

# ORGAN DONOR LAWS IN THE U.S. AND THE U.K.: THE NEED FOR REFORM AND THE PROMISE OF XENOTRANSPLANTATION

*"Ultimately the potential for organ transplantation will depend not only on advanced medical technology, but also on the progress in the legal technology of organ donation."*<sup>1</sup>

## I. INTRODUCTION

It is a mother's worst fear. Standing at the bedside of her child, who is lying there so peacefully, sleeping quietly while a vicious disease infects his liver. The doctors come, but the news is not good. All these months on the waiting list have produced nothing. Without a miracle, this precious life will not continue.

Too many mothers face this heartbreaking tragedy every day. Their children need life-saving surgeries, but no organs can be found. This suffering spans the globe and touches the lives of people in many nations. Legislators scramble to enact one organ procurement law after another, but the demand for organs is too great. Studies indicate that nothing they can do can retrieve enough organs to bring supply and demand into balance.<sup>2</sup> Something else will have to be done. That something else is xenotransplantation.

Xenotransplantation is the transfer of tissue or organs from one species to another.<sup>3</sup> It has been attempted several times in the past, but survival rates were poor.<sup>4</sup> The advent of new drugs that control the body's rejection of foreign substances and the ability to genetically alter potential animal donors to make their organs more compatible with humans, coupled with the desperate need for more transplantable organs, have caused a renewal of interest in the field of xenotransplantation.<sup>5</sup> Scientists predict that successful xenotransplantations can occur within two to five years.<sup>6</sup> However, laws lag

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1. Bernard M. Dickens et al., *Legislation on Organ and Tissue Donation*, in ORGAN AND TISSUE DONATION FOR TRANSPLANTATION 95 (Jeremy R. Chapman et al. eds., 1997) (quoting W.N. Gerson, *Refining the Law of Organ Donation: Lessons from the French Law of Presumed Consent*, 19 J. INT'L L & POL. 1013-32 (1987)).

2. See *infra* note 333.

3. See Committee on Xenograft Transplantation, INSTITUTE OF MEDICINE, XENOTRANSPLANTATION: SCIENCE, ETHICS, AND PUBLIC POLICY, 1 (1996).

4. See *infra* notes 219-226 and accompanying text.

5. See Charles Marwick, *British, American Reports on Xenotransplantation*, JAMA, Aug. 28, 1996, at 589.

6. See Andy Coghlan, *Heartening*, NEW SCIENTIST, Aug. 28, 1999, at 20.

behind science and hinder the advancement of the technology by their failure to provide authorization for human xenograft clinical trials.

Part II of this Note discusses the history of organ donation and explains the world's shortage of usable organs. It proceeds to discuss expressed consent and presumed consent as two legal systems of organ procurement that can be implemented to decrease this shortage. The problems and promises of each system are considered in the context of some of the nations that currently employ each. Part III of this Note looks at organ procurement laws in the United States; specifically, the Uniform Anatomical Gift Act and its revisions, as well as the National Organ Transplant Act. The major provisions of each piece of legislation are addressed and reasons why the Acts have failed to live up to their potential are examined. Part IV looks at organ procurement laws in Britain, namely, the Human Tissue Act of 1961 and the Human Organ Transplants Act of 1989. Again, the major provisions are reviewed and explanations are provided for their failure to sufficiently increase the supply of organs. Part V introduces the concept of xenotransplantation, noting its history and the ethical considerations involved in transplanting animal tissues and organs into humans. It also looks at the efforts of the United States and Britain to regulate xenotransplantation trials and advances some reasons why Britain is hesitant to proceed with human xenograft clinical trials. Part VI concludes the Note by proposing that, in light of recent findings that diseases are not as large a threat as originally anticipated, Britain should loosen its stance on xenotransplantation by lifting the moratorium on clinical trials. Finally, the Note suggests that Britain should not switch to a system of presumed consent but should expand the laws that it currently has in force to accommodate xenotransplantation.

## II. ORGAN DONATION

### A. *History of Organ Donation*

The ability to transplant organs developed around the turn of the twentieth century.<sup>7</sup> History indicates, however, that medical science has literally been moving toward organ transplantation for millenniums. More than five thousand years ago, the ancient Egyptians used transplanted tissues to reconstruct the noses of syphilis victims.<sup>8</sup> Scientists have made a variety of attempts at transplantation since that time. In the 1760s, scientists transplanted the teeth of female servants into the mouths of "fine ladies."<sup>9</sup>

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7. See Juliana S. Moore, *The Gift of Life: New Laws, Old Dilemmas, and the Future of Organ Procurement*, 21 AKRON L. REV. 443, 455 (1988).

8. See *id.*

9. See *id.* John Hunter, the "father of scientific surgery," with the help of a dentist, obtained teeth from maidservants and transplanted them into the mouths of more distinguished

The late 1800s brought the transplantation of skin.<sup>10</sup> Finally, in 1954, the first successful<sup>11</sup> solid organ<sup>12</sup> transplant was performed.<sup>13</sup> This breakthrough brought hope to many suffering from end stage organ failure.

Rejection<sup>14</sup> of the transplanted organs by the recipients overshadowed the promise of organ transplantation.<sup>15</sup> It was not until the development of the anti-rejection drug cyclosporine<sup>16</sup> in 1983 that the number of organ transplants

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ladies. See J. Englebert Dunphy, M.D., *The Story of Organ Transplantation*, 21 HASTINGS L.J. 67 (1969).

10. See Moore, *supra* note 7, at 455.

11. The American Council on Transplantation considers a transplant "successful" if the organ functions normally one year after the transplantation. See Theodore Cooper, *Survey of Development, Current Status, and Future Prospects for Organ Transplantation*, in HUMAN ORGAN TRANSPLANTATION: SOCIETAL, MEDICAL-LEGAL, REGULATORY, AND REIMBURSEMENT ISSUES 18 (Dale H. Cowan et al. eds., 1987).

12. Those in the transplant community distinguish solid organs from tissues. Interestingly, however, not all countries categorize organs and tissues in the same way. Generally, solid organs include the kidneys, heart, liver, pancreas, and lungs, while corneas, bone marrow, skin, and blood constitute tissues. See generally Bernard M. Dickens et al., *Legislation on Organ and Tissue Donation*, in ORGAN AND TISSUE DONATION FOR TRANSPLANTATION 95, 97 (Jeremy R. Chapman et al. eds., 1997).

13. This procedure took place at Peter Bent Brigham Hospital in Boston and involved the transplantation of a kidney between identical twins. See Cooper, *supra* note 11, at 18. The transplant was successful under the definition put forth by the American Council on Transplantation because the kidney functioned for nine years following the procedure. See *id.*

14. Rejection occurs as a response to the body's identification and elimination of a foreign organism or tissue. See Michael A. DeVita et al., *History of Organ Donation by Patients with Cardiac Death*, in PROCURING ORGANS FOR TRANSPLANT: THE DEBATE OVER NON-HEART-BEATING CADAVER PROTOCOLS 15, 17 (Robert M. Arnold, M.D. et al. eds., 1995). It is triggered when any organ is transplanted except those from an identical twin. See Howard S. Schwartz, *Bioethical and Legal Considerations in Increasing the Supply of Transplantable Organs: From UAGA to "Baby Fae,"* 10 AM. J.L. & MED. 397, 399 (1985). The immune system, which is responsible for this defensive function, is both sensitive and powerful. See DeVita et al., *supra* at 17. It can identify and eliminate a single foreign bacteria, as well as reject an entire organ in a few hours. See *id.* In order for the transplanted organ to be accepted, it must have the same genetic markers as the recipient. See *id.* This is one of the problems associated with xenotransplantation. Because the organs involved in the xenotransplantation procedure come from a donor of another species, the genetic markers do not match and rejection occurs. Technology now provides scientists the opportunity to "fool" the human body into accepting an animal organ by allowing them to inject human proteins into the organ, causing it to be identified as a human organ. For more information regarding this technology see *infra* note 260.

15. See Mark F. Anderson, *The Future of Organ Transplantation: From Where Will New Donors Come, To Whom Will Their Organs Go?*, 5 HEALTH MATRIX 249, 252 (1995).

16. Cyclosporine is an immunosuppressive drug discovered in 1972 by J.F. Borel at the Sandoz Pharmaceutical Corporation. See RENEE C. FOX & JUDITH P. SWAZEY, SPARE PARTS 3-6 (1992). The F.D.A. gave its approval for the marketing of cyclosporine in 1983. See *id.* By 1989, it was given alone or in combination with other drugs to almost every individual receiving a transplanted organ and was recognized as one of the key factors contributing to the "boom" in organ transplantation from the early 1980s through 1990. See *id.* Notwithstanding its promise for organ transplantation, the use of cyclosporine came into question beginning in 1991 after the medical community began to question the possible long-term effects of using the drug.

increased significantly.<sup>17</sup> Since then, the number of organ transplants performed in the United States each year has mushroomed,<sup>18</sup> and now everything from livers to corneas is being transplanted.<sup>19</sup>

The success of organ transplantation created problems that people in the medical community, as well as legislators, attempted to resolve. The increased viability of organ transplants led to a greater demand for usable organs.<sup>20</sup> This, in turn, resulted in an inadequate supply of organs available for

*See id.* See also Nancy L. Ascher, *The Pros and Cons of Cyclosporine*, in ORGAN SUBSTITUTION TECHNOLOGY: ETHICAL, LEGAL, AND PUBLIC POLICY ISSUES 306, 307 (Deborah Mathieu ed., 1988) (noting that cyclosporine has three major drawbacks: its expense, its toxic effect on kidneys, and the chance that one of its long-term side effects might be lymphoma). Nevertheless, cyclosporine remains "the cornerstone of clinical immunosuppression for renal transplantation." Paul A. Keown, *Molecular and Clinical Therapeutics of Cyclosporine in Transplantation*, in IMMUNOSUPPRESSION IN TRANSPLANTATION 1, 10 (Leo C. Ginns, et al. eds., 1999). Cyclosporine has decreased the incidence of rejection. The University of Pittsburgh reported that the one-year survival rates for liver transplants conducted there increased from 32% to 69% following the introduction of cyclosporine; the one-year survival rates for heart transplants increased from 62% to 76%. See Schwartz, *supra* note 14, at 400. Evidence exists that indicates that cyclosporine, used in combination with other agents, will allow immunosuppression in organ transplantation to achieve the following goals within the next decade: "patient survival greater than 95%, graft survival greater than 90%, rejection rates less than 10%, incidence of infection less than 10%, and incidence of lymphoma less than 1%." See Keown, *supra*, at 10.

17. See Anderson, *supra* note 15, at 252. The growth in transplantation was especially large between 1988 and 1997, when the number of transplant recipients increased 49% (from 12,786 in 1988 to 20,672 in 1997). See ORGANISATION FOR ECONOMIC CO-OPERATION AND DEVELOPMENT ("OECD"), XENOTRANSPLANTATION: INTERNATIONAL POLICY ISSUES 15 (1999).

18. See Anderson, *supra* note 15, at 252.

19. See Moore, *supra* note 7, at 455. The solid organs being transplanted in the United States and the success rates of these procedures from October 1987 to December 1995 are as follows:

Organ	# Trnsplnts	Survival	1 Yr. Survival	2 Yr. Survival	4 Yr. Survival
Cadaveric Kidney	64,346	Graft	81.9%	76.5%	66.0%
		Patient	93.6%	90.8%	84.8%
Living Kidney	20,236	Graft	91.7%	88.5%	80.9%
		Patient	97.3%	96.0%	92.8%
Liver	23,957	Graft	71.2%	66.6%	60.6%
		Patient	80.6%	76.9%	71.8%
Pancreas	4,963	Graft	75.2%	69.8%	60.6%
		Patient	91.3%	88.2%	82.7%
Heart	17,138	Graft	82.1%	77.8%	70.0%
		Patient	83.0%	78.9%	71.7%
Lung	3,537	Graft	72.5%	63.1%	45.8%
		Patient	74.0%	65.3%	48.8%
Heart/Lung	500	Graft	64.0%	54.9%	45.4%
		Patient	64.5%	56.0%	46.7%

See OECD, *supra* note 17 at 21.

