretary renewed the contract again for three years on September 30, 1990. Waiting list registration fees raise additional funds for operation of the Network.

NOTA also required the creation of a Scientific Registry to collect and analyze the information "necessary to an ongoing evaluation of the scientific and clinical status of organ transplantation."⁸³ On September 30, 1987, the DOT entered into a two-year, \$1.4 million per year contract with UNOS to establish and operate a Scientific Registry database for organ transplantation. That contract was renewed for three years on September 30, 1990.

In the Transplant Amendments Act of 1990,⁸⁴ Congress expanded the function of the Network and the types of organizations which could participate in its operation. For example, the operator of the Network is no longer required to be an organization "which is not engaged in any activity unrelated to organ procurement."⁸⁵ Instead, it may be any organization "that has expertise in organ procurement and transplantation."⁸⁶ Additionally, the Act requires the Network to assist in the nationwide and equitable distribution of organs, work actively to increase the supply of organs, and report annually to the Department of Health and Human Services on the comparative costs and patient outcomes at each transplant center.⁸⁷

81. 42 U.S.C. § 274(b) (1988).

82. *Id.* § 274(a).

83. 42 U.S.C. § 274(a) (Supp. V 1993).

84. *See* Transplant Amendments Act of 1990, *supra* note 75.

85. 42 U.S.C. § 274(b)(1)(A) (1988), amended by 42 U.S.C. § 274(b)(1)(A) (Supp. V 1993).

86. *Id.* § 274(b)(1)(A) (Supp. V 1993) (amending 42 U.S.C. § 274(b)(1)(A) (1988)).

87. *Id.* § 274(b) (Supp. V 1993).

The Omnibus Budget Reconciliation Act of 1986⁸⁸ required all transplanting hospitals, as a condition of participation in Medicare and Medicaid, (and OPOs, as discussed above) to be members of and agree to abide by the rules of the OPTN. Because of this development, the question was raised whether Congress' provision for the required membership of transplant centers and OPOs in the private OPTN (and the required compliance by these entities with the Network's rules) vested in the OPTN federal regulatory power. In the Health Omnibus Programs Extension of 1988,⁸⁹ Congress amended section 274 of the National Organ Transplant Act, to provide that the Secretary of Health and Human Services must establish procedures for receiving and evaluating comments from the public on the manner in which the Network is carrying out its statutory responsibilities. In September 1989, Acting Surgeon General James Mason notified Robert Corry, then President of UNOS, that UNOS rules and sanctions would be subject to approval by the Department of Health and Human Services.⁹⁰

The DOT renewed both the OPTN and the Scientific Registry contracts with UNOS for three years beginning September 30, 1993. The OPTN contract reimburses only fifteen percent—\$2.37 million over three years—of the cost; other funds are raised through fees charged to patients registered on the organ waiting lists. The Scientific Registry contract provides for \$4.9 million over three years. Both contracts contain new, detailed requirements concerning the operation of the OPTN and its relationship with the federal government. For example, the OPTN contract mandates creation of a data committee, random waiting list audits, twenty-four-hour electronic access to UNOS policies and by-laws and electronic access for the Health Resources and Services Administration, a communications plan, and professional education activities targeting trauma physicians and surgeons, emergency room nurses, coroners, and medical examiners. The contract also imposes limits on registration fees for the computer waiting lists.⁹¹

d. Prohibition on Sale

NOTA's fourth significant provision is the prohibition on buying or selling organs for "valuable consideration." NOTA defines the term "valuable consideration" to exclude "the reasonable payments associated with the removal, transportation, implantation, processing, preservation, quality control, and storage of a human organ or the expenses of travel, housing, and lost wages incurred by the donor of a human organ in connection with the donation of the organ."⁹²

88. See Omnibus Budget Reconciliation Act of 1986, *supra* note 80.

89. Health Omnibus Programs Extension of 1988, Pub. L. No. 100-607, 102 Stat. 3048 (codified at 42 U.S.C. §§ 273, 274, 274a-274e (1988)).

90. Letter from James Mason, Assistant Secretary for Health and Acting Surgeon General, Department of Health & Human Services, to Robert Corry, President, United Network for Organ Sharing (Sept. 22, 1989) (on file with author).

91. *New OPTN, Scientific Registry Contracts Foretell Increased Responsibilities*, UNOS UPDATE, Nov. 1993, at 2, 9.

92. 42 U.S.C. § 274e(c)(2) (1988).

