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ORGAN DONATION AS NATIONAL SERVICE: A PROPOSED FEDERAL ORGAN DONATION LAW*

Linda C. Fentiman†

America's organ transplantation system is in crisis. At a time when transplant survival rates are at an all-time high, with more than ninety percent of kidney transplant recipients alive two years after transplant,¹ the waiting list for organs grows longer every day. Today, there are more than 26,000 individuals on a waiting list to receive a kidney, more than 2,900 persons waiting for a heart transplant, and a total of 35,000 individuals waiting for one or more vital organs.² Since 1988, more than 10,000 people have died while on a waiting list, while thousands more never even made it to a list.³

Twenty-five years from now, the tragedy of death due to the lack of an organ transplant may seem like ancient history. Artificial organs and tissues, fetal tissue transplantation, gene insertion technology, improved drug treatments, and xenografts may develop to the point that organ transplantation will no longer be the preferred treatment for many otherwise fatal illnesses. Alternatively, the scarcity of economic resources to provide for Americans’ health may grow so severe that only the very wealthy will be able to afford organ transplantation or other expensive forms of medical care.

But at the moment, we are at the point in history known as “meanwhile.”⁴ With organ transplantation holding out the only hope of survival for many persons, and for many others, the only hope of a good quality of life, there is tremendous pressure on medical and governmental policymakers to reform the present organ transplantation system to be both more effective and more fair in saving lives.⁵

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¹ Telephone Interviews with Donna Johnston, Office Assistant, Corporate Communications Department, United Network for Organ Sharing (Oct. 11, 1993 & Aug. 17, 1994).
² Telephone Interview with Donna Johnston, Office Assistant, Corporate Communications Department, United Network for Organ Sharing (Aug. 17, 1994).
³ U.S. GENERAL ACCOUNTING OFFICE, ORGAN TRANSPLANTS: INCREASED EFFORTS NEEDED TO BOOST SUPPLY AND ENSURE EQUITABLE DISTRIBUTION OF ORGANS 2 (1993) [hereinafter GAO REPORT].
⁴ United States v. Wiley, 492 F.2d 547, 555 (D.C. Cir. 1973) (Bazelon, J., concurring) (noting in context of rape corroboration requirement that whatever the future may hold, rules need to be developed which fit the current situation).
⁵ Although organ transplantation is initially expensive, prolonging someone's life through organ transplantation rather than through drugs or artificial organs is ultimately cost-effective. The cost of surgery and the first year of care for an average kidney trans-
Academics, physicians, and government officials writing from many perspectives have criticized the present organ transplantation system, both for failing to adequately tap the potential pool of transplantable organs and for failing to allocate the organs that are available on a more equitable basis.6

In April 1993, the General Accounting Office released a study that was highly critical of the United Network for Organ Sharing (UNOS), the private organization that coordinates transplantation services across the country pursuant to a contract with the federal government.7 The report also criticized the Department of Health and Human Services for its failure to adequately oversee UNOS and to ensure that organs are allocated strictly on the basis of medical criteria and not on the fortuity of being on the right transplant center’s list when an organ becomes available.8 Critics, Congressman Henry Waxman prominent among them, have noted that wealthy foreigners are somehow able to receive organs which are not available to American

plant procedure is $80,000 (in 1990 dollars). Thereafter, the annual cost of maintaining a transplant recipient on immunosuppressive drugs drops to $7,000. In contrast, maintaining an individual on kidney dialysis, a much less successful, palliative technology, costs an average of $33,000. These figures do not include the costs of unemployment while recovering from transplant surgery or while being maintained on dialysis. END STAGE RENAL DISEASE FOUNDATION, HEALTH CARE FINANCING RESEARCH REPORT (1990).

6. Recent changes in both the law and public attitudes toward seat belt use and drinking and driving, along with broad demographic trends, have combined to decrease the pool of available donors. Id. Current estimates of the number of potential donors range from approximately 5,000 to 29,000 per year, with a leading study suggesting that there may be no more than 6,900 to 10,700 such donors. Roger W. Evans et al., The Potential Supply of Organ Donors: An Assessment of the Efficiency of Organ Procurement Efforts in the United States, 267 JAMA 239, 241-42 (1992). During the period from 1986 to 1989, approximately 4,000 persons’ organs were donated for transplant. Id. For many years, proponents of the system of voluntary organ donation have argued that all that is necessary for an adequate supply of transplantable organs is to educate the public and, to a lesser extent, health care professionals, about the need for organ donation. See Arthur L. Caplan, Professional Arrogance and Public Misunderstanding, HASTINGS CENTER REP., Apr.-May 1988, at 34, 35 (noting health care provider noncompliance with required consent laws has been a primary problem). Others, however, have argued that only a dramatic rethinking of our approach to organ procurement and allocation will provide a significant number of organs. E.g., Jesse Dukeminier, Jr., Supplying Organs for Transplantation, 68 Mich. L. Rev. 811 (1970); Theodore Silver, The Case for a Post-Mortem Organ Draft and a Proposed Model Organ Draft Act, 68 B.U. L. Rev. 681 (1988).

7. See GAO REPORT, supra note 3, at 4-5 (charging that UNOS policies are inadequately enforced due to their voluntary nature and a lack of adequate documentation); see also 42 U.S.C. §§ 273-274 (1988) (authorizing Secretary of Health and Human Services to contract with private organization to coordinate transplant activities).