20. See Chad D. Naylor, *The Role of the Family in Cadaveric Organ Procurement*, 65 IND. L. J. 167, 167 (1989).

transplant.<sup>21</sup> As of September 22, 1999, the number of organs needed by patients on the United Network for Organ Sharing (UNOS) waiting list was 65,686.<sup>22</sup> This number represents three times the number of transplants that actually occurred in the United States during 1998.<sup>23</sup> Statistics show that more than one-third of potential liver transplant patients die while waiting for a liver.<sup>24</sup> Well over fifty percent of children born with heart or liver deformities die without a transplant.<sup>25</sup> As of 1994, 150,000 Americans relied on renal

21. *See id.*

22. This number reflects the number of organs needed rather than the number of patients on the list because there are some patients waiting for multiple organ transplants. *See* United Network for Organ Sharing, *U.S. Facts About Transplantation* (visited Oct. 1, 1999) <[http://www.unos.org/Newsroom/critdata\\_main.htm](http://www.unos.org/Newsroom/critdata_main.htm)> [hereinafter UNOS, *U.S. Facts*]. In 1993 the number of potential recipients (rather than the number of organs needed) was roughly 30,000. *See* Robert M. Arnold et al., *Introduction: Back to the Future: Obtaining Organs from Non-Heart-Beating Cadaver Donors*, in *PROCURING ORGANS FOR TRANSPLANT: THE DEBATE OVER NON-HEART-BEATING CADAVER PROTOCOLS* 1, 1 (Robert M. Arnold, M.D. et al. eds., 1995). The number of potential recipients more than doubled from 1988 to 1994 as well. *See* UNOS, *The Transplantation Miracle Confronts a Lack of Organs* (visited Sept. 8, 1999) <<http://whyfiles.news.wisc.edu/007transplant/need.html>> [hereinafter UNOS, *Transplantation*]. The approximate numbers on the waiting list for that period are as follows:

Year	Number on the Waiting List (approx.)
1988	16,000
1989	19,500
1990	22,000
1991	25,000
1992	30,000
1993	35,000
1994	37,500

*Id.* The list of patients awaiting organ transplants in the United States increases every 16 minutes as another name is added. *See* Arlene Judith Klotzko, *Mankind's New Best Friend*, CHI. TRIB., Aug. 22, 1999, at 1.

23. The actual number of organ transplants performed in the United States during 1998 include:

Type of Transplant	Number
kidney-pancreas transplants	965
kidney alone transplants	11,990 (4,016 living donors)
pancreas alone transplants	253
liver transplants	4,450
heart transplants	2,340
heart-lung transplants	45
lung transplants	849
intestine transplants	69
TOTAL	20,961

*See* UNOS, *U.S. Facts*, *supra* note 22. Records indicate that almost 5000 people died in the United States during 1998 before receiving an organ transplant. *See* Klotzko, *supra* note 22, at 1.

24. *See* Arthur L. Caplan, *Humans Should Be Allowed to Receive Animal Organ Transplants*, in *BIOMEDICAL ETHICS OPPOSING VIEWPOINTS* 223, 224 (Terry O'Neill ed., 1994) [hereinafter Caplan, *Humans Should Be Allowed*].

25. *See id.* Statistics from Great Britain indicate that survival rates of infants who have

dialysis for their survival when kidney transplants would have proved less expensive<sup>26</sup> and would have given them a better quality of life.<sup>27</sup>

Rather than searching for ways to decrease demand, the focus has been on increasing the supply of transplantable organs.<sup>28</sup> One way to accomplish this is by creating legislation aimed at increasing the number of organ donors. Two sources of human organs for transplantation exist—living donors and cadavers.<sup>29</sup> Because living donors can only donate those organs or tissues that they can live without,<sup>30</sup> the potential supply from living donors is limited.<sup>31</sup> Since deceased donors provide a larger number of organs, cadavers represent the primary source of organs for transplant.<sup>32</sup> Each year, approximately 4500 cadaveric organs are procured and used in transplant procedures, a number far below the demand.<sup>33</sup> Experts expect this number to remain static, while the demand will continue to grow as survival rates increase, thus causing a more

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undergone liver transplants range from 75-78% for a five year period while those who have undergone heart transplants average about 70% survival for two years. See Deirdre Kelly & A.D. Mayer, *Paediatric Transplantation Comes of Age: The Main Problem Now is Shortage of Donors*, BRIT. MED. J., Oct. 3, 1998, at 897.

26. In 1988, the cost of treatment for Americans with kidney failure exceeded five billion dollars. See Caplan, *Humans Should Be Allowed*, *supra* note 24, at 225. It has been estimated that the Medicare system alone would save more than \$150 million over a five-year period of time if all patients awaiting kidney transplants received one because successful kidney transplants save as much as \$60,000 per patient for each five-year period. See Andrew C. MacDonald, *Organ Donation: The Time Has Come to Refocus the Ethical Spotlight*, 8 STAN. L. & POL'Y REV. 177, 179 (1997).

27. See Caplan, *Humans Should Be Allowed*, *supra* note 24, at 225.

28. See Anderson, *supra* note 15, at 255. Efforts to reduce the demand for organs would involve a broad array of public health efforts such as decreasing the risks of heart disease through proper diet and exercise, treating the hepatitis virus, and preventing alcoholism and drug abuse in order to avoid liver damage. See Jack M. Kress, *Xenotransplantation: Ethics and Economics*, 53 FOOD & DRUG L. J. 353, 360 (1998). While such efforts should be undertaken, evidence suggests that they would achieve only limited success. See *id.*

29. See Shelby E. Robinson, *Organs for Sale? An Analysis of Proposed Systems for Compensating Organ Providers*, 70 U. COLO. L. REV. 1019, 1022 (1999). See also Jason Altman, *Organ Transplantations: The Need for an International Open Organ Market*, 5 TOURO INT'L L. REV. 161, 163 (1994) (stating that live donors contribute nearly one-third of the organs donated in the United States and Great Britain. The World Health Organization, however, fears corruption resulting from the taking of organs from live persons and thus looks unfavorably upon live organ donation).

30. These include, for example, one kidney, blood, and bone marrow. See Robinson, *supra* note 29, at 1023.

31. See *id.*

32. See *id.*

33. See David E. Jefferies, *The Body as Commodity: The Use of Markets to Cure the Organ Deficit*, 5 IND. J. GLOBAL LEGAL STUD. 621, 624 (1998).

severe discrepancy between supply and demand.<sup>34</sup> Because one donor's organs can help as many as nine recipients,<sup>35</sup> each potential donor is significantly important.

## B. *Types of Organ Donor Laws*

Legislation aimed at increasing the number of organ donors takes two forms: encouraged volunteerism and presumed consent. While different countries accept and reject different specific underlying concepts, most have laws encompassing one of these two systems.

### 1. *Volunteerism and Expressed Consent*

Expressed consent represents the first approach to organ procurement. The idea that individuals voluntarily donate their organs by expressing prior consent to their removal underlies the system of expressed consent.<sup>36</sup> Consent may be expressed in various ways, including orally, by will,<sup>37</sup> by donor card, or by driver's license.<sup>38</sup> There are also indications that some non-traditional means, such as tattoos, constitute a valid consent for the harvesting of organs.<sup>39</sup>

Expressed consent laws exist in Canada, the United Kingdom, the Netherlands, and Turkey.<sup>40</sup> The United States employs a variation of expressed consent called required request.<sup>41</sup> Under expressed consent laws, organ donors may not receive compensation for their donations other than to

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34. See *id.*

35. The organs that can be taken from a single donor include the heart, lungs, kidneys, liver, pancreas, corneas and small intestine. See Kelly & Mayer, *supra* note 25, at 897 and Moore, *supra* note 7, at 455. See also REG GREEN, *THE NICHOLAS EFFECT: A BOY'S GIFT TO THE WORLD* 23 (1999) (telling the story of a young boy from California who was killed on an Italian highway during a family vacation. His parents elected to donate his organs and seven individuals benefited from their generosity).

36. See Christian Williams, *Combatting the Problems of Human Rights Abuses and Inadequate Organ Supply Through Presumed Donative Consent*, 26 CASE W. RES. J. INT'L L. 315, 333 (1994).

37. In the United States, gifts of organs made by will are effective immediately upon the death of the donor without waiting for probate. See Uniform Anatomical Gift Act, §4 (a-b), reprinted in MANSON, *infra* note 108, at 5; Melissa N. Kurnit, *Organ Donation in the United States: Can We Learn From Successes Abroad?*, 17 B.C. INT'L & COMP. L. REV. 405, 411 (1994).

38. See Altman, *supra* note 29, at 164.

39. See *id.*

40. See OECD, *supra* note 17, at 18.

41. Required request laws mandate that hospitals and doctors inform patients or their families about the possibility of organ donation. See *id.*; see *infra* note 52 and accompanying text.

have their expenses paid.<sup>42</sup> Therefore, the motivation for organ donation under these laws lies elsewhere. Altruism,<sup>43</sup> coercion, and moral obligation signify reasons why an individual might donate his organs.<sup>44</sup> Of these, altruism represents the primary incentive.<sup>45</sup>

An underlying assumption of expressed consent is that something resembling a property right exists in the body that survives even after an individual's death. This explains, to some degree, why some nations might choose expressed consent over other systems of organ procurement. A nation, such as the United States, with a history of support for individual rights,<sup>46</sup> might find those organ donor laws that stress the individual's right to choose what happens to his body fit more closely with the nation's social conscience.

In theory, expressed consent laws allow doctors to proceed with organ harvesting upon recognition of some form of donor consent.<sup>47</sup> In practice, however, medical personnel in most countries usually do not act without the consent of the donor's family as well.<sup>48</sup> Common law recognizes that the family of the deceased has certain rights to his remains that are enforceable by an action in damages.<sup>49</sup> Modern statutes limit this right by extending protection from liability to a physician acting in good faith.<sup>50</sup>

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42. See Williams, *supra* note 36, at 333; *infra* notes 51-60 and accompanying text.

43. Altruism is the "consideration for other people without any thought of self as a principle of conduct." WEBSTER'S ENCYCLOPEDIA DICTIONARY 27 (2d ed. 1990).

44. See Williams, *supra* note 36, at 333.

45. Altruism provides social benefits not existent in other forms of donation. See Ann McIntosh, *Regulating the "Gift of Life"—The 1987 Uniform Anatomical Gift Act*, 65 WASH. L. REV. 171, 178 (1990). "Organ donation affirms socially valued human interactions. The donor's experience in enhancing or saving another's life brings the social community together." *Id.*

46. For discussion of an individual's right to make decisions regarding his body see *Roe v. Wade*, 93 S.Ct. 705 (1973) (affirming a woman's right to have an abortion); *Moore v. Regents of the University of California*, 793 P.2d 479 (1990) (stating that a man had no property rights to his spleen after it was removed by doctors in a surgical procedure). But see *Washington v. Glucksberg*, 117 S.Ct. 2302 (1997) (denying an individual's right to assistance in committing suicide). Interestingly, the United States, while adopting an organ donation system based on the individual's right to determine for himself whether to donate, actually limits individual rights in certain ways. Richard A. Epstein, University of Chicago law professor, argues that the failure of the United States to allow a market in organs (The National Organ Transplants Act of 1984 forbids the commercialization of organs in the United States. See *infra* note 147 and accompanying text.) abrogates the rights of the individual donor to select the recipient of his body parts. See Kress, *supra* note 28, at 358.