Congress apparently was galvanized into action banning the sale of human organs and tissues largely in response to a plan by H. Barry Jacobs, who established a company in Virginia to broker human kidneys. According to press reports, Jacobs, whose license to practice medicine was revoked in 1977 after a mail fraud conviction involving Medicare and Medicaid reimbursement, intended to broker kidneys from healthy, living donors at an agreed-upon price to which Jacobs would add \$2,000 to \$5,000 for his services.⁹³ Jacobs testified before Congress that he also intended to bring Third World indigents to the United States so that the company could sell their kidneys. Congress responded by banning the sale of human organs and tissues.

The most notable feature of NOTA is what it does not do. Compared to the wealth of regulation that surrounds the dispensing of prescription drugs or the provision of medical care, the 1984 NOTA stands in stark contrast with its bare skeletal nature, the relatively small funding authorized to carry out its programs, and the congressional willingness that NOTA evidences to defer the standardization and regulation of organ procurement, distribution, and transplantation services to private industry and to the states. The decade since passage of NOTA, however, has witnessed significant expansion of the OPTN and of the DOT, greatly increased federal oversight of the OPTN, OPOs, and transplanting hospitals, and new legislation promising further federal regulation.

2. *Pending Organ Transplant Legislation and Regulation*

Bills to reauthorize NOTA were introduced in both the House and the Senate in 1993. Although neither passed, due largely to the controversy surrounding health care reform generally, the provisions of the two major bills reflected a widespread consensus to substantially increase federal regulation of organ transplantation.⁹⁴ For example, the bills required the creation of a single national list for U.S. citizens and permanent residents and a single national list for foreign nationals. The OPTN would no longer be free to allocate organs based on the consensus of medical professionals. Similarly, the bills required each OPO to maintain a single waiting list and to centralize the waiting lists for organs and the lists of potential bone marrow donors. The legislation subjected OPTN user fees to approval by the Secretary of Health and Human Services. The bills also initiated a General Accounting Office investigation into procurement and distribution practices.

Whereas NOTA focused on transplant-related institutions (e.g., the OPTN, OPOs, transplanting hospitals), the proposed legislation focused instead on individuals involved in the transplant process such as donors, people on the waiting list, recipients, and their families. For example, the bills reduced the OPTN board of directors from thirty-two to twenty-one members and would have required that at least one-third of both the UNOS board and OPO boards be recipients, recipient families, donor families, people waiting for organs, and their families.

93. Margaret Engel, *Doctor Plans Company to Arrange Sale of Human Kidneys*, WASH. POST, Sept. 19, 1983, at A9.

94. 139 Cong. Rec. S14,529, S14,537 (daily ed. Oct. 27, 1993) (statement of Sen. Kennedy); 139 Cong. Rec. H4756 (daily ed. July 15, 1993) (statement of Rep. Franks).

While the proposed legislation did not pass during the 1994 legislative year, the Secretary of Health and Human Services finally did issue the comprehensive regulations governing organ procurement and distribution first promised in 1989.⁹⁵ The September 8, 1994, release includes interim final rules governing OPOs and a notice of proposed future rules applicable to the OPTN and transplant programs.

III. THE ROLE OF LAW

The expanding legal regime governing transplantation is almost wholly at odds with the legal principles that are emerging in the larger health policy context. Health policy analyst and law professor James Blumstein has characterized those trends in the broad health policy context as "market-oriented" values, including the increased use of financial incentives and enhanced respect for pluralism and decentralization.⁹⁶ The government's organ transplant policy runs directly counter to these trends, emphasizing instead altruism, centralization, and a weighing of competing interests that focuses on the needs of donor and donor families to the virtual exclusion of the interests of would-be recipients whose lives hang in the balance and of society as a whole.⁹⁷ Perhaps because it is so out of synch, that policy has proven to be ill-conceived, poorly implemented, underfunded, and rarely enforced.

In the case of organ donation, transplant law offers no incentives for individuals to donate or for health professionals and institutions to facilitate donation. On the contrary, the law largely impedes donation. For example, despite overwhelming public support for transplantation, current law assumes that no one wishes to donate organs or tissues upon death. According to a 1990 Gallup poll, ninety-four percent of Americans report having heard or read about organ transplants; eighty-four percent believe that transplants are successful in prolonging and improving the quality of life; eighty-nine percent said that they were likely to honor loved ones' requests that their organs be donated after their death.⁹⁸ Still, the law presumes an unwillingness to donate.