8. See GAO REPORT, supra note 3, at 3 summarizing findings that HHS inadequately monitors and evaluates activities of UNOS and organ procurement organizations).
citizens and permanent resident aliens. In addition, a number of recent studies have documented significant disparities between the rate at which white and black Americans receive organs for transplant and the amount of time they must wait for transplant organs. In part, these disparities are attributable to unequal distribution of human leukocyte antigens (HLAs) among different racial groups. These antigens are what trigger a "rejection" response when the body rejects a "foreign" (i.e., not genetically identical) organ transplant, and historically the extent of HLA matching, or the lack of mismatching, has been important in selecting the most suitable organ recipient. The difference in HLA tissue antigens in persons of various races has been offered to explain the disparity in transplantation statistics. However, reliance on HLA tissue matching as a major factor in organ allocation has been challenged on both scientific and ethical grounds.

In response to these and other concerns about the organ transplantation system, in the last Congress, the House of Representatives passed a bill requiring the Department of Health and Human Services to immediately promulgate regulations to replace the voluntary guidelines which now govern UNOS and organ transplantation centers. This law mandated the development of a single list of organ recipients for each organ procurement organization, with allocation to be made on the basis of strictly medical criteria. At the same time, American citizens and permanent resident aliens would receive absolute priority.


10. See e.g., Robert S. Gaston et al., Racial Equity in Renal Transplantation: The Disparate Impact of HLA-Based Allocation, 270 JAMA 1352, 1352 (1993) (reporting that blacks have highest incidence of chronic renal failure, yet receive fewer transplant organs); Fred P. Sanfilippo et al., Factors Affecting the Waiting Time of Cadaveric Kidney Transplant Candidates in the United States, 267 JAMA 247, 247-52 (1992) (exploring factors that may contribute to longer waiting periods for African-American transplant candidates). In 1990, African-Americans, who represent 12% of the general population, represented 31% of Americans awaiting kidney transplant, yet they received only 22% of the cadaveric kidney transplants. Gaston, supra, at 1352. The average waiting time for such a transplant was nearly 14 months, while Caucasian Americans had a wait of less than eight months. Gaston, supra, at 1352.


12. See Gaston, supra note 10, at 1355 (concluding alternatives to HLA-based allocation must be developed to remedy racial disparities); cf. GAO REPORT, supra note 3, at 24-26 (discussing UNOS criteria for organ transplantation and alternate selection criteria).


over foreign nationals in the allocation of organs for transplant.\textsuperscript{15} Finally, the law would diversify the membership of UNOS and other organ provider organizations to include more “citizen,” and less institutional, representatives.\textsuperscript{16} The Senate also addressed these and other issues in a similar bill, sponsored by Senator Edward Kennedy and others.\textsuperscript{17}

Yet even if these bills were to be reenacted by the new Congress, they would be insufficient to realize the promise of organ transplant technology for the thousands of Americans who die each year while awaiting a transplant. Since the late 1960s, when the development of immunosuppressive drugs made possible the receipt of an organ from a nongenetically related donor,\textsuperscript{18} academics and public policymakers have collaborated to develop mechanisms to encourage the donation of organs and tissues for transplant but have achieved only limited success. The Uniform Anatomical Gift Act (U.A.G.A.), first proposed in 1968, has been adopted by every state and the District of Columbia.\textsuperscript{19} The goal of the U.A.G.A. was to appeal to Americans’ altruism and to make it easy to volunteer to donate one’s organs and tissues, simply by signing a “donor card” (usually on obtaining a driver’s license) declaring the individual’s intent to donate his or her organs at the time of death.\textsuperscript{20} Yet despite the fact that sixty-two percent of Americans say they would like to donate their organs upon death, and that an even larger percentage indicate their willingness to donate the organs of a loved one,\textsuperscript{21} donor cards and the U.A.G.A. have had only minimal impact on increasing the supply of organs and tissue for donation. Many Americans have not signed a donor card, or their card is not found at the time they are declared dead.\textsuperscript{22}

\begin{itemize}
\item \textsuperscript{15} Id. (amending 42 U.S.C. § 273).
\item \textsuperscript{16} Id. (amending 42 U.S.C. § 273(b)(1)(G)).
\item \textsuperscript{17} S. 1597, 103d Cong., 2d Sess. (1993).
\item \textsuperscript{18} See Lloyd R. Cohen, \textit{Increasing the Supply of Transplant Organs: The Virtues of a Futures Market}, 58 GEO. WASH. L. REV. 1, 3 n.2 (1989) (tracing events that led to widespread availability of organ transplants).
\item \textsuperscript{21} See Evans, supra note 6, at 244-45 (noting surveys finding 45 to 50% willing to donate organs for transplant); Mimi Modarress, \textit{Organ Donation and Transportation: The Need for a Multipronged Approach for Equitable Avocation}, 37 HOSP. & HEALTH SERVICES ADMIN. 549, 553 (1992) (noting Gallup polls in 1980s found 70 to 80% willing to donate organs for transplant); Daphne M. Sipes, \textit{Does It Matter Whether There Is Public Policy for Presumed Consent in Organ Transplantation?}, 12 WHITTIER L. REV. 505, 506 n.6 (1991) (reporting study finding 73% indicated willingness to donate loved one’s organs).
\item \textsuperscript{22} See Robert M. Arnold & Stuart J. Youngner, Reply to Letters to the Editor, 270 JAMA 1930, 1931 (1993) (noting many do not have driver’s licenses and donor cards often
\end{itemize}
Whether this is due to people's psychological unwillingness to confront their death in a concrete manner, to procrastination, or simply to disorganized wallets, the fact remains that very few organ transplants occur solely on the basis of a donor card. Indeed, almost all American physicians and nurses refuse to go forward with retrieving organs for transplant without the consent of the dead donor's next of kin, despite the U.A.G.A.'s explicit provisions protecting those who rely on a donor card from legal liability. At the same time, because many health care providers are reluctant to approach grieving families with a request for organ donation, many opportunities for organ donation are lost. A number of factors have been offered to explain this reluctance, including a lack of education or cultural sensitivity on the part of health care workers, a concern about the appearance of overreaching a bereaved family, fear of legal liability, and the health care professional's own discomfort with death.