47. See Altman, *supra* note 29, at 164.

48. See *id.* at 165.

49. These property rights, however, do not allow the donation of organs for commercial purposes. See EUGENE B. BRODY, *BIOMEDICAL TECHNOLOGY AND HUMAN RIGHTS* 102 (1993). In Ireland, the Netherlands and Spain, the family not only has rights to the body of their relative, but the wishes of the family regarding donation of his organs take priority over the wishes of the individual donor. See DAVID LAMB, *ORGAN TRANSPLANTS AND ETHICS* 145 (1990).

50. The Uniform Anatomical Gift Act (UAGA) states in section 7(c): "A person who acts in good faith in accord with the terms of this Act or with the anatomical gift laws of another



state [or foreign country] is not liable for damages in any civil action or subject to prosecution in any criminal proceeding for his act." UAGA, *reprinted in* STATUTORY REGULATION OF ORGAN DONATION IN THE UNITED STATES 7 (R. Hunter Manson ed., 2d ed. 1986). Some states have expressly adopted the UAGA, while others have substantially adopted it: Alabama (Ala. Code §22-19-47(c) (1984)); Alaska (ALASKA STAT. §13.50.060(c) (1972)); Arizona (ARIZ. REV. STAT. ANN. §36-847(c) (1974)); Arkansas (ARK. STAT. ANN. §82-410.11(c) (1976)); California (CAL. HEALTH & SAFETY CODE §7155.5(d-e) (1984) (Supp. 1986)) [California omits reference to liability for acting in accord with gift laws of other states or foreign countries and makes reference to gifts on drivers' licenses]; Colorado (COLO. REV. STAT. §12-34-108(3) (1985)); Connecticut (CONN. GEN. STAT. ANN. §19a-278(c) (1986)) [Connecticut makes no reference to acting under the gift laws of another state or foreign nation]; Delaware (DEL. CODE ANN. tit. 24 §1786 (c) (1981)); District of Columbia (D.C. CODE ANN. §2-1507(c) (1981)) [D.C. omits reference to acting under the laws of a foreign nation]; Florida (FLA. STAT. ANN. §732.917(3) (1976 & Supp. 1984)) [Florida adds a provision to its statute that says that a person who acts without negligence in accord with UAGA is not civilly or criminally liable]; Georgia (GA. CODE ANN. §44-5-148(c) (1982)) [Georgia omits reference to acting under other state or foreign laws]; Hawaii (Hawaii Rev. Stat. §327-7(c) (1976 & Supp. 1984)); Idaho (IDAHO CODE §39-3407(3) (1977)); Illinois (ILL. ANN. STAT. ch. 110 1/2 §308(c) (Smith-Hurd 1978 & Supp. 1984)); Indiana (IND. CODE ANN. §29-2-16-4(g) (Burns Supp. 1986)) [Indiana requires that the doctors act without actual notice of revocation and limits protection to civil liability]; Iowa (IOWA CODE ANN. §142A.7(3) (1972 & Supp. 1984)) [Iowa omits reference to acting under laws of a foreign nation]; Kansas (KAN. STAT. ANN. §65-3215(c) (1980)); Kentucky (KY. REV. STAT. ANN. §311.225(3) (Bobbs-Merrill 1983)) [Kentucky omits reference to acting under the laws of a foreign nation]; Louisiana (LA. REV. STAT. ANN. §17:2357(c) (West 1982)) [Louisiana protects persons from both civil and criminal liability if they act in good faith and without actual knowledge of revocation and in accord with the Louisiana UAGA or the laws of the state in which the gift document was executed]; Maine (ME. REV. STAT. ANN. tit. 22, §2907(3) (1980)); Maryland (MD. EST. & TRUSTS CODE ANN. §4-508(b) (1974)); Massachusetts (MASS. GEN. LAWS ANN. ch. 113, §13(c) (West 1983); Michigan (MICH. COMP. LAWS ANN. §333.10108(3) (West 1980)); Minnesota (MINN. STAT. ANN. §525.927(3) (West 1975)) [Minnesota adds that a person must also comply with the drivers' license gift laws in order to escape liability]; Mississippi (MISS. CODE ANN. §41-39-45 (1981)) [Mississippi makes no mention of acting in accordance with the laws of another state or foreign nation and protects the actor only from liability for civil damages]; Missouri (MO. ANN. STAT. §194.270(3) (Vernon's 1983)) [Missouri also requires that a person act without negligence in order to escape liability]; Montana [Montana makes no provision for non-liability]; Nebraska (NEB. REV. STAT. §71-4807(3) (1981)) [Nebraska does not mention acting in accord with the laws of a foreign country]; Nevada (NEV. REV. STAT. §451.580(3) (1985)) [Nevada substitutes "the state of Nevada" for "another state or foreign country."]; New Hampshire (N.H. REV. STAT. ANN. §291-A:7(III) (1978)) [New Hampshire omits reference to acting in accord with the laws of another state or foreign country]; New Jersey (N.J. STAT. ANN. §26:6-63(c) (West Supp. 1984)); New Mexico (N.M. STAT. ANN. 24-6-7(C) (1981)) [New Mexico does not make reference to the gift laws of a foreign country]; New York (N.Y. PUB. HEALTH LAW §4306(3) (McKinney 1985)) [New York omits reference to acting under the laws of a foreign country]; North Carolina (N.C. GEN. STAT. §130A-409(c) (Supp. 1983)) [North Carolina omits reference to acting under the laws of a foreign country and substitutes the words "with due care" for acting "in good faith."]; North Dakota (N.D. CENT. CODE 23-06.1-07(3) (Supp. 1983)); Ohio (OHIO REV. CODE ANN. §2108.08 (Page 1976)) [Ohio omits reference to acting under the laws of a foreign country]; Oklahoma (OKLA. STAT. ANN. tit. 63, §2208(c) (West 1984)); Oregon (OR. REV. STAT. §97.290(3) (1983)) [Oregon substitutes acting "with probable cause" for acting "in good faith."]; Pennsylvania (20 PA. CONS. STAT. ANN. §8607(c) (Purdon 1975)); Rhode Island (R.I. GEN. LAWS §23-18.5-7(c) (1985)); South Carolina (S.C. CODE ANN. §44-43-380(c) (Law. Co-op. 1985)) [South Carolina

Some nations with laws based on expressed consent find that the system does not increase the number of available organs for transplant. These countries have changed from their systems of volunteerism to either presumed consent or systems of required request and routine inquiry.<sup>51</sup> Required request and routine inquiry resemble volunteerism in that an individual may still donate his organs and his family has the ability to consent to such donation as well. The focus of these two systems, however, shifts from one relying on altruism to one that takes a proactive approach to organ procurement by involving the direct action of hospitals and medical personnel.

Under routine inquiry, hospitals must inform the family of the opportunity to donate the organs,<sup>52</sup> and then let the family make the decision about whether that is what it wants to do. Required request places the burden on the hospitals to expressly request that the deceased's family donate his organs.<sup>53</sup>

Some suggest that routine inquiry and required request represent a better alternative to encouraged volunteerism for a number of reasons. First, those most closely associated with the potential donor are his family members. These people most likely know the wishes of the individual regarding the taking of his organs, the existence and location of a donor card, and if any other written directives exist that indicate a desire to donate the individual's organs.<sup>54</sup> Second, the inquiry made under these systems would come to be expected by the public and consent to the donation of organs would be less suspect because the family has had time to discuss the options together beforehand rather than being confronted with it during the family's time of

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omits reference to a foreign country and provides that civil immunity shall not extend to cases of "provable malpractice"; South Dakota (S.D. CODIFIED LAWS ANN. §34-26-39 (1977)); Tennessee (TENN. CODE ANN. §68-30-108 (c) (1983)); Texas (TEX. STAT. ANN. art. 4590-2 §8(c) (Vernon 1976)) [Texas protects individuals acting under the Texas UAGA if the prerequisites for an anatomical gift have been met under the laws in effect when the gift was made]; Utah (UTAH CODE ANN. §26-28-5 (1984)); [Utah requires that doctors have actual notice of revocation in order to be held liable and specifies only that such doctors shall not be liable in damages]; Vermont (VT. STAT. ANN. tit. 18, §5237(c) (Supp. 1984)); Virginia (VA. CODE §32.1-295(D) (1985)); Washington (WASH. REV. CODE ANN. §68.08.560(3) (Supp. 1984-85)); West Virginia (W. VA. CODE §16-19-7(c) (1979)); Wisconsin (WIS. STAT. ANN. §155.06(7)(c) (West 1974 & Supp. 1984)); and Wyoming (WYO. STAT. §35-5-107(c) (1977)). All of these statutes are reprinted in *STATUTORY REGULATION OF ORGAN DONATION IN THE UNITED STATES* (R. Hunter Manson ed., 2d ed. 1986).

51. See Kurnit, *supra* note 37, at 406. The United States is an example of a country that employs a system of required request.

52. See Kurnit, *supra* note 37, at 412.

53. See *id.*

54. See Arthur L. Caplan, *Obtaining and Allocating Organs for Transplantation*, in *HUMAN ORGAN TRANSPLANTATION: SOCIETAL, MEDICAL-LEGAL, REGULATORY, AND REIMBURSEMENT ISSUES* 5, 15-16 (Dale H. Cowan, M.D., J.D. et al. eds., 1987) [hereinafter Caplan, *Obtaining and Allocating Organs*].

grief.<sup>55</sup> Third, these systems may have the desired effect of increasing the number of available organs because they still respect the rights of individuals to decide not to donate their organs, they do not jeopardize the right of the individual to leave a written or oral statement about his wishes, and they actually protect the individual's wishes by attempting to involve his relatives who can speak for the deceased.<sup>56</sup> The respect for the individual's right to choose whether or not to donate constitutes the most important aspect of these systems.<sup>57</sup> This is extremely important in a system that depends upon altruism for organ procurement.<sup>58</sup> People are unlikely to donate their organs on their own.<sup>59</sup> By adopting a system that requires hospital personnel to ask for donation and that brings the public to expect questioning about organ donation, altruism is encouraged and the supply of organs is increased.<sup>60</sup>

## 2. *Presumed Consent*

Presumed consent offers an alternative to expressed consent. Unlike expressed consent, this system operates under the presumption that an individual desires to donate his organs unless he affirmatively acts to register his opposition.<sup>61</sup> Once registered, the individual carries a card indicating his objection to the procedure.<sup>62</sup>

Presumed consent laws exist in seventeen different countries<sup>63</sup> and in some U.S. states.<sup>64</sup> Although all are based on the presumption that an individual wishes to donate his organs, the statutes vary from nation to nation

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55. By making the inquiry routine, the request would be more easily accepted, as in the case of autopsies performed when death occurs under suspicious circumstances and reports that are completed when a person dies for any reason. *See id.* at 16.

56. *See id.*

57. *See id.*

58. *See id.*

59. *See id.*

60. *See id.* at 16-17.

61. *See* Fred H. Cate, *Human Organ Transplantation: The Role of Law*, 20 IOWA J. CORP. L. 69, 83 (1994).

62. *See id.*

63. Austria, Belgium, Czechoslovakia, Denmark, Finland, France, Greece, Israel, Italy, Japan, Norway, Poland, Singapore, Spain, Sweden, and Switzerland. *See id.* In January 1998, Brazil also adopted a system of presumed consent. *See* Andrea McDaniels, *Brazil Mandates Organ 'Donation' for Transplants*, CHRISTIAN SCIENCE MONITOR, Jan. 16, 1998, at 1. Nations that employ presumed consent have seen no clear-cut relationship between the laws and high donation rates. *See* OECD, *supra* note 17, at 19. In fact, some nations that operate under presumed consent (such as Switzerland (14.3 cadaveric donors per million population (pmp)), Greece (3.7 cadaveric donors pmp), and Italy (11.6 cadaveric donors pmp)) actually suffer from lower donor rates than some nations using expressed consent (United Kingdom (14.5 cadaveric donors pmp), United States (21.3 cadaveric donors pmp), and Canada (14.5 cadaveric donors pmp)). *See id.* at 17. Recently, the trend in Europe has been away from presumed consent and toward opt-in legislation. *See id.* at 19.