The law provides two avenues around this presumption. First, an individual may sign a donor card or otherwise indicate a willingness to donate.⁹⁹ But many impediments prevent a donor card from having any effect. While every state and the District of Columbia mention organ donation in connection with drivers licenses, only ten have a donor card as part of the license.¹⁰⁰ Of those states providing a check-off box,

95. Organ Procurement and Transplantation Network, 59 Fed. Reg. 46,482 (1994) (providing notice of proposed rulemaking); Medicare and Medicaid Programs; Conditions of Coverage for Organ Procurement Organizations, 59 Fed. Reg. 46,500 (1994) (providing interim final rule).

96. See James F. Blumstein, *The Case for Commerce in Organ Transplantation* 5 (1992) (unpublished manuscript, on file with author) [hereinafter *The Case for Commerce*]; James F. Blumstein, *Reevaluating the Federal Role in Organ Transplantation Policy: The Relationship Between the Government and the Organ Procurement and Transplantation Network*, Address at the Impact of Changing Structure on Standards of Health Care Conference, University of Virginia School of Law (June, 1989); James F. Blumstein, *Government's Role in Organ Transplantation Policy*, 14 J. HEALTH POL., POL'Y & L. 5 (1989).

97. See, e.g., *The Case for Commerce*, *supra* note 96, at 2-5.

98. GALLUP ORGANIZATION, *THE U.S. PUBLIC'S ATTITUDES TOWARD ORGAN TRANSPLANTS/ORGAN DONATION* 3 (1990).

99. UAGA § 2(a)-(c), 8A U.L.A. 19, 33-34 (1993).

100. *Driver's License Survey Completed*, UNOS UPDATE, Jan. 1992, at 1. Arkansas, Colorado, Illinois,

twelve states and the District of Columbia cover their licenses in a nonmarkable laminated surface, so that the box must be checked prior to issuance of the license.¹⁰¹ Twenty-eight percent of those surveyed in the 1990 Gallup poll reported completing a donor card—less than a third of those who claimed they were willing to donate¹⁰²—and very few people who complete the cards have them in their possession at the time of death.¹⁰³

Despite laws in most states placing an obligation on law enforcement officials to search for a donor card on accident victims,¹⁰⁴ “[n]o state has a comprehensive procedure to be followed by law enforcement and medical personnel who might be involved with accident victims for determining if a potential donor is carrying a card.”¹⁰⁵ On the contrary, procedures for emergency fire and hospital personnel quickly separate injured people from their wallets and purses.

Even if a valid donor card is found and presented to the physician in charge of the patient’s care, doctors and hospitals fear professional criticism and legal liability if they procure organs against the wishes of the next-of-kin. Donor cards are legally binding in forty-eight states¹⁰⁶ and health professionals who act on them are immune from liability under the UAGA in every state,¹⁰⁷ but the cards have proven to be useless unless next-of-kin approve the donation.

The second, and by far more important, means to obtain consent is from the next-of-kin.¹⁰⁸ But federal and state routine inquiry and required request laws have proven to be ineffective. One study found that thirty percent of the families of medically appropriate potential donors were never asked, despite the legal obligation to do so.¹⁰⁹ Another, more recent study found that forty-seven percent of medically suitable patients were “overlooked” by hospital personnel.¹¹⁰ Even where requests are made, families increasingly refuse to donate. In fact, “[t]he most common reason for lost donors . . . is denial of consent from next-of-kin. In 1989, more than half of those asked said no.”¹¹¹

The reasons for the increase in refusals are unclear, but certainly include both inappropriate, ill-timed, and insensitive requests and declining public confidence in the

Iowa, Kentucky, Missouri, Nebraska, New Hampshire, New York, and Virginia are the states which have donor cards as part of their licenses. *Id.*

101. *Id.* at 3.

102. GALLUP ORGANIZATION, *supra* note 98, at 3, 6.

103. Arthur L. Caplan, *Organ Procurement: It's Not in the Cards*, HASTINGS CENTER REP., Oct. 1984, at 10.

104. UAGA § 5(c), 8A U.L.A. 19, 47 (1993).

105. Thomas D. Overcast et al., *Problems in the Identification of Potential Organ Donors*, 251 JAMA 1559, 1561 (1984).

106. *Developments—Medical Technology and the Law*, 103 HARV. L. REV. 1520, 1619 (1990). Florida and New York grant certain family members the right to veto the deceased’s decision to donate organs. FLA. STAT. ANN. § 732.912(3) (West Supp. 1990); N.Y. PUB. HEALTH LAW § 4301(3) (McKinney Supp. 1994).

107. UAGA § 11(c), 8A U.L.A. at 59-60.

108. *Id.* § 3(a), at 40.