In response to the organ shortage under a system of voluntary organ donation, in 1986 Congress enacted "Routine Inquiry" legislation, mandating that all hospitals receiving Medicare or Medicaid reimbursement establish protocols pursuant to which all families of dead or dying potential organ donors will be asked to consider donating the organs of their loved one. Yet despite this law, and similar laws

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25. Id.; see also James F. Blumstein, Government's Role in Organ Transplantation Policy, 14 J. HEALTH POL. POL'Y & L. 5, 17 (1989) (stating that it is customary to seek family approval rather than rely on donor card).


27. See Caplan, supra note 6, at 35 (asserting that physician reluctance to approach families regarding organ donation is a primary obstacle).

28. See Blumstein, supra note 22, at 468-69 (discussing the "potentially ghoulish character" of approaching grieving family about organ donation); M.K. Gaedeke Norris, Required Request: Why It Has Not Significantly Improved the Donor Shortage, 19 HEART & LUNG 685, 685-86 (1990) (urging education and training of health care workers with respect to requesting organ donation); Peter A. Singer, A Review of Public Policies to Procure and Distribute Kidneys for Transplantation, 150 ARCHIVES INTERNAL MED. 523, 524 (1990) (suggesting that fear of legal liability and the emotional demands of requesting donation make physicians reluctant to approach families).

29. See 42 U.S.C. § 1320b-8 (1988) (requiring participating hospitals to establish protocol to ensure that families of potential donors are informed of donation option); accord 42
which have been enacted by more than thirty states, organ donation has remained static over the last several years, and in some localities, has actually declined.

Thus, it is time to consider an alternative approach to organ procurement and allocation—one that relies on presumed consent to organ donation, combined with incentives which recognize the communal basis of the obligation to donate one's organs after death. Such a system must provide numerous opportunities for "opting out" of donation in order to promote individual autonomy and use economic and eleemosynary incentives for persons to contribute their organs after death. Mere mention of the words "presumed consent" and "compensated donation" may raise ethical eyebrows. However, a system of presumed consent to compensated organ donation should be considered as a rational response to the present organ shortage. We must view organ donation as an act of community service, and support it in the way that we currently encourage service in a volunteer military or the Peace Corps, with the provision of subsidized education, health, and other benefits to those who serve.

Under my proposed statute, all mentally competent individuals over the age of eighteen would be presumed to have consented to the retrieval of their organs at the time of death. Medical personnel could


30. See Singer, supra note 28, at 524 (noting widespread enactment of state legislation requiring donation request).

31. See Singer, supra note 28, at 524 (stating that the organ supply in Oregon and California remained constant or decreased after legislation enacted); cf. Evans, supra note 6, at 242 (noting that attempts to increase organ supply have had only modest success).

32. These incentives include a provision that individual transplant centers may have "first crack" at the organs obtained from donors dying there, which is contrary to the proposal of House bill 2659. Model Statute § IV(A)(1). This provision makes it more likely that organs will be returned to the community from which they were obtained, potentially eliminating some of the racial disparities now apparent in organ allocation. The statute also provides for federal oversight of incentives offered to potential donors, through the establishment of the National Organ and Tissue Research and Transplantation Board (NOTRTB), which would annually determine the maximum compensation permitted for the donation of an organ. Model Statute § III(B)(2)(a), (C)(1).

33. The model statute also permits the parents of an anencephalic infant to donate their child's organs prior to death, recognizing anencephalics as a group of children who are sui generis. See infra note 51 and accompanying text (noting ethical debate over whether anencephalic infants should be permitted to be organ donors).


35. At least for the present, donation of minors' organs should not be presumed, in order to limit state intrusion at a time of parental grief. However, it is hoped that the national discussion on presumed consent to donation by adults would raise parental awareness of the possibility of donating a child's organs. A recent study of pediatric organ dona-
then begin the process of preparing a deceased individual's body for organ transplantation without waiting to find a donor card or the next of kin, which would enhance the viability of organs for transplant. Physicians would no longer need to confront a grieving family with the need to make a quick decision about organ donation, because that decision would be out of the family's hands. Concerns about a conflict of interest when an individual's organs are harvested for transplant to another patient at the same hospital would also be eliminated, because agreement to transplant would already be presumed.

The idea of a system of presumed consent is not new. It has been proposed by a variety of commentators over the last twenty-five years.\textsuperscript{36} It has also been adopted, in a variety of forms, in several European countries, notably Austria, Belgium, and the former Yugoslavia, as well as Israel, New Zealand, Singapore, and Tunisia.\textsuperscript{37} In more than twenty states, a presumed consent system for the donation of specific organs, most often the cornea and the pituitary gland, has been adopted for cases in which the decedent's body is under the authority of the medical examiner or coroner.\textsuperscript{38} This has resulted in the

\textsuperscript{36} See Dukeminier, supra note 6, at 837-42 (proposing legislation permitting organ removal unless donor previously objected).


restoration of sight to more than one-half million people, with only infrequent challenges.\(^{39}\)

Yet proposals for presumed consent to organ donation could be attacked as “un-American,” unsuited to a nation in which respect for individual autonomy and self-determination are at the pinnacle of the collective value system, and in which appeals to fears of creeping Big Brotherhood are often successful. Thus, it is important to explain why this proposal for presumed compensated organ donation meets objections based on autonomy, and how it can be seen as an appropriate community response to a community tragedy—the death of those whose lives could have been saved through the donation of organs from a person no longer living.