64. *See* LAMB, *supra* note 49, at 140.

in both their scope and application. Presumed consent statutes take one of two forms: one of strong presumed consent, and one of weak presumed consent.<sup>65</sup> Under a system of strong presumed consent, the presumption of consent may be rebutted only by the express wishes of the decedent.<sup>66</sup> A system of weak presumed consent, on the other hand, allows the decedent's family to oppose the donation.<sup>67</sup> Presumed consent in the United States takes the form of weak presumed consent.<sup>68</sup> Those U.S. states that have adopted the system allow for the removal of the corneas and the pituitary gland, but do not permit doctors to take solid organs from the donors.<sup>69</sup> Before removal of the corneas, however, many of the states require that the medical personnel make "a reasonable search" to determine whether the individual donor or his family objects.<sup>70</sup> Similarly, doctors in Finland, Greece, Italy, Japan, Norway, and Spain ask the donor's family for objections to the procedure.<sup>71</sup> Laws in Austria, Czechoslovakia, Denmark, France, Israel, Poland, Singapore, and Switzerland, however, allow for the removal of all organs if the doctor finds no recorded objection, but in practice, doctors seldom proceed without the approval of family members.<sup>72</sup>

Critics of presumed consent argue that the system essentially gives the state a right of eminent domain over the body parts of a potential donor.<sup>73</sup> Nations that take this approach have been denounced as historically lacking respect for human rights.<sup>74</sup> Some argue that "if the body is essential to the individual's identity, in a society that values personal integrity and freedom, it must be the individual's first of all to control after . . . life is gone as well. If it is to be made available to others . . . it must be a gift."<sup>75</sup>

Theoretically, a system of presumed consent should result in a greater number of organs for transplant than would a system of expressed consent.

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65. See MacDonald, *supra* note 26, at 181.

66. See *id.*

67. See *id.*

68. See Cate, *supra* note 61, at 83-84.

69. See LAMB, *supra* note 49, at 140. See also Cate, *supra* note 61, at 84 (indicating that twenty-one states have presumed consent laws that allow for the removal of corneas and seventeen states allow for the removal of pituitary glands).

70. See Cate, *supra* note 61, at 84.

71. See *id.* at 83.

72. See *id.*

73. See BRODY, *supra* note 49, at 102. In Ontario, Canada, the State has the authority to turn unclaimed bodies over to medical schools to use for research. See Altman, *supra* note 29, at 167. John Locke made a statement with regard to the rights of individuals to make determinations about their own bodies that is used as a basic criticism against a system of presumed consent. He said that "every man has a property in his own person; this nobody has a right to but himself." See Andrew Trew, *Regulating Life and Death: The Modification and Commodification of Nature*, 29 U. TOL. L. REV. 271, 277 (1998).

74. See BRODY, *supra* note 49, at 102.

75. *Id.* (quoting R. VEATCH, *DEATH, DYING AND THE BIOLOGICAL REVOLUTION. OUR LAST QUEST FOR RESPONSIBILITY* 213 (1989)).

Generally, this is not so. Several nations that have adopted presumed consent are finding that presumed consent provides only a slight advantage over expressed consent in the number of organs procured.

a. *Presumed Consent in France*

France adopted presumed consent in 1976 when the Caillavet Law<sup>76</sup> was passed. This law allows a person to "opt out" of organ donation by signing a writing that expresses his wishes not to donate.<sup>77</sup> It further provides that should a person choose not to donate he, or anyone witnessing his objection, may register that objection at the hospital.<sup>78</sup> Upon the death of the individual, the physician must check the hospital register for an objection to organ harvesting before proceeding.<sup>79</sup> Knowledge of an objection obtained from a third party, even absent a registered objection by the patient, bars the physician from taking the organs.<sup>80</sup> The system of presumed consent in France works like a system of expressed consent in that it requires the doctor to put forth a reasonable effort to find out the decedent's wishes; however, it does not require that the doctor put forth such effort to determine the wishes of the next of kin.<sup>81</sup> Most doctors do make that effort, however, as research shows that in 90.7% of cases, doctors in France notify the deceased's family before removing the organs.<sup>82</sup>

Presumed consent in France has not achieved the goal of meeting the demand for transplantable organs.<sup>83</sup> After twelve years of presumed consent, the nation still experienced a shortage in each area of organ demand.<sup>84</sup>

76. The Caillavet Law was named after its sponsor and signed into law December 22, 1976 by French President Giscard d'Estaing. See William N. Gerson, *Refining the Law of Organ Donation: Lessons from the French Law of Presumed Consent*, 19 NYU J. INT'L L. & POL. 1013, 1022 (1987). "It states that 'organ procurement may be done for therapeutic or scientific ends on the cadaver of a person who had not made known his objection to such procurement during his lifetime.'" *Id.*

77. See Jefferies, *supra* note 33, at 636; Williams, *supra* note 36, at 338-39.

78. See Jefferies, *supra* note 33, at 636; Kurnit, *supra* note 37, at 421-22.

79. See Jefferies, *supra* note 33, at 636.

80. See *id.*

81. See *id.*

82. See *id.* at 637; Kurnit, *supra* note 37, at 443.

83. The failure of organ supply to increase commensurate with demand may be attributed to the fact that doctors in France continue to consult with family members before harvesting the organs. See Jami H. Levine, *The Organ Procurement Dilemma: Altruism v. Commercialism*, 2 KAN. J. L. & PUB. POL'Y 113, 117 (1992).

84. Transplants performed in France and the number of patients remaining on waiting lists in 1988:

Organs	Transplants performed in 1988	Number remaining on waiting list
Kidneys	1,808	4,075
Heart	555	523
Liver	409	189

### b. *Presumed Consent in Belgium*

The results in Belgium resemble those in France. Belgium adopted presumed consent in 1987.<sup>85</sup> The law provided for a computerized central Health Authority registry that tracks all individuals objecting to the harvesting of their organs.<sup>86</sup> If doctors find no objections noted on the registry, they may legally proceed though, as in France, Belgian doctors usually seek the consent of family members first.<sup>87</sup>

The success of presumed consent in Belgium is questionable. While the number of organs procured and transplanted appears to have increased,<sup>88</sup> scholars debate whether this increase is attributable to the adoption of presumed consent or the fact that more hospitals now engage in organ procurement.<sup>89</sup> Regardless of this increase, however, a significant gap still exists between the number of transplants that occur and the number of patients waiting to undergo the procedure.<sup>90</sup>

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Lung	67	163
Pancreas	43	16
TOTAL	2,882	4,966

See Jefferies, *supra* note 33, at 637.

85. Some suggest that presumed consent has actually been practiced in Belgium since 1965 when Professor R. Dierkens, Secretary-General of the World Association for Medical Law, introduced a regulation in the teaching hospital of the University of Ghent. See J. A. Farfor, *Organs for Transplant: Courageous Legislation*, *BMJ*, Feb. 19, 1977, at 497, 498.

86. See Kurnit, *supra* note 37, at 422-23.

87. See *id.*

88. A study performed in 1990 found that cadaveric kidney procurement increased 86%, organ procurement on the whole increased 183%, and the total number of organ transplants increased 140%. Another study completed in 1991 showed the increase in cadaveric kidney procurement to be 119% and even greater for multi-organ procurement. See *id.* at 444.

89. See *id.* Those experts who believe that the increases are due to the enactment of presumed consent laws discuss their beliefs in the following: L. Roels et al., *Three Years Experience With a 'Presumed Consent' Legislation in Belgium: Its Impact on Multi-Organ Donation in Comparison with Other European Countries*, 23 *TRANSPLANTATION PROC.* 903, 904 (1991); L. Roels et al., *Effect of Presumed Consent Law of Organ Retrieval in Belgium*, 22 *TRANSPLANTATION PROC.* 2078, 2079 (1990).

90. Transplants performed in Belgium and the number of patients on the waiting list in 1988:

Organs	Transplants performed in 1988	Number remaining on waiting list
Kidneys	342	803
Heart	96	34
Liver	123	35
Lung	4	4
Pancreas	5	12
TOTAL	570	888

See Jefferies, *supra* note 33, at 638.

c. *Presumed Consent in Austria*

Austria is the only country to operate under a "pure" system of presumed consent.<sup>91</sup> Such a system eliminates the role of the family in consenting to organ donation, making it possible for doctors to proceed without obtaining the family's approval.<sup>92</sup> Austrian law requires a written statement of an individual's objection to organ donation in order for the objection to be legally binding.<sup>93</sup> Unlike other nations, however, physicians in Austria have no affirmative duty to make reasonable efforts to locate documents that indicate consent or nonconsent.<sup>94</sup> Furthermore, when doubt exists about the wishes of the decedent, doctors may legally proceed with organ removal.<sup>95</sup>

Austria enjoys a higher rate of cadaveric organ donors than any other country as a whole.<sup>96</sup> It has been alleged, however, that if this success were attributable to the presumed consent laws, then donor rates in each category of organs covered by the law would be higher than donor rates in other countries.<sup>97</sup> Statistics show otherwise. Austrian procurement rates for livers exceed similar rates in France and Belgium only slightly, and procurement rates for hearts fall below those in France and Belgium.<sup>98</sup> Success in Austria, therefore, may result more from its two very active transplant teams located in Innsbruck and Vienna than from its adoption of presumed consent.<sup>99</sup> Whatever the source of Austria's success in increasing the number of procured organs, demand for usable organs still greatly exceeds supply.<sup>100</sup>

91. See Kurnit, *supra* note 37, at 423.

92. See *id.*

93. See W. Land & B. Cohen, *Postmortem and Living Organ Donation in Europe: Transplant Laws and Activities*, 24 *TRANSPLANTATION PROC.* 2165, 2165 (1992).

94. See Kurnit, *supra* note 37, at 423.

95. See *id.*

96. See Land & Cohen, *supra* note 93, at 2166; see also Williams, *supra* note 36, at 340 (stating that, in Austria, there are 60 cadaveric kidneys retrieved for every one million individuals. This rate is twice that of the United States and most other European countries).

97. See Kurnit, *supra* note 37, at 445.

98. See *id.*

99. See *id.*

100. Transplants occurring in Austria and the number of patients on the waiting list in 1988:

Organs	Transplants occurring in 1988	Patients remaining on waiting list
Kidney	270	1,116
Heart	46	15
Liver	32	10
Lung	3	8
Pancreas	8	12
TOTAL	359	1,161

See Jefferies, *supra* note 33, at 639.

### III. ORGAN DONATION LAWS IN THE UNITED STATES

Organ donation regulation in the United States takes its roots in the English common law belief that no one has a property interest in a dead body.<sup>101</sup> While maintaining this basic premise, state courts began to interpret the regulations as granting a "quasi-property right" to the family of the deceased, which allowed them to gain control of the body following death for the purpose of providing it a proper burial.<sup>102</sup> As organ transplantation technology developed and the need for donors increased, the limitations of these laws were tested. As a result, statutes began springing up in the states that allowed an individual and his next of kin to donate.<sup>103</sup> These laws were often confusing and contradictory.<sup>104</sup> To remedy this, the National Conference of Commissioners on Uniform State Laws (NCCUSL) met in 1968 and drafted the Uniform Anatomical Gift Act (UAGA)<sup>105</sup> Together with the National Organ Transplant Act (NOTA) which followed in 1984, the UAGA provides the foundation for organ donation in the United States.