109. ASSOCIATION OF ORGAN PROCUREMENT ORGANIZATIONS, OPO DIRECTORS SURVEY 1 (1989).

110. Steven E. Ross et al., *Impact of a Required Request Law on Vital Organ Procurement*, 30 J. TRAUMA 820 (1990).

111. Michael Evanisko, *The Organ Donation Enigma . . . A Medical Crisis With a Cure*, FOR PATIENTS ONLY, Nov.-Dec. 1991, at 14, 16.

fundamental fairness of transplantation.¹¹² It comes as no surprise that if the government requires overworked health professionals to make a request that is difficult and unpleasant, for which neither training nor reimbursement is offered, those requests are not likely to succeed. And to date, there is no reported case of a government agency seeking to enforce routine inquiry or required request laws.

The law thus presumes that a person does not want to donate and then minimizes the likelihood that a donor's legally expressed desire to donate will be respected. Those laws that encourage transplantation, such as required request statutes, frequently receive inadequate resources to assure their implementation and little if any enforcement. In short, the legal framework is stacked against donation.

IV. ALTERNATIVES

The legal system is not without options for addressing some of the problems with transplantation that it has contributed to creating. Alternatives to the voluntary consent and required request systems currently are used in various states and foreign countries. The real question is whether sufficient political will exists to investigate and, where appropriate, implement those alternatives.

A. *Presumed Consent*

The most dramatic alternative to the voluntary consent system—under which it is presumed that a person does *not* wish to donate human body parts—is a “presumed consent” system, under which the presumption is that the decedent *does* want to donate. Instead of registering consent by carrying a donor card, under a presumed consent system one registers a desire *not* to donate by carrying a “*non-donor*” card or through some other system.

Presumed consent systems are being used, to varying degrees, in sixteen countries.¹¹³ In Finland, Greece, Italy, Japan, Norway, and Spain, doctors ask the next-of-kin whether they object to the donation. In Austria, Czechoslovakia, Denmark, France, Israel, Poland, Singapore, and Switzerland, the law permits doctors to proceed with removal of needed organs absent notice of a prior objection by either the decedent or the next-of-kin, though in actual practice doctors seldom do.¹¹⁴

Another form of presumed consent presumes the decedent's consent to donate organ and tissues only after a “reasonable” or “diligent” search is made to determine whether the decedent objected to donation prior to dying. Most likely, the search should

112. *Id.* at 16. Evanisko states that “an ineffective request was a key contributing factor.” *Id.*

113. Austria, Belgium, Czechoslovakia, Denmark, Finland, France, Greece, Israel, Italy, Japan, Norway, Poland, Singapore, Spain, Sweden, and Switzerland.

114. See Theodore Silver, *The Case for a Post-Mortem Organ Draft and a Proposed Model Organ Draft Act*, 68 B.U. L. REV. 681, 703 (1988); William M. Gerson, Note, *Refining the Law of Organ Donation: Lessons from the French Law of Presumed Consent*, 19 N.Y.U. J. INT'L L. & POL. 1013 (1987); A. Cantaluppi et al., *Legal Aspects of Organ Procurement in Different Countries*, 16 TRANSPLANTATION PROC. 102 (1984); Frank P. Stuart et al., *Brain Death Laws and Patterns of Consent to Remove Organs for Transplantation From Cadavers in the United States and 28 Other Countries*, 31 TRANSPLANTATION 238, 239 (1981).

involve trying to notify the decedent's next-of-kin to give the next-of-kin an opportunity to rebut the presumption of consent.

This alternative is followed in a number of states which permit coroners to remove body parts for research or transplant purposes from cadavers within the coroner's jurisdiction or for which an autopsy is required, or both. For instance, twenty-one states currently have some form of presumed consent law that applies to the removal of corneas for transplantation.¹¹⁵ These laws generally provide that a coroner or medical examiner may remove the corneas from a cadaver in the course of a legally-required autopsy, provided that a need for the tissues is demonstrated and that no objection from either the decedent or the next-of-kin is known. Many of these states require that before removing corneas, the coroner or medical examiner make a reasonable search to determine whether such objection exists. Seventeen states permit the removal of pituitary glands under similar conditions.¹¹⁶

The revised UAGA permits a coroner or medical examiner to remove body parts from a cadaver within the official's custody provided that the parts are needed, and a "reasonable effort" is made first to determine if the decedent had objected to making an anatomical gift.¹¹⁷ The UAGA also permits the local public health officer to release a cadaver that is not already within the custody of the coroner or medical examiner for the purpose of removing organs and tissues for transplantation or therapy.¹¹⁸