The first challenge that could be raised is that this statute would eliminate the opportunity for individual choice about whether to donate organs. Yet in fact, the statute I propose provides six separate occasions on which an objection to organ donation could be made. These are: when obtaining or renewing a driver’s license; on filing an income tax return; when applying for welfare disability or other governmental benefits; on every visit to a hospital or doctor’s office, when a health care provider explicitly requests a patient to consider donating her organs, and when executing a living will or health care proxy document.\(^{40}\) Each person’s objections to presumed donation would be recorded in a national computerized registry, which would be updated on a daily basis, and would be protected by appropriate back-up systems to prevent losing any objection.\(^{41}\) Some religious, civic, and civil liberties groups would undoubtedly react to the enactment of this

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\(^{39}\) See Emile J. Farge et al., The Impact of State Legislation on Eye Banking, 112 ARCHIVES OPHTHALMOLOGY 180, 183 (1994) (reporting that states’ limited presumed consent laws have led to a dramatic increase in corneal transplant donations); infra note 63 (noting litigation challenging presumed consent procedures).

\(^{40}\) Model Statute § III(C)(2).

\(^{41}\) Model Statute § III(C)(6).
proposed legislation by urging their members to opt out of the presumed consent system, thus promoting free and open debate and education about the propriety of organ donation. Because every citizen would have the ability to choose not to participate in the presumed consent system, respect for individual dignity and autonomy would be ensured.

Others might object that permitting compensation of any kind for the donation of organs and tissues is dehumanizing and that the proposed statute provides unseemly incentives for the poor to lose the last vestiges of their humanity through the violation of their corpse. But one must recognize that our society already grants the poor numerous opportunities to compromise their humanity and to risk their health based on monetary concerns. Among the examples which leap to mind are prostitution and other selling of their labor at relatively high wages in high-risk, low-prestige jobs, the poor’s lesser ability to buy safer cars than the wealthy, and poor adults’ inability to afford comprehensive health insurance for themselves and their families.

Further, under the current organ transplantation system, everyone profits except the organ donors: the transplant surgeons receive ego gratification, prestige, and money for their labor on the transplant team; the transplant center and its workers gain both an enhanced reputation and income; the nonprofit organ procurement organization maintains its raison d’etre — the business of organ procurement and allocation; and, of course, the organ recipient receives the gift of life itself. It is, frankly, hard to understand why even the offer of compensation for the donation of an organ will suddenly transform the vast American organ transplantation enterprise from an exalted and altruistic endeavor into a tawdry and venal business deal, the medical equivalent of haggling with a street vendor.42

In addition, if a poor (or a wealthy) person might choose to donate his or her organs after death in exchange for a decent burial, payment for medical treatment prior to death, priority in receiving an organ

42. Moore v. Regents of the Univ. of Cal., 51 Cal. 3d 120, 160, 793 P.2d 479, 506 (1990) (Broussard, J., concurring and dissenting) (rejecting the majority’s refusal to recognize a cause of action for conversion when a patient’s organ is removed and used as the basis for lucrative commercial medical research); 51 Cal. 3d at 165, 793 P.2d at 509-10 (Mosk, J., dissenting) (arguing that the concept of property, as a “bundle of rights,” ought to be construed broadly to include the power to receive valuable consideration for certain uses of one’s discarded organs). Indeed, a survey sponsored by UNOS found that 52% of the Americans surveyed supported the use of nonfinancial compensation for organ donation. A.H. Barnett & David L. Kaserman, The Shortage of Organs for Transplantation: Exploring the Alternatives, 9 Issues L. & Med. 117, 124-25 (1993).
transplant should the donor need one,\(^{43}\) a college tuition voucher for his or her children or grandchildren, or a gift to a favorite charity, it would be parentalistic interference of the worst sort to deny the donor the ability to make that rational trade-off. Since the National Organ and Tissue Research and Transplantation Board would establish maximum, uniform compensation for organ donation, all persons would be treated equally, both in deciding to opt "in" or "out" of the presumed consent system and in their receipt of compensation for the gift of life.

Finally, this statute achieves important communital goals because the statute treats organs and tissues as community resources, which are made available to medically appropriate candidates within that community. The statute states a preference that organs be offered first to a recipient from the donor's community.\(^{44}\) While allocation of scarce resources such as organs should generally be made in accordance with medical, not social, criteria, a blind insistence on absolute medical equity\(^{45}\) will cause other important goals to be overlooked, including increasing the organ supply by providing incentives to donate.\(^{46}\) Thus, for example, to the extent that young, urban African-Americans or other persons of color are likely to suffer an accidental or violent death and become a potential organ donor, a system of presumed consent, compensated donation, and preference for local use of organs will make more organs available to those communities which are presently not receiving an appropriate share.

The proposed model statute recognizes that organ donation is a powerful act of virtue. By relying on presumed consent and compensated donation and by giving a preference to local organ recipients, the model statute encourages persons to act on their altruistic impulses and makes it possible to save more lives through organ donation.

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43. See Kleinman & Lowy, supra note 24, at 109-10 (proposing incentive program that assures donors priority in the event that they need transplant in future).

44. Model Statute § IV(A)(1). This is contrary to current UNOS guidelines and rejects the GAO Report's recommendation that organs be allocated pursuant to a single list based solely on medical criteria, drawn from a wider geographical area. GAO REPORT, supra note 3, 5-6.

45. Indeed, it is impossible to reach consensus on just what "strictly medical" criteria should be used, or on the weight each criterion should be accorded. Gaston, supra note 10, at 1354.