#### A. *The Uniform Anatomical Gift Act*

In order to arrive at a comprehensive plan for the procurement of organs, the drafters of the Uniform Anatomical Gift Act (UAGA) faced the challenging task of balancing several important competing interests.<sup>106</sup> These interests included protecting the wishes of the potential donor, respecting the wishes of the donor's family, and recognizing that the state needed to execute successful organ procurement procedures to meet society's demand for usable organs.<sup>107</sup> The UAGA addressed these concerns by attempting to answer twelve legal questions ranging from who may donate his organs to whether a physician should be precluded from taking part in the transplant because of his interest in preserving the donor's life.<sup>108</sup> On the whole, the UAGA has

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101. See Daphne D. Sipes, *Does It Matter Whether There is Public Policy or Presumed Consent in Organ Transplantation?*, 12 WHITTIER L. REV. 505, 508 (1991).

102. See *id.* See also Andrew J. Love, *Replacing Our Current System of Organ Procurement with a Futures Market: Will Organ Supply be Maximized?*, 37 JURIMETRICS J. 167, 172 (1997). See, e.g., *State v. Powell*, 497 So.2d 1188, 1192 (Fla. 1986).

103. See Sipes, *supra* note 101, at 509; Cate, *supra* note 61, at 71. The first state to enact a statute allowing an individual to donate his organs was New York. See David Sanders & Jesse Dukeminier, Jr., *Medical Advance and Legal Lag: Hemodialysis and Kidney Transplantation*, 15 UCLA L. REV. 357, 401 (1968).

104. See Sipes, *supra* note 101, at 509.

105. See *id.*

106. See Moore, *supra* note 7, at 444.

107. See *id.*

108. The 12 questions are as follows:

1. Who may during his/her lifetime make a legally effective gift of his body or a part thereof?



addressed these questions; however, scholars point out that medical technology was not the same in 1968 as it is today, so the UAGA should not be looked at as an inflexible document, but one requiring regular modifications.<sup>109</sup>

The UAGA received a warm welcome from the states. By 1972, four years after adoption by the NCCUSL, every state and the District of Columbia enacted some version of it into their laws.<sup>110</sup>

The UAGA provides that any eighteen-year-old who possesses a sound mind may, upon his death, donate all or part of his body.<sup>111</sup> Absent an indication of the donor's wishes, certain others receive the right to determine

2. What is the right of the next-of-kin, either to set aside the decedent's expressed wishes, or themselves to make the anatomical gifts from the dead body?
3. Who may legally become donees of the anatomical gift?
4. For what purposes may such gifts be made?
5. How may gifts be made, such as by will, by writing, by a card carried on the person, or by the telegraphic or recorded telephonic communications?
6. How may a gift be revoked by the donor during his lifetime?
7. What are the rights of survivors in the body after removal of the donated parts?
8. What protection from legal liability should be afforded to surgeons and others involved in carrying out anatomical gifts?
9. Should such protection be afforded regardless of the state in which the document of gift is executed?
10. What should the effect of an anatomical gift be in case of conflict with laws concerning autopsies?
11. Should the time of death be defined by law in any way?
12. Should the interest in preserving life by the physician in charge of a decedent preclude him from participating in the transplant procedure by which the donated tissue or organ is transferred to a new host?

Uniform Anatomical Gift Act (Introduction), *reprinted in* STATUTORY REGULATION OF ORGAN DONATION IN THE UNITED STATES v, v (R. Hunter Manson ed., 2d ed. 1986).

109. Wayne L. Anderson & Janolyn D. Copeland, *Legal Intricacies of Organ Transplantation: Regulations and Liability*, 50 J. MO. B. 139, 140(1994).

110. *See* Cate, *supra* note 61, at 71. The UAGA has undergone minor modification in some states. Of the modifications made, the most apparent today relate to defining death, outlining procurement protocol, and prohibiting the sale of organs. *See* Moore, *supra* note 7, at 445. For example, Illinois has added subsection (g) to section 1 defining death as "the irreversible cessation of total brain function, according to usual and customary standards of medical practice." *See* ILL. ANN. STAT. ch. 110 1/2, §302 (Smith-Hurd 1978), *reprinted in* STATUTORY REGULATION OF ORGAN DONATION IN THE UNITED STATES 139 (R. Hunter Manson ed., 2d ed. 1986). California added a section entitled "Determination of Nonavailability" which outlines the procedures for a hospital to perform while making a diligent search for the persons who are to give consent for the use of a donor's organs. *See* CAL. HEALTH & SAFETY CODE §7151.6 (West Supp. 1984), *reprinted in* STATUTORY REGULATION OF ORGAN DONATION IN THE UNITED STATES 47 (R. Hunter Manson ed., 2d ed. 1986). West Virginia supplemented its law in 1987 to include a provision making it unlawful "for any person to knowingly acquire, receive, or otherwise transfer for valuable consideration any human organ for use in human transplantation." *See* W. VA. CODE §16-19-7a (Supp. 1987), *reprinted in* STATUTORY REGULATION OF ORGAN DONATION IN THE UNITED STATES 192 (Nell M. King ed., Supp. 1987).

111. *See* Uniform Anatomical Gift Act, §2 (a), *reprinted in* STATUTORY REGULATION OF ORGAN DONATION IN THE UNITED STATES 4 (R. Hunter Manson ed., 2d ed. 1986).

whether to donate the decedent's organs.<sup>112</sup> Donation may be indicated in a will or other written document,<sup>113</sup> and may be directed to a specific recipient.<sup>114</sup> The donor may, at any time before death, amend or revoke the document expressing his desire to donate, even if delivery of the document to the specific recipient occurred.<sup>115</sup> When organ donation actually occurs, the UAGA requires that the person taking the organs do so in a way that avoids mutilating the body before turning the body over to the family for disposal.<sup>116</sup> Finally, the UAGA provides protection from civil and criminal liability for any person who acts in good faith under any anatomical gift law, whether it be the UAGA, a state law, or the laws of a foreign nation.<sup>117</sup>

Opponents of the UAGA criticize the Act on three main grounds. The first concerns the donor card system. Studies show that while the American public, generally, favors organ donation,<sup>118</sup> most do not carry donor cards.<sup>119</sup> Furthermore, even in the presence of a signed donor card, removal of organs

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112. The people who may make the decision on behalf of the donor are listed in order of priority: "the spouse, an adult son or daughter, either parent, an adult brother or sister, a guardian of the person of the decedent at the time of his death, any other person authorized or under obligation to dispose of the body." *See id.*, §2 (b), at 4.

113. Should the donor choose to express his desire to donate in a will, the gift becomes effective at the death of the donor, without having to go through probate. *See id.* §4(a-b), at 5. If the will is not probated, or if the court holds it to be invalid for testamentary reasons, the gift is still valid if it was made in good faith. *See id.* Should the donor choose to express his desire to donate by way of other documents, the document must be signed by the donor in the presence of two witnesses who must also sign the document in his presence. *See id.* Today, the requirement of two witnesses no longer applies unless the donor expresses his intent to donate orally. *See Cate, supra* note 61, at 73.

114. *See* Uniform Anatomical Gift Act, *supra* note 111, §4 (c), at 5-6.

115. If the donor has designated a specific recipient and has delivered the document to the donee, he may revoke the gift by (1) delivering to the donee a signed statement, (2) making an oral statement in the presence of two witnesses that is communicated to the donee, (3) making a statement to an attending physician during a time of terminal illness or injury that is communicated to the donee, or (4) signing a card or other document that can be found on his person or in his effects. *See id.*, §6(a), at 6-7. If the document has not been delivered to the donee, the donor may do any of these four steps or cancel the gift by destruction, cancellation, or mutilation of the document and any existing copies. *See id.* §6(b), at 7. If the donor made the gift by will, he may amend or revoke the gift using any of the four steps outlined above, or by doing so as provided in the laws regulating the amendment and revocation of will. *See id.* §6(c), at 7.

116. *See id.* §7(a), at 7.

117. *See id.* §7(c), at 7. *See also supra* note 50 (describing each state's position with regard to the liability of physicians engaged in transplantation).

118. A Gallup poll conducted in 1990 indicates that, at that time, 94% of Americans were aware of organ transplants, 84% percent believed that transplants were successful in prolonging and improving the quality of life, and 89% percent said that they would respect their relative's request to donate his organs. *See Cate, supra* note 61, at 81. A similar poll taken in 1993 indicates that 85% percent of Americans are in favor of organ donation. *See MacDonald, supra* note 26, at 180.

119. *See MacDonald, supra* note 26, at 180.

usually does not occur without the consent of the family.<sup>120</sup> The doctor's fear of becoming caught up in conflicts with family members over the removal of the donor's organs, despite provisions in the UAGA releasing a doctor acting in good faith from liability, represents the primary reason for the doctor's failure to proceed with organ removal.<sup>121</sup>

The failure to sufficiently define the time of death constitutes a second criticism of the UAGA. Section 7(b) of the UAGA says only that death shall be determined by the attending physician.<sup>122</sup> To alleviate fears that a physician will have conflicting interests in helping his patient survive and in procuring organs for transplant, the UAGA provides that the attending physician shall have no part in obtaining the organs.<sup>123</sup>

At common law, the cessation of cardiac and respiratory function constituted death.<sup>124</sup> In 1968, Black's Law Dictionary defined death as "[t]he cessation of life; the ceasing to exist; defined by physicians as a total stoppage of the circulation of the blood, and a cessation of the animal and vital functions consequent thereon, such as respiration, pulsation, etc."<sup>125</sup> With the advent of routine organ transplantation and the ability to artificially maintain the heart and lungs, a definition of death focusing on the cessation of brain activity became more appropriate.<sup>126</sup> The Uniform Determination of Death

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120. See Moore, *supra* note 7, at 446.

121. See *id.* The Uniform Anatomical Gift Act States that "A person who acts in good faith in accord with the terms of this Act or with the anatomical gift laws of another state [or a foreign country] is not liable for damages in any civil action or subject to prosecution in any criminal proceeding for his act." Uniform Anatomical Gift Act §7(c), *supra* note 111, at 7. For information regarding the position of each state on this issue, see *supra* note 50. For cases in which suit has been brought against the doctor in an organ procurement situation, see *Williams v. Hoffman*, 233 N.W.2d 844, 847 (1974) (stating that the UAGA does not apply to "treatment of the donor prior to death" and that its liability protection did not extend to doctors in a wrongful conduct case in which a woman was sustained on life support so that her kidneys could be removed after her husband had been told that she was dead); *Colton v. New York Hospital*, 414 N.Y.S. 2d 866, 876 (1979) (extending liability protection to a doctor involved in a situation where a living donor suffered deafness as a result of a kidney transplant, after having signed a release form. The court in that case also stated that the wife did have a cause of action against the doctors for loss of consortium because she was not a party to the release.).