B. Compensation

Another significant alternative to elicit donations is the use of financial incentives. As noted above, NOTA prohibits the purchase and sale of human organs and tissues for "valuable consideration."¹¹⁹ This provision acts as a positive prohibition on the use of

115. See ARIZ. REV. STAT. ANN. § 36-851 (1993); CAL. GOV'T CODE § 27491.47 (West 1988); COLO. REV. STAT. § 30-10-620 (1986); CONN. GEN. STAT. ANN. § 19a-281 (West 1986); DEL. CODE ANN. tit. 29, § 4712 (1991); FLA. STAT. ANN. § 732.9185 (West Supp. 1994); GA. CODE ANN. § 31-23-6 (1991); ILL. REV. STAT. ch. 110½, para. 351 (1991); KY. REV. STAT. ANN. § 311.187 (Michie/Bobbs-Merrill 1990); MD. CODE ANN. EST. & TRUSTS § 4-509.1 (1991); MASS. GEN. L. ch. 113, § 14 (1992); MICH. COMP. LAWS ANN. § 333.10202 (West 1992); MISS. CODE ANN. § 41-61-71 (1993); NEB. REV. STAT. § 71-4813 (1990); N.Y. PUB. HEALTH LAW § 4222 (McKinney 1985 & Supp. 1994); N.C. GEN. STAT. § 130A-391 (1992); OHIO REV. CODE ANN. § 2108.60 (Baldwin 1987); TEX. HEALTH & SAFETY CODE ANN. §§ 693.012 (West 1992); VA. CODE ANN. § 32.1-287 (Michie 1992); WASH. REV. CODE ANN. § 68.08.300 (West 1985); W. VA. CODE § 16-19-3a (1991).

116. See ARK. CODE ANN. § 12-12-320 (Michie 1987); CAL. GOV'T CODE § 27491.46 (West 1988); COLO. REV. STAT. § 30-10-621 (1986); CONN. GEN. STAT. ANN. § 19a-281 (West 1986); KAN. STAT. ANN. § 19-1033 (1981); MICH. COMP. LAWS ANN. § 333.2855 (West 1992); MINN. STAT. § 390.36 (1992); MISS. CODE ANN. § 41-61-71 (1993); MO. REV. STAT. § 58.770 (1986); NEB. REV. STAT. § 71-4813 (1990); N.Y. PUB. HEALTH LAW § 4222 (McKinney 1985 & Supp. 1994); OHIO REV. CODE ANN. § 2108.53 (Baldwin 1987); OKLA. STAT. tit. 63, § 944.1 (1991); TENN. CODE ANN. § 68-30-301 (1992); VT. STAT. ANN. tit. 18, § 510 (Supp. 1993); VA. CODE ANN. § 32.1-287 (Michie 1992); WASH. REV. CODE § 68.50.106 (1992 & Supp. 1993).

117. UAGA § 4(a), 8A U.L.A. at 43.

118. *Id.* § 4(b), at 43.

119. 42 U.S.C. § 274e(a) (1988). The term "organ" is defined by this section of the Act to include: "the human (including fetal) kidney, liver, heart, lung, pancreas, bone marrow, cornea, eye, bone, and skin, . . . and any other human organ . . . specified by the Secretary of Health and Human Services by regulation." *Id.*

financial incentives to encourage organ donation, even in the face of dramatic organ shortages and increasing waiting lists. This section was adopted without study of the possible consequences and without justification for the exclusion of financial incentives from this one area of medical practice. Moreover, the text of the prohibition permits payments to everyone involved in the transplant process *except* the donor and his or her family. The government's determination not to allow payment for organs and tissues has restricted the development of any type of financial incentive for enhancing the supply of organs, despite the widely recognized fact that the supply of transplantable organs falls far short of the need. The decision has raised concerns about the seriousness of the government's commitment to saving lives with transplantation and the fundamental fairness of the transplant system. The public cannot be expected to tolerate indefinitely payment to everyone *except* organ donors. Consider this item from the February 21, 1991, UPI newswire:

MOORE, Okla. (UPI)—Susan Sutton's heart offered extended life to an Oklahoma City man, her liver was donated to a patient in Pennsylvania and her corneas went to Texas for eye transplants.

Her bones will be used for reconstructive surgery and some of her skin will provide grafts for victims of burns.

The rest of her body was to be buried Wednesday in an unmarked grave.