46. Wayne B. Arnason, Directed Donation: The Relevance of Race, HASTINGS CENTER REP., Nov.-Dec. 1991, at 13, 17-18 (proposing consideration of recipient's race to alleviate discrimination resulting from HLA-based allocation of kidneys); Gaston, supra note 10, at 1354-55 (analyzing current HLA-based allocation of kidneys which results in disproportionate number of transplants to Caucasians).
MODEL ORGAN AND TISSUE TRANSPLANTATION STATUTE

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Preamble

The Congress of the United States hereby declares that there is a crisis in the provision of organ and tissue transplants to those Americans who will die without an organ or tissue transplant. The Congress further finds that there is a concomitant crisis in the lack of organs and tissues available to research the causes of a number of diseases which lead to premature death. These two crises consist of the following interrelated problems:

(1) a lack of sufficient organs and tissues to meet the demand for transplantation and research,

(2) an inequitable allocation of the existing supply of organs and tissues,

(3) inadequate protection of the interests of organ and tissue donors and donees in making an informed and autonomous decision, and
(4) inconsistent treatment of different organs, tissues, and organ and tissue systems under current federal and state law and private contract.

In order to remedy these inadequacies the United States Congress hereby enacts the following statute.

SECTION I: DEFINITIONS

The following terms have the meanings indicated:

(1) "Cell line" means a culture of cells derived from a human body and developed through recombinant DNA technology that is capable of reproducing indefinitely and exists apart from a human body.

(2) "Competent" means legally competent to will property in accordance with the law of testamentary capacity of a particular jurisdiction.

(3) "Individual" means any member of the species homo sapiens.

(4) "Organ" means any organ, tissue, organ group, or tissue group of the species homo sapiens.

(5) "Organ provider organization" (OPO) is an organization that provides administrative and logistical support for the transplantation of organs within a locality or region.

SECTION II: UNIFIED FEDERAL AUTHORITY OVER ORGANS AND TISSUES FOR TRANSPLANT AND RESEARCH

All organs and tissues retrieved in the United States, whether they are to be used for transplantation or research, shall be retrieved and allocated in accordance with uniform federal laws.47 There is hereby established the National Organ and Tissue Research and Transplantation Board (NOTRTB), an independent federal agency under the authority of the Secretary of Health and Human Services. The Board shall have authority to promulgate regulations to govern all aspects of organ and tissue procurement and distribution, in accordance with the mandate of this statute.48

47. This statute seeks to provide a uniform federal legal structure for organ and tissue transplantation and research, while simultaneously meeting the goals of federalism. Thus, to the extent that particular aspects of organ and tissue transplantation or research raise issues similar to those created by medical or surgical procedures, they should be treated comparably under applicable state or local law. See Model Statute § III(B)(1)(b) (concerning application of state law to the issue of informed consent to participation in organ transplantation and research); Model Statute § III(C)(2)(e), (5) (relating to use of living wills, durable powers of attorney for health care, and health care proxies to elect not to donate).

48. It is the goal of this statute to eliminate duplicative and inconsistent federal regulation and oversight of a variety of organ and tissue products. For example, organ and tissue products, including cell lines, which are "genetically engineered" through the use of recom-
SECTION III: INCREASING THE SUPPLY OF ORGANS

A. Organ Harvestibility

(1) Any individual may be a candidate for the removal of his or her organs or tissues, if any one of the following criteria is met:

(a) the individual has sustained irreversible cessation of circulatory and respiratory functions,\textsuperscript{49} or

(b) the individual has sustained irreversible cessation of all functions of the entire brain, including the brain stem,\textsuperscript{50} or

(c) the individual was born with all or a portion of his or her brain absent.\textsuperscript{51}

(2) A determination of whether one of the enumerated criteria has been met must be made according to accepted medical practice, by persons who are not part of any transplant or research team that would benefit, either directly or indirectly, from the use of harvested organs or tissues.

B. Provisions Relating to the Free Alienation of Homo Sapiens Organs and Tissue

(1) All competent individuals over the age of eighteen may donate any or all of their non-gametes\textsuperscript{52} organs or tissues whose presence in the body of any individual is not necessary to sustain his or her life.\textsuperscript{53}

\begin{itemize}
\item \textsuperscript{49} UNIF. DETERMINATION OF DEATH ACT § 1, 12 U.L.A. 386 (Supp. 1993).
\item \textsuperscript{50} Id. Thirty-one jurisdictions have adopted the "brain death" definition of death used in the Uniform Determination of Death Act. A number of other states have achieved the same result through either another statute or judicial decision.
\item \textsuperscript{51} This would permit anencephalic infants to be organ and tissue donors.
\item The model statute supports the idea that parents should be able to donate the organs of an anencephalic child, even though such a donation would accelerate the child's inevitable death. Because such children are "born dying" and can feel no pain, and because of the severe shortage of pediatric and newborn organs, it is believed that parental privacy and autonomy should be respected in this narrowly defined class of donors. \textit{But see} Committee on Bioethics, American Academy of Pediatrics, \textit{Infants with Anencephaly as Organ Sources: Ethical Considerations}, 89 PEDIATRICS 1116, 1118-19 (1992) (opposing organ donation from anencephalic infants with brain stem function). This statute proposes that parents of anencephalic infants be permitted to donate the infants' organs and tissues.
\item This statute does not preclude the donation or sale of \textit{homo sapiens'} gametes. Rather, the issue of whether such actions are appropriate is treated as outside the statute's scope. The extraction and use of fetal tissue is addressed in Professor Steven Hicks' article, \textit{The Regulation of Fetal Tissue Transplantation: Different Legislative Models for Different Purposes}, 27 SUFFOLK U. L. REV. 1613 (1993).
\item Whether or not a particular organ or tissue is necessary to sustain human life will change as medicine and medical technology evolve. Currently, for example, one may sur-
\end{itemize}
subject to conditions set forth in section (3). All competent individuals over the age of eighteen may donate any or all of their non-gamete organs whose presence in the body of the individual is necessary to sustain his or her life. However, such donation may not be effectuated until after the individual's organs are capable of being harvested, pursuant to section III(A), supra.54

(2) Donation of organs shall be subject to the following provisions:

(a) If the donation of the organ or tissue is to be compensated,55 the compensation provided may be no greater than the maximum permitted by the National Organ and Tissue Research and Transplantation Board (NOTRTB),56

(b) The individual shall be informed of the risks and benefits of the medical procedures necessary to remove the organ or tissue from his or her body as required by the applicable tort law57 of his or her jurisdiction and the provisions of this statute;58

(c) Prior to any organ or tissue being donated, the institutional review board (IRB) of the institution at which the removal will take place shall review the protocol under which the organ or tissue is being removed and determine that all ethical and legal requirements have been met;

vive with only one kidney and with a portion of one's liver. Additionally, a person may survive after donating a replenishable bodily tissue, such as blood or bone marrow.