122. See Uniform Anatomical Gift Act §7(b), *supra* note 111, at 7.

123. See *id.*

124. See Schwartz, *supra* note 14, at 416.

125. BLACK'S LAW DICTIONARY 488 (4th ed. 1951). A more recent version of BLACK'S defined death as "The cessation of life; permanent cessations of all vital functions and signs." BLACK'S LAW DICTIONARY 400 (6th ed. 1990). That version further indicates that statutory definitions of death have been adopted in numerous states that embrace a definition of death as including brain-related criteria. *Id.*

126. See Schwartz, *supra* note 14, at 416.

Act states that death occurs when an individual sustains "either (1) irreversible cessation of circulatory and respiratory functions, or (2) irreversible cessation of all functions of the entire brain, including the brain stem. . . ." <sup>127</sup>

The third criticism of the UAGA involves its failure to substantially increase the number of available organs.<sup>128</sup> The reasons offered for this failure include a general lack of public awareness about organ donation; an unwillingness to donate organs; primarily for religious reasons; and for the fear of death.<sup>129</sup>

Inadequacies such as these led to the drafting of a new UAGA. It was adopted by the NCCUSL in 1987 and by the American Bar Association in 1988.<sup>130</sup> The 1987 UAGA adopts the system of routine inquiry and required request. This requires hospitals to ask each entering patient whether he is a donor and request a copy of the document authorizing the gift, or discuss organ donation with the patient.<sup>131</sup>

The 1987 UAGA also requires law enforcement officers, firemen, paramedics, other emergency rescuers, and hospital personnel to make a reasonable effort to find information indicating the individual's wishes.<sup>132</sup> Failure to conduct a reasonable search results in administrative sanctions rather than criminal or civil penalties.<sup>133</sup>

Finally, the 1987 UAGA forbids the commercialization of organs by disallowing the purchase or sale of body parts for "valuable consideration . . . if the removal of the part is intended to occur after the death of the decedent."<sup>134</sup> Valuable consideration, within the meaning of the Act, includes "reasonable payment for the removal, processing, disposal, preservation, quality control, storage, transportation, or implantation of a part."<sup>135</sup> States have not been as receptive to the 1987 UAGA as they were to its 1968

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127. See *Defining Death: A Report on the Medical, Legal, and Ethical Issues in the Determination of Death*, in HUMAN ORGAN TRANSPLANTATION: SOCIETAL, MEDICAL-LEGAL, REGULATORY, AND REIMBURSEMENT ISSUES, app. C, 407 (Dale H. Cowan et. al. eds., 1987).

128. See Moore, *supra* note 7, at 447.

129. See *id.* This lack of awareness concerns the organ donor programs in general. See David E. Chapman, *Retailing Human Organs Under the Uniform Commercial Code*, 16 JOHN MARSHALL L. REV. 393,400 (1983). In recent years, public awareness about organ donor programs has increased. See *supra* note 118. While religious objections have been stated as a reason for low donor rates, approximately 30 world religions support organ donation. See RAYMOND S. EDGE & JOHN RANDALL GROVES, *ETHICS OF HEALTH CARE: A GUIDE FOR CLINICAL PRACTICE*, app. C, at 292 (2d ed. 1999); Stan Simbal, *Does My Religion Approve of Organ Donation?* (visited Sept. 8, 1999) <[http://www.transweb.org/qa/qa\\_txp/faq\\_religion.html](http://www.transweb.org/qa/qa_txp/faq_religion.html)>.

130. See Cate, *supra* note 61, at 73.

131. See *id.*

132. See Uniform Anatomical Gift Act (1987), §5(c), 8A U.L.A. 19, 47 (1993).

133. See *id.* §5(f), at 47.

134. *Id.*, §10(a), at 58.

135. *Id.*, §10(b), at 58.

counterpart. To date, only fifteen states have adopted the Act.<sup>136</sup> Some attribute this lack of enthusiasm to the inclusion of the required request provision and possibly the prohibition on organ sales.<sup>137</sup>

### B. *The National Organ Transplant Act*

Regulation of organ transplantation exists on the federal level as the National Organ Transplant Act (NOTA). The Act, adopted by Congress and signed into law by President Reagan in 1984, constitutes the primary federal regulation of organ donation in the United States.<sup>138</sup> Congress enacted NOTA in order to alleviate the shortage of organs and to improve the matching of donors and recipients by using a national system for organ procurement and distribution.<sup>139</sup>

There are six basic components to NOTA:

1) to establish a task force on Organ Procurement and Transplantation that is comprised of twenty-five members who study a broad range of medical, legal, ethical, economic, and social issues related to organ procurement and transplantation;<sup>140</sup>

2) to require the Secretary of Health and Human Services to convene a conference on the feasibility of establishing a national registry of voluntary bone marrow donors;<sup>141</sup>

3) to create the Division of Organ Transplantation;<sup>142</sup>

4) to empower the Secretary to make grants for the planning, creation, initial operation, and expansion of organ procurement organizations;<sup>143</sup>

5) to require the Secretary to contract for an Organ Procurement and Transplantation network and a Scientific Registry;<sup>144</sup> and

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136. The 1987 UAGA has been adopted in Arkansas, California, Connecticut, Hawaii, Idaho, Minnesota, Montana, Nevada, North Dakota, Rhode Island, Utah, Vermont, Virginia, Washington, and Wisconsin. See Table of Jurisdictions Wherein Act Has Been Adopted, Uniform Anatomical Gift Act (1987), 8A U.L.A. 19 (1993).

137. See Robinson, *supra* note 29, at 1027-28.

138. See Lisa E. Douglass, *Organ Donation, Procurement and Transplantation: The Process, the Problems, the Law*, 65 UMKC L. REV. 201, 207 (1996). Secondary federal legislation affecting organ donation in the United States includes: The Public Health Service Act (42 U.S.C. 262), The Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.), The Social Security Act (42 U.S.C. 1320b-8), The Animal Welfare Act (7 U.S.C. 2131), and The Omnibus Budget Reconciliation Act of 1986 (Pub. L. No. 99-509, §9318, 100 Stat. 1874, 2009-2010) (amending the Social Security Act).

139. See Douglass, *supra* note 138, at 207.

140. National Organ Transplantation Act of 1984, Public Law 98-507 (codified in scattered sections of 42 U.S.C.) at §101 (b)(1)(A)).

141. See *id.* § 401(a).

142. See *id.* § 375.

143. See *id.* § 371.

144. See *id.* § 372.

6) to prohibit the purchase and sale of human organs for valuable consideration.<sup>145</sup>

NOTA symbolizes an important piece of legislation in the United States for a number of reasons.<sup>146</sup> By prohibiting the sale of human organs in interstate commerce,<sup>147</sup> Congress relieved the fears that indigent members of U.S. society and the Third World would be preyed upon as a source of organs.<sup>148</sup> Further, the Task Force on Organ Transplantation (Task Force) created under the Act, recommended that hospitals in the United States adopt a system of routine inquiry and required request to help identify potential donors and provide the next-of-kin with the opportunity to donate on behalf of their relative.<sup>149</sup> Congress accepted this recommendation in the Omnibus Budget Reconciliation Act of 1986 (OBRA).<sup>150</sup> As a result, hospitals failing to establish "written protocols for the identification of potential donors" may lose their Medicare and Medicaid funding.<sup>151</sup> While this provision of OBRA appears to grant a great degree of power over the hospitals to the federal government, inadequate supervision of the system hinders the realization of any increase in available organs.<sup>152</sup>

NOTA also established the framework for organ procurement and distribution in the United States.<sup>153</sup> The Act created the Organ Procurement

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145. *See id.* § 301.

146. *See Robinson, supra* note 29, at 1028.

147. Anyone caught in the purchase or sale of organs commits a felony punishable by a fine of \$50,000 and/or five years imprisonment. *See National Organ Transplantation Act of 1984, supra* note 140, at §301.

148. It seems these fears were justified. Evidence of a commercial market for organs in the United States prompted Congress to pass NOTA. *See Robinson, supra* note 29, at 1028. This evidence consisted of a plan by Dr. H. Barry Jacobs to broker human kidneys from live donors. *See id.* at 1036. He established an organization named the "International Kidney Exchange Ltd." for the purpose of procuring kidneys from indigent Third World residents. *See id.* The potential organ donors would set the price for the purchase of their kidneys under Jacobs' plan, and Jacobs would collect \$2000 to \$5000 for his brokerage services. *See id.*

149. *See id.* at 1029. Some believe that NOTA has failed because it gave too much discretion to the task force to study those issues it (the task force) deemed important, allowing the problem of finding solutions to the organ deficit to be neglected. This lack of direction seems to show that Congress' efforts were really aimed at expanding the role of the federal government in organ procurement rather than increasing the number of available organs. *See Moore, supra* note 7, at 450.

150. *See Public L. No. 99-509, 100 Stat. 1874, 2009 (1986) (codified at 42 U.S.C. §1320b-8 (1994)), reprinted in STATUTORY REGULATION OF ORGAN DONATION IN THE UNITED STATES 215 (Nell M. King ed. Supp. 1987).*

151. *See 42 U.S.C. §1320b-8(a)(1)(A)(i)-(iii) (1994).* These protocols should: "(i) assure that families of potential donors are made aware of the option of organ or tissue donation and their option to decline; (ii) encourage discretion and sensitivity with respect to the circumstances, views, and beliefs of such families; and (iii) require that an organ procurement agency designated by the Secretary pursuant to subsections (b) (1) (F) of this section be notified of potential organ donors. . . ." *Id.*

152. *See Douglass, supra* note 138, at 211.

153. *See Robinson, supra* note 29, at 1030.

and Transplantation Network (OPTN) to supervise the allocation of organs throughout the country.<sup>154</sup> The United Network for Organ Sharing (UNOS), which already exists as a central registry of potential kidney recipients, administers the OPTN.<sup>155</sup>

NOTA also authorized the establishment of regional organ procurement organizations (OPO).<sup>156</sup> These organizations find and transport the donor organ under the NOTA requirements that the OPO "engage in a systematic effort to acquire all usable organs from potential donors, preserve these organs, and arrange to transport them to transplant centers within the OPO's area."<sup>157</sup>

While admirable, the efforts of the UAGA and the NOTA are not enough. Despite their thirty years of regulation of organ donation in the United States, the Acts simply fail to sufficiently solve the organ deficit.<sup>158</sup> The United States must look to other ways of addressing the shortage of organs available for transplant.

#### IV. ORGAN DONATION LAWS IN BRITAIN

Government regulation of transplantation occurred in Britain sixteen years before the Uniform Anatomical Gift Act provided a model for U.S. state laws and thirty-two years before the United States adopted its own federal legislation—the National Organ Transplant Act. In 1952, Parliament passed the Corneal Grafting Act, the first statute to directly address tissue transplantation.<sup>159</sup> This Act was repealed nine years later as the need for a more general law dealing with other tissues and organs became necessary.<sup>160</sup>

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154. *See id.*

155. *See id.* The Department of Health and Human Services, in April 1998, proposed regulations that would insure that UNOS "develop an organ allocation system that functions on a 'national' rather than a 'local-regional' basis and gives preference to the most medically urgent patients, defined as those who are very ill but who, according to their physician, have a reasonable likelihood of post-transplant survival." Gail L. Daubert, *Politics, Policies, and Problems with Organ Transplantation: Government Regulation needed to Ration Organs Equitably*, 50 ADMIN. L. REV. 459, 465, 487 (1998).

156. *See* 42 U.S.C.A. §273 (1994); Robinson, *supra* note 29, at 1030.

157. Robinson, *supra* note 29, at 1030 (quoting Charles K. Hawley, *Antitrust Problems and Solutions to Meet the Demand for Transplantable Organs*, 1991 U. ILL. L. REV. 1101, 1104 (1991)).

158. *See supra* note 23 and accompanying text.

159. *See* LAMB, *supra* note 49, at 145. The Corneal Grafting Act was "[a]n Act to make provision with respect to the use of eyes of deceased persons for therapeutic purposes." Corneal Grafting Act, 1952, 15 & 16 Geo. 6 & 1 Eliz., 2 ch. 28 (Eng.). This Act provided that an individual, a person in possession of the body, or the person in control of the hospital may request that the donor's eyes be used for therapeutic purposes after his death. *See id.* at §1.

160. *See* LAMB, *supra* note 49, at 145.