Her mother, Judy Sutton of Moore, said it isn't right that her 27-year-old daughter, who died Friday of a self-inflicted gunshot wound, should be buried in a pine box without a marker because her family cannot pay for anything better.¹²⁰

There are alternatives to the outright sale of a body part. Examples include: a controlled, government-regulated market;¹²¹ tax incentives;¹²² allowing the hospital in which the donor died to reduce the donor's hospital bill by an amount not to exceed the value of the organ or tissue removed; a discount on insurance premiums in exchange for a binding commitment to donate body parts upon death, for which the insurance company would be reimbursed by the hospital or the government; payment to the charity of the donor's choice;¹²³ preferential access to an organ or tissue bank;¹²⁴ and credits for college tuition or vocational training expenses.¹²⁵ Compensation may not

§ 274e(c)(1). This definition obscures the difference between organs and tissues, and indicates that federal regulations dealing solely with organs, at least with regard to the prohibition against selling organs, apply to tissues as well.

120. *Organ Donor Goes to Unmarked Grave*, UPI, Feb. 21, 1990, available in LEXIS, Nexis Library, UPI File.

121. See Henry Hansmann, *The Economics and Ethics of Markets for Human Organs*, 14 J. HEALTH POL., POL'Y & L. 57 (1989); Richard Schwindt & Aidan R. Vining, *Proposal for a Future Delivery Market for Transplant Organs*, 11 J. HEALTH POL., POL'Y & L. 483, 489 (1986).

122. See generally Note, *Tax Consequences of Transfers of Bodily Parts*, 73 COLUM. L. REV. 842, 856 (1973).

123. Schwindt & Vining, *supra* note 121, at 495.

124. *Id.*; see also Note, *The Sale of Human Body Parts*, 72 MICH. L. REV. 1182, 1218 (1974).

125. Schwindt & Vining, *supra* note 121, at 496.

need to reflect the approximate value of the donated organs or tissues in order to provide an effective incentive for donation. Even a relatively insignificant payment may serve as a sufficient incentive or a symbolic motivator to cause those people who are already predisposed to donate to execute a donor card.

Debate over what property interests exist in the human body exacerbates the issue of incentives. The issue should be of more than passing interest—not only because of its profound ethical implications—but because the current confusion over whether a donor has property rights in donated organs and tissues is a significant impediment to the success of the altruistic supply system.¹²⁶

Professors Richard Schwindt and Aidan Vining have written that “[p]roblems emerge when something of value, in this case a human organ, is not clearly owned by anyone.”¹²⁷ If human organs and tissues were treated with the same official respect as real property—which, for instance, the police will act immediately and forcefully to protect upon the death of the owner—a far greater supply of transplantable body parts would result. Because no automatic transference of property interests in organs or tissues upon death to would-be recipients exists, the legal system does not protect the interests of recipients. People die for lack of those organs, but the legal system treats those organs as having no value.

Ill-defined legal interests in human bodies affect financial incentives for organ procurement and transplantation, developing mechanical and chemical means for prolonging organ viability, developing medical treatments involving transplantation, research using donated organs and tissues, insurance coverage for transplant facilities and procedures, and legal standing for enforcing procurement and processing standards.

C. Medical Alternatives

Important medical advances may help reduce the shortage of organs, but each of these poses significant legal, as well as ethical, issues. For example, one issue to reevaluate is how to measure the absence of brain activity in order to determine death. The Uniform Determination of Death Act merely refers to “accepted medical standards,” but those standards vary from state to state and, in fact, from hospital to hospital. Some medical standards still require that two electroencephalograms be performed twenty-four hours apart. If approximately fifty percent of all potential donors succumb within twenty-four hours of admission to a hospital, however, one-half of the potential pool of donors is ineligible to donate under such a standard.¹²⁸

This standard is particularly important when we consider the use of anencephalic infants as organ donors. Anencephaly is “uniformly and rapidly fatal,”¹²⁹ but because

126. See, e.g., *Moore v. Regents of the Univ. of Cal.*, 793 P.2d 479, 483 (Cal. 1990) (stating that whatever property interest in his cells the plaintiff at one time possessed, the court doubted whether he retained any ownership interest following their removal; however, “a physician who is seeking a patient’s consent for a medical procedure must, in order to satisfy his fiduciary duty and to obtain the patient’s informed consent, disclose personal interests unrelated to the patient’s health, whether research or economic, that may affect his medical judgment”).

127. Schwindt & Vining, *supra* note 121, at 486.

128. Roger W. Evans et al., *Donor Availability as the Primary Determinant of the Future of Heart Transplantation*, 255 JAMA 1892 (1986).