54. This section makes possible the formation of an executory contract to donate organs post-mortem.

55. To the extent that donors would be permitted to receive an economic benefit for their donation, that portion of the National Organ Transplant Act which criminalizes the sale of human organs must be repealed. See 42 U.S.C. § 274e (1988) (criminalizing any transfer of transplant organs in exchange for valuable consideration). Many state codes have similar provisions prohibiting the sale of organs for transplant. E.g., GA. CODE ANN. § 16-12-160 (Michie 1992); HAW. REV. STAT. § 327-10 (1991); UTAH CODE ANN. § 26-28-10 (Supp. 1993).

56. The Board will annually establish the maximum compensation to be awarded for any bodily organ or tissue or group of organs or tissues. The maximum compensation may be calculated either as a dollar amount, or as the provision of certain defined services (such as the payment of the donor's burial or medical expenses), as the provision of a college tuition voucher, a tax-deductible gift to a charity chosen by the donor, or as a percentage of the profits to be derived from the commercial exploitation of the individual's tissues. But see Moore v. Regents of the Univ. of Cal., 51 Cal. 3d 120, 141-43, 793 P.2d 479, 497 (1990) (holding that a patient did not have a cause of action for conversion, permitting recovery of profits from the commercial exploitation of cell line derived from his spleen).

57. This includes both the common law and statutory law of torts.

58. This subsection, and the ones that follow, endeavor to meet the need for special vigilance to protect the interests of both donors and recipients which the law of informed consent generally seeks to protect. While, under this statute, organ procurement and allocation would take place in accordance with uniform federal procedures, the statute also acknowledges that organ and tissue transplantation and research are also a form of medical practice and technology, which should, insofar as possible, be governed by state law.
(d) The National Organ and Tissue Research and Transplantation Board will establish, through notice and comment rule-making under the Administrative Procedure Act, general ethical and legal requirements to ensure that informed consent has been obtained from all persons donating their organs or tissues, that there is sufficient scientific merit to a particular transplantation or research protocol to justify the risks involved to both the donor and recipient of the organ or tissue, and that no overreaching or undue pressure has been applied to either the donor or recipient of the organ or tissue;

(e) The National Organ and Tissue Research and Transplantation Board will promulgate regulations governing the review of particular research or transplant protocols which each institutional review board shall follow;\(^\text{59}\)

(f) The National Organ and Tissue Research and Transplantation Board shall annually publish a regulation in the Federal Register listing transplantation procedures which it deems so experimental as to not justify reimbursement by any third-party payor under the American Health Security Act.\(^\text{60}\)

C. Presumed Compensated Donation

(1) All competent individuals over the age of eighteen who have not opted out of the organ donation system, in the manner prescribed below, shall be presumed to have agreed to donate any needed organs or tissues and shall be offered by the organ recipient the amount of compensation established by the National Organ and Tissue Research Transplantation Board.\(^\text{61}\)

\(^{59}\) These regulations might be patterned on current Department of Health and Human Services rules governing institutional review board (IRB) oversight of human subject experimentation if it is determined that these regulations are effective in protecting vulnerable human subjects. See 45 C.F.R. § 46.109 (1993) (requiring IRB review of research protocols to ensure compliance with regulations).

\(^{60}\) The statute is written with the expectation that in the next several years there will be significant health care reform, at both the federal and state level. The Board would, for example, review autologous bone marrow transplants, to determine their efficacy and appropriateness for treatment of particular forms of cancer.

\(^{61}\) The presumed agreement to make a compensated donation has two goals. First and foremost, it recognizes the reality that the goals of a transplantation and research system based on the ideal of voluntary organ and tissue donation have not been realized and that the ever increasing success of organ and tissue transplantation has not been matched by an adequate supply of organs and tissues. See supra notes 21-31 and accompanying text (discussing failure of "required request" and "routine inquiry" legislation to fulfill current organ transplant needs).

Second, faced with the static number of potential organ and tissue donors, a number of institutions and commentators have suggested extreme measures to expand the pool of potential donors. One institution has developed a mechanism to orchestrate the manner and moment of dying in a way that enhances the number of persons who can be declared
(2) All competent individuals over the age of eighteen shall be provided the opportunity not to donate their organs or tissues, on all of the following occasions:

(a) when they file their annual federal income tax return,
(b) when they receive or renew a license to operate a motor vehicle,
(c) when they apply for benefits under Aid to Families with Dependent Children and other living assistance programs, including unemployment compensation and disability benefits,
(d) when they enter a hospital or physician's office for any treatment or procedure,
(e) when a health care professional specifically proposes to procure one or more of their organs or tissues, and
(f) when executing a living will or health care proxy document, as provided in (5) below.

(3) On each of these occasions, all competent individuals over the age of eighteen years shall be given the opportunity to elect what form of compensation, if any, they wish to receive if their organs are given for transplant.