Today, two statutes govern organ and tissue transplantation in Britain—the Human Tissue Act and the Human Organ Transplants Act.<sup>161</sup>

A. *Human Tissue Act of 1961*

The Human Tissue Act of 1961 provides the United Kingdom with statutory regulation that governs cadaveric transplants without specific reference to particular tissues or organs.<sup>162</sup> The provisions of the Act resemble the Uniform Anatomical Gift Act that exists in the United States.<sup>163</sup> Like the UAGA, the Human Tissue Act creates a system of expressed consent or volunteerism based on the individual's right to determine for himself whether to donate his organs.<sup>164</sup>

Section 1(1) allows an individual to request the donation of his organs following his death for the purposes of therapy, education, or research.<sup>165</sup> Individuals donate organs by executing a written document or making an oral request for donation in the presence of two witnesses.<sup>166</sup> Section 1(2) indicates that, absent a request for donation, the person in possession of the body may authorize donation after making a reasonable attempt to insure that neither the donor nor his relatives objected to the donation.<sup>167</sup>

Some criticize the ambiguity of the Human Tissue Act.<sup>168</sup> One area of ambiguity concerns the sufficiency of donor cards. Citizens easily obtain donor cards in Britain,<sup>169</sup> and opinion polls repeatedly indicate support for

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161. See Siobhan Deehan, *The Gift of Life*, NEW L.J., Aug. 12, 1994, at 1143 [hereinafter Deehan, *The Gift*].

162. See LAMB, *supra* note 49, at 145.

163. See Schwartz, *supra* note 14, at 420.

164. See *id.* at 420-21. Prior to 1961, it was illegal for an individual in Britain to dispose of his own body. This changed with the adoption of the 1961 Suicide Act. See Trew, *supra* note 73, at 277.

165. See Human Tissue Act, 1961, 9 & 10 Eliz 2, ch. 54 (Eng.).

166. See *id.*

167. See *id.*

168. See LAMB, *supra* note 49, at 145.

169. See *id.* When people in the United States think of making an anatomical gift, they generally think of making note of their desires on their driver's licenses. Indeed, some U.S. states, such as Colorado, require individuals to say yes or no to organ donation at the time they apply for or renew their licenses. See Schwartz, *supra* note 14, at 420. All fifty U.S. states and the District of Columbia have a way for donors to indicate their intent on the license. Furthermore, approximately twenty states maintain registries through the Motor Vehicle Association that indicate a driver's choice regarding donation. See Karen L. Smith & Judith B. Braslow, *Public Attitudes Toward Organ and Tissue Donation*, in ORGAN AND TISSUE DONATION FOR TRANSPLANTATION 34, 42-43 (Jeremy R. Chapman et al. eds., 1997). The opportunities for completing organ donor cards are much greater in Britain, where there is more publication of the need for donors. In 1988, British Telecom mailed four million donor cards with its telephone bills in the London area. Donor cards were also distributed to spectators at a basketball game involving special teams made up of heart transplant patients from the United States. A proposal made in Britain was "transplant days," which would be held once a year, and



organ donation.<sup>170</sup> Despite this support, however, the majority of the public does not carry donor cards.<sup>171</sup> Even if it did, questions arise as to whether the donor cards satisfy the requirement that organ donation requests occur in an "authorised form."<sup>172</sup>

A second area of ambiguity concerns section 1(2) of the Act. This section provides for the person in possession of the body to authorize donation when no known request for donation exists and reasonable efforts to determine whether the donor or his surviving relatives have any objection to the procedure.<sup>173</sup> No clear authority indicates who constitutes the person "lawfully in possession of the body."<sup>174</sup> Furthermore, the Act fails to define "surviving relative" and "reasonable enquiries."<sup>175</sup> The question arises as to what happens when death occurs? Who asks permission to harvest the organs, and from whom does that person seek consent?

The concern for saving time in the transplantation process renders these questions significant. After death, doctors have a limited amount of time to retrieve a potential donor's organs before they become unusable.<sup>176</sup> Knowing prior to death who is responsible for seeking and giving consent to donation saves time otherwise lost.

Finally, critics find the Act ambiguous because it fails to provide a definition of death.<sup>177</sup> Doctors and lawyers have attempted to clarify the

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would allow the public to actually meet transplant surgeons and organ recipients. See LAMB, *supra* note 49, at 149-150.

170. A Gallup poll conducted on December 30, 1988 showed that 85% of those polled favored organ transplants. Another poll conducted that same year by the British Kidney Patients Association found that 70% of the people responding were willing to donate. See LAMB, *supra* note 49, at 147.

171. In the poll conducted by the British Kidney Patients Association in 1988, only 29% of those responding to the survey said that they possessed donor cards. See *id.* A later survey again found that 70% of the population favored donating their organs after death, but only 27% possessed donor cards. Of that number, only two-thirds (19% of the total population) usually carried the cards with them. See Deehan, *The Gift*, *supra* note 161, at 1143.

172. *Id.*

173. See Human Tissue Act, 1961, 9 & 10 Eliz 2, ch. 54 (Eng.).

174. See Deehan, *The Gift*, *supra* note 161, at 1143.

175. See *id.*

176. Body tissue deteriorates rapidly. See Thomas D. Overcast, *Legal Aspects of Death and Informed Consent in Organ Transplantation*, in HUMAN ORGAN TRANSPLANTATION: SOCIETAL, MEDICAL-LEGAL, REGULATORY, AND REIMBURSEMENT ISSUES 55, 62 (Dale H. Cowan et al. eds., 1987). Without a constant supply of blood, human organs lose their viability. That is why it is important for organ harvesting to be performed soon after death, or for the individual to be maintained on artificial life support until the harvesting can occur. See Schwartz, *supra* note 14, at 416. The time in which an organ or tissue remains viable differs from organ to organ. Livers and hearts endure for only hours, while kidneys may last approximately one and one-half days. See *id.* at 399. The "banking" of these organs is not feasible as it is for blood, which can be stored for up to twenty-one days. See *id.*

177. See Deehan, *The Gift*, *supra* note 161, at 1143.

meaning of death within the context of the Human Tissue Act.<sup>178</sup> The Conference of Medical Royal Colleges and their faculties issued statements in 1976 and in 1979 recognizing brainstem death as the criteria for death in the United Kingdom.<sup>179</sup> Nevertheless, confusion and fear of organ harvest before actual death occurs remain to the point that an aversion to organ donation exists.<sup>180</sup>

Despite these shortcomings, the Human Tissue Act of 1961 still plays a large role in the regulation of organ donation and transplantation in Britain. Approximately ninety percent of all organs used for transplants in that country are obtained from deceased donors.<sup>181</sup> All of these fall under the province of the Human Tissue Act, the governing legislation for cadaveric organ procurement and transplantation in Britain. Unfortunately, the Human Tissue Act has failed to achieve equality between the number of organs needed and the number available.<sup>182</sup>

### B. Human Organ Transplant Act of 1989

The Human Organ Transplant Act of 1989 (HOTA) comprises the second piece of legislation concerning organ procurement and transplantation in Britain. While the Human Tissue Act of 1961 addressed the procurement of cadaveric organs, HOTA focuses on procuring organs from live donors.<sup>183</sup>

Controversy surrounding the marketing of organs in Britain gave birth to HOTA. The triggering event occurred when allegations made against doctors accused of transplanting the kidneys of Turkish peasants into wealthy

178. *See id.*

179. The brainstem is defined as "the vertebrate brain excluding the cerebellum and cerebrum." WEBSTER'S ENCYCLOPEDIA DICTIONARY 116 (1990). Brainstem death requires only death of the brainstem, whereas brain death implies death of the brainstem and cerebral death. *See* Ian Y. Pearson, *Brain Death*, in ORGAN AND TISSUE DONATION FOR TRANSPLANTATION 69, 78 (Jeremy R. Chapman et al. eds., 1997). Medical professionals used to rely on brain death rather than brainstem death for determining the point at which death of an individual actually occurred. Its characteristics included coma, absent brainstem and tendon reflexes and an electrically silent brain. *See* LAMB, *supra* note 49, at 31-32. Through the work of Mohandas and Chou in Minneapolis in 1971, it was found that, once irreversible damage to the brainstem occurred, there was no chance of survival. *See id.*, at 34. It was not until the 1980s, however, that the gradual realization that the death of the brainstem was synonymous with the death of the individual actually occurred. *See id.* at 36.

180. A study conducted in Britain in the early 1990s indicated that 30 % of the families refused when asked about donating their relative's organs. *See* Deehan, *The Gift*, *supra* note 161, at 1143.

181. *See id.*

182. *See* Siobhan Deehan, *New Labour, New Laws?*, NEW L.J., July 31, 1998, at 1138 [hereinafter Deehan, *New Labour*].

183. A donor is generally defined in HOTA as being a person, either living or dead from whom it is proposed to remove an organ. *See* Human Organ Transplants Act, 1989, ch. 31, §1(1)(a) (Eng.).

Indian and Pakistani recipients became public.<sup>184</sup> Soon after this case, Parliament passed the Human Organ Transplants Act of 1989.<sup>185</sup>

HOTA resembles the National Organ Transplant Act that exists in the United States in that it prohibits the sale or purchase of human organs.<sup>186</sup> It forbids soliciting an organ to buy, negotiating or initiating negotiations for the purchase of an organ, and advertising the sale or purchase of an organ.<sup>187</sup> Furthermore, in an effort to eliminate the commercialization of organ procurement, HOTA prohibits the transplantation of organs from living donors into non-genetically-related recipients<sup>188</sup> unless certain regulations are met, including evidence that no compensation has been made for the organ.<sup>189</sup>

Criticisms of HOTA tend to focus on the provision against non-related transplants. Questions exist as to why HOTA requires the approval of ULTRA before allowing non-related persons to receive organs but not related individuals.<sup>190</sup> While related individuals may not be as likely to be involved in the transplant for compensation, the possibility exists that emotional

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184. See BRODY, *supra* note 49, at 115. The allegations against the doctors resulted in the suspension from private practice of Dr. Maurice Bewick, a prominent kidney transplant surgeon, who was found to have transplanted a kidney that had been purchased for \$4000 from one Turkish man to another. See Ronald Bailey, *The Buying and Selling of Organs Saves Lives*, in BIOMEDICAL ETHICS: OPPOSING VIEWPOINTS 73, 78 (Terry O'Neill ed., 1994). Supposedly, the two men traveled to Britain together for the purpose of carrying out the procedure. See *id.* At the time the transplant occurred, the sale of organs in Britain was not illegal, however there were guidelines established by the British Transplantation Society that looked at such transactions with disfavor. See *id.*

185. See Bailey, *supra* note 184, at 78.

186. See Human Organ Transplants Act, 1989, ch. 31, §1 (Eng.).

187. See *id.*

188. An individual is genetically related to:

1. his natural parents and children;
2. his brothers and sisters of the whole or halfblood;
3. the brothers and sisters of the whole or halfblood of either of his natural parents; and
4. the natural children of his brothers and sisters of the whole or halfblood or of the brothers and sisters of the whole or halfblood of either of his natural parents;

*Id.* One of these relationships must be proven as specified in regulations made by the Secretary of State. See *id.*

189. The Human Organ Transplants Regulations SI 1989 No. 2480 establish a regulatory authority to oversee the transplantation of organs from a living donor into a non-genetically related recipient. See David Price & Ronnie Mackay, *The Trade in Human Organs*, NEW L.J., Sept. 27, 1991, at 1307. It is called the Unrelated Live Transplant Regulatory Authority (ULTRA) and it consists of a chairman and seven to eleven other members. See *id.* At least three of these members must be registered doctors, and at least four must be non-registered doctors. See *id.* In order for a transplant between non-related persons to be approved, ULTRA must be satisfied that compensation is not involved in the transaction, and the doctor referring the case to ULTRA has clinical responsibility for the donor. See *id.* Furthermore, if the removal of the organ is not for the medical treatment of the donor, ULTRA must be convinced that the donor has been made aware of the risks involved, understands the nature and scope of the procedure, and consents to its performance. See *id.*

190. See Deehan, *The Gift*, *supra* note 161, at 1143.

coercion may influence the family member's decision to donate.<sup>191</sup> Furthermore, by focusing on genetic relations, HOTA overlooks the opportunity of spouses and cohabitants<sup>192</sup> to donate organs.<sup>193</sup>

HOTA also requires the satisfaction of other regulations separately created by the Secretary of State in order for the procedure to occur.<sup>194</sup> One of these regulations dictates that the donor voluntarily consent to the procedure upon fully understanding the risks involved.<sup>195</sup> This particular regulation appears extreme in that it requires more of a non-related organ donor than English law imposes in common informed consent cases.<sup>196</sup> The necessity of the regulation also appears questionable because the motivation for the donor to make the gift is the psychological and spiritual benefits involved.<sup>197</sup> Certainly, no physical benefit to the donor occurs from the procedure.<sup>198</sup>

A final criticism of HOTA rests in the assertion that its provisions negatively affect donor rates. By making certain forms of organ donation illegal, HOTA contributes to a general public aversion to donation and enlarges the problem of organ scarcity.<sup>199</sup> Organs remain scarce in Britain, despite the efforts of the Human Tissue Act and the Human Organ Transplants Act.<sup>200</sup> Notwithstanding the good intentions behind these initiatives, such poorly drafted, outdated, and restrictive legislation does not produce more organs for transplantation.<sup>201</sup>

Recognizing that the current system of organ procurement fails to achieve the goal of equalizing supply and demand, reformists in Britain began to push for a change. Sir John Biggs-Davison<sup>202</sup> proposed an amendment to the Human Tissue Act of 1961 that would revamp existing regulation by making organ donation a matter of "opting out" rather than "opting in."<sup>203</sup> In

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191. See *id.*

192. "Cohabit" means "to live together, esp[ecially] as husband and wife when not married." WEBSTER'S ENCYCLOPEDIA DICTIONARY 190 (1990). A "cohabitee," therefore, would be an individual who resides with the potential recipient.