129. Dale L. Moore, *Anencephalic Infants as Sources of Transplantable Organs*, 30 JURIMETRICS J. 189,

of the current brain death criteria, it is often impossible to determine whether any infant less than seven days old—much less an anencephalic infant—has suffered “irreversible cessation of all functions of the entire brain, including the brain stem.”¹³⁰ All too often, by the time the criteria are met, the infant’s organs have become unusable for transplantation. The concern is not how death is defined; rather, it is how death is determined.

The use of living donors, both related and unrelated, should be reexamined. Once cadaveric transplantation became routine, the medical community largely abandoned the use of living kidney donors. Yet studies suggest that kidneys from living related donors make better transplants and that the procedure poses little risk to the donor.¹³¹ Moreover, the transplantation of portions of livers from living, related donors has the very real potential of expanding the supply of organs.

Xenotransplantation—the use of animal organs and cells—offers increasing promise.¹³² Dr. Thomas Starzl’s transplantation of a baboon liver into a thirty-five-year-old man with hepatitis B in 1992, like the case of Baby Fae years earlier, has raised both hopes for the future of xenotransplantation and a storm of ethical debate.

Medical technology now makes it possible to remove kidneys from non-heart-beating cadaveric donors.¹³³ To do so, however, immediately after death, physicians must insert a catheter and perform a cooling procedure necessary for subsequent salvaging of the kidneys. Performing these procedures on a cadaver which neither consented to donation while alive nor for whom consent was obtained from next-of-kin raises important issues. In fact, each of these advances, like transplantation itself, raises serious legal and ethical issues.

V. THE ROLE OF LAWYERS

Lawyers have at least three roles to play if we are to eliminate the current ambiguity surrounding the impact of law on transplantation and contribute to resolving the fatal shortage of transplantable organs. First, lawyers must help investigate alternatives to current transplant practice and, where necessary, participate in altering the existing legal structure to make it possible for new procedures to be implemented.

Second, because of relationships of trust between lawyers and clients, the legal profession has an unusual opportunity to raise the issue of donation, to provide accurate information concerning the legal right of every adult to donate, and to both provide advice to and act on behalf of clients to assure that a decision to donate is followed when medically appropriate.

189 (1990).

130. UDDA § 1, 12 U.L.A. 414, 414 (Supp. 1994).

131. C.F. Anderson et al., *The Risks of Unilateral Nephrectomy: Status of Kidney Donors 10 to 20 Years Postoperatively*, 60 MAYO CLINIC PROC. 367 (1985).

132. J.S. Najarian, *Overview of In Vivo Xenotransplantation Studies: Prospects for the Future*, 24 TRANSPLANTATION PROC. 733 (1992).

133. David Anaise et al., *An Approach to Organ Salvage From Non-Heartbeating Cadaver Donors Under Existing Legal and Ethical Requirements for Transplantation*, 49 TRANSPLANTATION 290 (1990).

The third and most important role for lawyers to play, however, is guaranteeing the integrity of the organ procurement, distribution, and transplantation system. For transplantation to truly succeed, the public—as citizens and as potential donors—must have confidence in the basic fairness and accuracy of the systems that regulate transplantation in this country. A Caucasian on the kidney waiting list has a one-in-six chance of transplantation within one year of being listed.¹³⁴ An African-American has a one-in-thirteen chance.¹³⁵ On average, African-Americans wait twice as long as Caucasians.¹³⁶ While African-Americans constitute twelve percent of the population in the United States, they account for approximately thirty percent of patients on the national kidney waiting list. The organ distribution system does not appear to be fair. Not surprisingly, studies show that African-Americans and other minorities are far less likely than Caucasians to donate.¹³⁷

Similarly, no one is placed on the national waiting list for an organ unless he or she demonstrates the ability to pay—the so-called “green screen.” Transplants are very expensive—in many cases over \$100,000.¹³⁸ In addition, permanent maintenance on immunosuppressive drugs and other medical care associated with the transplant may cost between \$17,000 and \$68,000 annually.¹³⁹ According to Roger Evans, organ acquisition charges are increasing far above inflation—sixty-four percent for hearts and sixty-two percent for livers since 1985—and costs vary widely—between \$11,289 to \$24,161 for a kidney.¹⁴⁰ The efficiency of OPOs in obtaining organs varies as well, with OPOs obtaining organs from between twenty-five and ninety percent of potential donors.¹⁴¹ “Some transplant hospitals routinely mark up by as much as 200 percent the charges that are billed by organ procurement organizations.”¹⁴²

While Medicare pays for most kidney transplants, and Medicare, Medicaid, and private insurers now cover most other transplants, an estimated sixty million people do not have insurance that covers transplants. They can give organs and tissues, but are virtually ineligible to receive them. Approximately thirty-seven million Americans have no effective access to health care at all. Nonetheless, although they are denied access—to transplantation and even to basic health services—we do not hesitate to ask for their organs. “It becomes,” in the words of Harvard immunologist Terry Strom, “the rich buying health at the expense of the poor.”¹⁴³ The law has an important role to play in addressing these inequities—both perceived and real—in the transplant system.