"brain dead" in a hospital setting, permitting their organs to be quickly harvested. See Michael A. DeVita & James V. Snyder, Development of the University of Pittsburgh Medical Center Policy for the Care of Terminally Ill Patients Who May Become Organ Donors After Death Following the Removal of Life Support, 3 KENNEDY INST. ETHICS J. 131, 136-41 (1993) (discussing protocol developed to permit organ harvesting immediately after withdrawal of life support). But see Alan A. Weisbard, A Polemic on Principles: Reflections on the Pittsburgh Protocol, 3 KENNEDY INST. ETHICS J. 217, 223-25 (1993); and Renee C. Fox, "An Ignoble Form of Cannibalism": Reflections on the Pittsburgh Protocol for Procuring Organs from Non-Heart-Beating Cadavers, 3 KENNEDY INST. ETHICS J. 231, 233-34 (1993) (criticizing the rush to avoid tissue damage due to warm ischemia at any cost). Others have suggested that the criteria for the harvesting of organs should be redefined to include persons in a persistent vegetative state and anencephalic newborns. Each of these proposals has a number of detractors. It is ultimately a moral question as to whether it is appropriate to drastically alter conventional notions of death and dying in order to increase the supply of organs and tissues. It is a political question as to whether public enthusiasm for organ donation is so strong that people will be willing to support such radical redefinitions of life and death.

The proposal to permit people to agree to donate their organs in exchange for some form of compensation is not new. See Cohen, supra note 18, at 2 (proposing to permit persons to contract for sale of their organs, to be harvested after death); Kleinman & Lowy, supra note 24, at 133-34 (concluding that compensation and organ markets are most preferable alternatives to the current donation system). However, despite the objections of many commentators to reliance on market forces to achieve a greater supply of organs and tissues, the fact remains that appeals to altruistic instincts to assist our fellow human beings have not been successful, and there are a number of psychological and organizational barriers to the successful recruitment of voluntary donors. A system of presumptive compensated donation would eliminate many of these hurdles, while still respecting the value of individual autonomy, by providing people with numerous opportunities to opt out of the system.
(4) The individuals may indicate that they:
(a) do not wish to donate any organs, or
(b) do not wish to donate specific organs.

(5) Any individual may declare, in a writing that meets the require-
ments of the laws of his or her jurisdiction relating to living wills, natu-
ral death, health care proxies, or durable power of attorney for health
care, that he or she does not wish to donate any organ or tissue at a
time when he or she meets the criteria for organ harvestibility.

(6) The names and addresses of all persons who have objected to
becoming an organ donor, under all or limited circumstances, shall be
maintained in the National Organ Availability Registry (NOAR), a
computerized registry which shall be maintained on a nationwide and
statewide basis, updated daily, and made available to qualified
health care personnel and employees of state and/or local medical ex-
aminers’ offices and funeral homes. This registry shall be maintained
in strict compliance with all applicable state and federal statutes gov-
erning patient privacy and confidentiality.

(7) Unless an individual has opted out, as described above, he or
she will be conclusively presumed to have agreed to divest himself or
herself of all medically needed and suitable organs at the moment that
he or she meets the criteria of organ harvestibility.

(8) No relative or friend of the individual may object to his or her
becoming an organ or tissue donor under these circumstances.

(9) No physician, health care provider, medical examiner, or fu-
neral home employee shall be held civilly or criminally liable for the
removal of any or all suitable organs and/or tissues if he or she checks
the National Organ Availability Registry and finds no record of objec-
tion to donation by the individual and has no other notice of the indi-
vidual’s objection.63

62. This daily updating mechanism ensures that not only will competent individuals be
able to “opt out” of organ sale or donation whenever they choose, but also that individuals
who previously opted out may, at any time, change their minds and opt in. This could
readily happen if a dying or ill individual was faced with an explicit request to donate, or if
an individual, confronted with the possibility of the death of a loved one, is asked to donate
an organ to that person. In both of these cases, the law of informed consent and the rigor-
ous procedures adopted by the National Organ and Tissue Research and Transplantation
Board will operate to ensure that no overreaching of vulnerable potential donors and sell-
ers occurs. See Model Statute § III(B), supra; cf: Arthur Caplan, Am I My Brother’s
biologically-related and emotionally-related living donors).

63. This provision is aimed at eliminating lawsuits such as those that have arisen chal-
 lenging actions under state presumed consent laws. See Brotherton v. Cleveland, 923 F.2d
477, 482 (6th Cir. 1991) (allowing suit against coroner who donated corneas of decedent
where spouse had refused donation at hospital); State v. Powell, 497 So. 2d 1188, 1191 (Fla.
1986) (holding statute providing presumed consent for corneal transplant constitutional);
SECTION IV: ENSURING MORE EQUITABLE ALLOCATION OF ORGANS AND TISSUES

A. The Principle of Geographic Priority: All Organs Shall Be Allocated First to the Community Where They Were Obtained

(1) All organs and tissues obtained for transplantation and research shall be offered first to the transplant or research center that is most closely associated with the locus of obtaining the organ or tissue.65

Nicoletta v. Rochester Eye and Human Parts Bank, Inc., 136 Misc. 2d 1065, 1067, 519 N.Y.S.2d 928, 930 (Sup. Ct. 1987) (complaint alleging hospital donated decedent’s eyes without ascertaining whether person who gave consent was decedent’s spouse); Callsen v. Cheltenham York Nursing Home, 154 Pa. Commw. 541, 544, 624 A.2d 663, 665 (1993) (suit against funeral home and hospital for failing to locate decedent’s family to obtain permission to donate body).

64. Organs and tissues shall be allocated for research or transplant on the basis of a ratio to be determined by the Federal Organ and Tissue Research and Transplantation Board. The Board shall annually determine, through notice and comment rulemaking under the Administrative Procedure Act, the appropriate percentage for each organ and tissue category that shall be allocated to the needs of research or transplantation. No individual or health care provider or institution shall be able to appeal from or otherwise challenge the allocation decisions of the Board.