134. OFFICE OF INSPECTOR GENERAL, DEPT. OF HEALTH AND HUMAN SERVICES, *THE DISTRIBUTION OF ORGANS FOR TRANSPLANTATION: EXPECTATIONS AND PRACTICES* (1991).

135. *Id.*

136. See Testerman, *supra* note 14, at 1 (citing Dr. Clive O. Callender, Director of the Howard University Hospital Transplant Center).

137. L.M. Perez et al., *Organ Donation in Three Major American Cities With Large Latino and Black Populations*, 46 *TRANSPLANTATION* 553 (1988).

138. EVANS, *supra* note 3, at 24.

139. *Id.* at G-12.

140. Evans, *supra* note 20, at 3113.

141. *Id.*

142. *Id.*

143. Joel L. Swerdlow & Fred H. Cate, *Why Transplants Don't Happen*, *ATLANTIC*, Oct. 1990, at 99.

In addition to fairness, public confidence also depends on the system being rational. The federal government's policy of paying for immunosuppressive drugs only for the first eighteen months—recently extended to thirty-six months¹⁴⁴—following the transplant operation does little to bolster public confidence. Without a lifetime of daily doses of immunosuppressive, antirejection drugs—for which the government will not pay—the patient rejects the donated kidney and must be transplanted again—a procedure for which Medicare will pay. Similarly, the steadfast refusal of the government and transplant professionals to consider creative, if provocative, solutions to the dramatic shortage of organs does not build faith in the system. What do we say to Susan Sutton's mother: "Sorry, we'd like to help but Congress won't let us." It won't fly, as we are learning from declining consent rates throughout the nation.

Members of the Bar are uniquely skilled in influencing, critiquing, and challenging the government's legislative and regulatory activities. Attorneys are well-trained to spark a reexamination of laws and regulatory policies that are not working for the thousands who die while waiting for organs and the even greater number who are never listed. Lawyers can bring actions to assure that each individual's legal right to donate is respected. They can push for enforcement of required request and routine inquiry laws or argue for their repeal if they are ill-conceived. Lawyers can bring their experience in other health policy arenas to help design creative alternatives to the current system and lobby for the necessary legislative or administrative changes to see them implemented.

VI. CONCLUSION

State and federal laws relating to transplantation could aptly be described as schizophrenic. The Uniform Anatomical Gift Act and the Uniform Determination of Death Act created the essential groundwork for widespread clinical transplantation. Yet states have resisted enforcing requirements contained in these laws, such as routine inquiry and required request. Similarly, Congress' creation of the National Organ Procurement and Transplantation Network and of organ procurement organizations served vital needs in the procurement and distribution of organs. However, Congress reflected an apparent reluctance to commit adequate government resources or funds to these important tasks. Since passage of NOTA in 1984, Congress and the Department of Health and Human Services have steadily increased the regulatory mandate of the OPTN and regulation of the OPTN, OPOs, and transplanting hospitals, while waiting more than four years (thus far) to actually issue the regulations with which transplant-related organizations must comply. Congress has stressed consensus in decision making and the important role of patients, donors, and their families, while also pushing for increased centralization.

As was the case more than twenty years ago, when lawmakers were debating the legal definition of death and the ways in which an individual could consent to donation, transplantation today is confronted with significant issues that require, at least in part, a regulatory response. Administering the transplant system fairly and efficiently, allocat-

144. Omnibus Budget Reconciliation Act of 1993, Pub. L. No. 103-66, 107 Stat. 31 (codified at 42 U.S.C. § 1395x(s)(2)(J)(v) (Supp. 1993) (amending 42 U.S.C. § 1395x(s)(2)(J) (1988)).

ing scarce organs, and increasing the supply of organs for transplantation all urgently demand the attention of lawmakers and regulators. In a very real sense, transplantation today is constrained not by medical issues, but by legal ones, and their resolution is essential to save lives and reduce human suffering. Lawyers alone will not find right answers, but—as people well-placed in society—they must be part of asking the right questions.