65. This requirement is a change from current transplantation practice. Under the recently amended definition of “local unit” used by the United Network for Organ Sharing, “the [L]ocal unit will be the organ provider organization in most cases” and “[t]here should be a single waiting list for each organ within each local unit.” United Network for Organ Sharing Rule No. 3.1.7. This definition of “local unit” was designed to ensure a more equitable allocation of available organs and tissues, in response to criticism expressed in the April 1993 GAO Report.

This definition, however, will have a number of undesirable consequences. First, organs that are procured in one locale within the jurisdiction of an Organ Provider Organization may have to be transported hundreds of miles to another, distant locale within that OPO, reducing the likelihood of successful transplant because the viability of organs deteriorates rapidly over a 24 hour period. Thus, the goal of more “equitable” organ distribution may be achieved at the price of reducing the total number of lives saved through transplantation.

Second, both human nature and the economic and prestige interests of individual transplant centers may lead to a situation in which organs are not procured as aggressively as possible if health care personnel of a particular hospital know that the organ they seek to harvest will not be used to meet the needs of a local patient. This may be so despite the requirement under this statute’s presumed consent framework that the organs of all potential donors who have not opted out be taken for transplantation or research.

Third, under current practice, many recipients are on the waiting list of more than one transplant center—a practice which has been found to frequently shorten the time that a patient waits for an organ transplant. Sanfilippo, supra note 10, at 250. To the extent that wealthier and better educated donors are more often on multiple waiting lists, the United Network for Organ Sharing rule perpetuates the discriminatory impact of our current two-tier health care system.

Finally, the communal underpinnings of the proposed statute require that, where possible, locally procured organs be returned to the community in which the donor lived. This approach responds to the frequently voiced concern that persons of color are underrepresented in the organ recipient population, despite being overrepresented in the donor

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(2) If there is no suitable local organ or tissue recipient who meets the criteria of section B, infra, the organ or tissue shall be offered to the closest regional Organ Provider Organization.  

(3) If there is no suitable local or regional organ or tissue recipient who meets the criteria of section B, infra, the organ or tissue shall be offered to the national registry of potential organ recipients.

B. Criteria for Receiving an Organ or Tissue for Transplant

Medical suitability, and American citizenship or legal resident alien status shall be the sole criteria for the receipt of an organ or tissue. Compliance and social worth criteria shall not be used in the allocation of organs or tissues for transplant.

(1) Medical suitability criteria for organ or tissue receipt shall be determined by the National Organ and Tissue Research and Transplantation Board, which shall annually publish a list of eligibility criteria for each organ, tissue, or organ group. These criteria must be applied by all transplant professionals in reviewing the suitability of particular potential organ recipients.

(2) No more than ten percent of all organ or tissue transplants performed at an individual transplant center shall be performed on persons who are not citizens of the United States of America or legal resident aliens thereof. In addition, no more than ten percent of the population because they are disproportionately likely to be the victims of accidents and violent crime. See supra notes 10-12 & 44-46 and accompanying text (discussing racial disparities of the current allocation system).

66. Currently, OPOs are certified by a private entity, the United Network for Organ Sharing, if they meet its requirements. The GAO Report sharply criticized the Department of Health and Human Services' lax oversight of UNOS and the lack of meaningful federal authority over OPOs and transplant centers. GAO REPORT, supra note 3, at 3; see also supra notes 7-8 and accompanying text (discussing criticisms of current approach to organ donation). The model statute envisions that in the future such certification will occur under the direct authority of the federal government.

67. The GAO recently emphasized the need for federal government articulation of medical criteria for the selection of recipients for organ or tissue transplantation. GAO REPORT, supra note 3, at 5.

68. Alternatively, if problems under the North American Free Trade Agreement are foreseen, this section could read, "No more than ten percent of all organ or tissue transplants performed at an individual transplant center shall be performed on persons who are not citizens of North America."

Although the limitation on the transplantation of "American" organs and tissues into "non-American" bodies might appear to be niggardly, if not xenophobic, it represents a logical extension of the communital philosophy underlying this statute—that individual organs and tissues are a community resource and can be drafted for the national good, subject to the opting-out provisions of section III(C), supra. On a practical level, this provision will minimize concerns that wealthy foreigners who need transplant surgery will come to the United States and contribute large sums of money to major teaching hospitals that also operate transplant centers.
organs and tissues donated may be obtained from individuals who are not American citizens or legal resident aliens of the United States of America.69

SECTION V: PROTECTION OF THE PUBLIC FROM THE TRANSMISSION OF INFECTIOUS DISEASES THROUGH TRANSPLANT

A. The National Organ Transplant and Research Board shall promulgate regulations to ensure that no person who receives an organ or tissue or product thereof, either directly or indirectly, shall be infected with any disease present in the original organ or tissue.70

B. All health care providers, either individuals or institutions, who comply with these regulations shall have a complete defense to any suit brought:

(1) as the result of any organ or tissue recipient developing an infectious disease due to that receipt, or

(2) out of fear that one might develop an infectious disease due to the transplant.

SECTION VI: PAYMENT FOR TRANSPLANTATION

A. All organ and tissue transplantation procedures shall be paid for in accordance with the Guaranteed National Benefits Package Plan of the American Health Security Act provided that:

(1) they are deemed medically necessary and appropriate by the recipient's physician, and

(2) they are deemed non-experimental by the regulations of the National Organ and Tissue Research and Transplantation Board.71

B. Such payments shall include all necessary immunosuppressive drugs and other treatment modalities and procedures necessary to ensure the long-term success of the transplant.

69. At the same time, the 10% limitation on non-American donors anticipates concerns that poor, especially Third World, individuals would be lured to the United States by the prospect of being paid for their vital organs.


71. See Model Statute § III(B)(4), supra (directing the Board to publish a list of procedures deemed too experimental to merit reimbursement).