193. See Deehan, *The Gift*, *supra* note 161, at 1143.

194. See Human Organ Transplants Act, 1989, ch. 31, §2 (Eng.).

195. See Price & Mackay, *supra* note 189, at 1307.

196. See *id.* English informed consent laws follow the case of *Sidaway v. Board of Governors of the Bethlem Royal Hospital and the Maudsley Hospital*, 1 All E.R. 643 (H.L. 1985).

197. See Price & Mackay, *supra* note 189, at 1307.

198. See *id.*

199. See Deehan, *The Gift*, *supra* note 161, at 1143.

200. See *id.*

201. See *id.*

202. Sir John Biggs-Davison is a conservative member of Parliament from Epping Forest. See Ruth Redmond-Cooper, *Transplants Opting Out or In—the Implications*, NEW L.J., Aug. 3, 1984, at 648.

203. See *id.* Two polls conducted in Britain indicated that the public was evenly divided on the issue of presumed consent. A follow-up poll that clearly and simply explained presumed

1993, the Advisory Council on Science and Technology (Council) published a recommendation that the Government study the feasibility of introducing such a system.<sup>204</sup> Dr. Peter Doyle, the chairman of the Council, believes that Britain should adopt presumed consent for two reasons.<sup>205</sup> First, the reliance on donor cards to contract into donation clearly fails to satisfy the demand for organs.<sup>206</sup> Second, in those countries using a presumed consent system, very few people registered their objections to the harvesting of their organs.<sup>207</sup>

Presumed consent has not yet been adopted in Britain. The failure of the British Medical Association (BMA) to support the system constitutes the primary reason for the reluctance of the country to change.<sup>208</sup> The reason for the BMA's lack of enthusiasm toward presumed consent is a fear that many of society's disadvantaged would not understand the mechanics of the legislation and would not know how to register their objections to organ donation.<sup>209</sup>

Some argue that this fear can be relieved by allowing revocation of the registration and by guaranteeing that, absent an indication that the donor did not want to donate his organs, the doctors would be barred from proceeding without the prior consent of the patient's family.<sup>210</sup> The studies of presumed

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consent resulted in twice as many citizens supporting presumed consent than opposing it. See Paul Michielsens, *Informed or Presumed Consent Legislative Models*, in *ORGAN AND TISSUE DONATION FOR TRANSPLANTATION* 344, 356 (Jeremy R. Chapman et al. eds., 1997).

204. See Deehan, *New Labour*, *supra* note 182, at 1138.

205. See *id.*

206. Dr. Doyle observed that in 1990, there were no kidneys used in transplantation that had been taken from someone carrying a donor card. See *id.*

207. See *id.* It has been argued that, in some nations, the government has made it difficult to register. Therefore, the statistics indicating that people in presumed consent countries do not register their objections may not be accurate. Furthermore, there is no clear-cut evidence that high donation rates result from presumed consent laws. See OECD, *supra* note 17, at 19. In fact, some nations that employ presumed consent actually have lower donor rates than some nations with expressed consent laws. See *supra* note 63 and accompanying text.

208. See Deehan, *New Labour*, *supra* note 182, at 1138. Depending upon the position of a particular doctor, his attitude toward presumed consent may vary. Approximately 40% of British doctors working in the area of transplantation support presumed consent, while 31% of those same doctors favor expressed consent. See Michielsens, *supra* note 203, at 357. A large majority of doctors in the ICUs, however, oppose presumed consent. See *id.* Studies also show that presumed consent is not favored by the British public. In 1998, surveys showed that only 25% of the people in the United Kingdom favored mandatory donation. See OECD, *supra* note 17, at 18.

209. See Deehan, *New Labour*, *supra* note 182, at 1138. This argument is similar to that made against the commercialization of organ procurement in Britain. In fact, the Human Organ Transplants Act of 1989 was adopted in response to the very situation where the poorer segments of society were being taken advantage of. See *supra* note 184 and accompanying text. It seems that the BMA is afraid that if presumed consent is embraced, the lower classes of society might unwillingly become organ donors because they have less knowledge about what must be done to register their objections.

210. See Deehan, *New Labour*, *supra* note 182, at 1138.

consent in France and Belgium<sup>211</sup> show, however, that requiring consent of the family weakens the presumed consent system, causing it to behave as a system of expressed consent.

Perhaps another reason why Britain has not yet embraced presumed consent is that a majority of the general public dislikes it. Surveys conducted by Miranda and Matesanze in 1998 indicate that only twenty-five percent of the population of the United Kingdom supports a system of mandatory organ donation.<sup>212</sup> Should presumed consent ever be adopted in Britain, the lack of public support would surely reduce its effectiveness and probably erase any advantage that presumed consent might have over the current British system of volunteerism.

Another, perhaps more likely, reason for the BMA's unwillingness to support presumed consent is that it legally shifts the decision about organ donation from the family to doctors themselves.<sup>213</sup> Fear of litigation causes the doctors to be more hesitant about embracing a system that exposes them to possible liability. Again, the study of other nations emphasizes that even though doctors may escape liability if they act according to the law, they are usually very reluctant to proceed with organ harvesting without gaining the consent of the family.<sup>214</sup>

Given the failure of existing organ procurement regulations to increase the number of organs available for transplant and the reluctance of the medical community, as well as the public, to accept a system of presumed consent, it becomes necessary to look to other ways of increasing the supply of transplantable organs. Xenotransplantation offers an alternative that appears to overcome many of the shortfalls of existing law while potentially bringing an end to the organ supply crisis.

## V. XENOTRANSPLANTATION

Xenotransplantation is not a new phenomenon; however, the term itself is so new that many non-medical dictionaries do not list it.<sup>215</sup> Generally, "xenotransplantation" refers to the replacement, usually by a surgical operation, of a damaged or diseased human organ with a comparable healthy organ from an animal.<sup>216</sup>

The first hint of xenotransplantation, animal-human transfusions, occurred in the mid-1660s, shortly after the realization that blood circulated

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211. See *supra* notes 76-90 and accompanying text.

212. See OECD, *supra* note 17, at 18.

213. See Michielsen, *supra* note 203, at 357.

214. See *supra* note 48 and accompanying text.

215. See Kress, *supra* note 28, at 353.

216. See *id.* The word is actually derived from the Greek word "xeno" meaning different. Thus, xenotransplantation means the transplantation of organs from different species.

throughout the body.<sup>217</sup> Dr. Richard Lower conducted the first authenticated transfusion in which he injected lamb's blood into the veins of a 'mildly melancholic' man in 1667, apparently with no resulting harm.<sup>218</sup> Jean Baptiste Denys, a French philosopher, conducted four similar transfusions in experimental procedures.<sup>219</sup> Three of the patients survived the transfusions; however, the fourth died, causing the philosopher to be charged with murder.<sup>220</sup> The court exonerated him, but a subsequent decree limited further transfusions.<sup>221</sup>

Three hundred years later, scientists performed the first somewhat successful animal-human organ transplants. In the 1960s, several primate-human kidney transplantations occurred.<sup>222</sup> A gentleman in Mississippi received a chimpanzee heart in 1964; however, he survived only ninety minutes following the operation.<sup>223</sup> In a subsequent attempt, a man lived for three days after receiving a chimpanzee's heart in 1977.<sup>224</sup> The famous case of "Baby Fae" occurred in 1984 at Loma Linda, California. It involved the transplantation of a baboon heart into a fourteen day old baby.<sup>225</sup> Baby Fae survived two and one-half weeks.<sup>226</sup>

As these examples indicate, low survival rates plagued early efforts at xenotransplantation. The development of immunosuppressive drugs, however, made the likelihood of longer survival rates following

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217. See LAMB, *supra* note 49, at 111.

218. See *id.*

219. See *id.*

220. See *id.*

221. Perhaps one reason that the decree was issued was the statement that Denys gave describing the results of the transfusion of incompatible blood. It stated:

As soon as the blood entered into his Veins, he felt the same heat all along his arm and in the Armpits which he had done before. His Pulse was forthwith raised, and a while after we observed a great Sweat sprinkled all over his face. His pulse, at this moment was very much altered; and he complained of a great Pain and Illness in his Stomach and that he should be presently choaked, unless we would let him go . . . By and by he was laid on his bed, and after he had for two hours sustained much violence, vomited up divers liquors which had disturbed his Stomach, he fell into a profound sleep about ten a clock, and slept all that night without intermission till eight a clock the next day . . . When he awakened he seemed wonderfully composed and in his right mind, expressing the Pain and universal weariness he felt in all his members. He pist a large glass full of such black Urine that you would have said it has been mixed with soot.

*Id.* at 111-112.

222. See *id.* at 112.

223. See *id.* For medical information regarding this procedure, see James D. Hardy, M.D. et al., *Heart Transplant in Man*, JAMA 1132-40 (1964).

224. See LAMB, *supra* note 49, at 112.

225. See Schwartz, *supra* note 14, at 431. For medical information regarding this procedure see Thomasine Kushner & Raymond Belliotti, *Baby Fae: A Beastly Business*, 11 J. MED. ETHICS 178-83 (1985).

226. See Schwartz, *supra* note 14, at 431.

xenotransplantation procedures possible.<sup>227</sup> Coupled with the fact that current legislation fails to meet the demand for usable organs,<sup>228</sup> increased survival indicates that xenotransplantation represents a real possibility in the effort to eliminate the organ shortage.<sup>229</sup>

Xenotransplantation offers several advantages over traditional cadaveric organ transplantation.<sup>230</sup> Perhaps the most important is the availability of organs for transplant.<sup>231</sup> Scientists agree that the animal of choice for xenotransplantation purposes is the pig. Unlike the non-human primates, some of which are on the endangered species list,<sup>232</sup> pigs, generally, are healthier than primates, which often harbor many viruses that might eventually manifest themselves in the human organ recipients.<sup>233</sup> Furthermore, pigs breed easily and often have larger litters than primates,<sup>234</sup> thus producing a greater number of potential organs.

The ability to make transplants elective procedures constitutes a second advantage of xenotransplantation.<sup>235</sup> A successful transplant depends greatly

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227. Monkey hearts transplanted into baboon functioned an average of 296 days in experiments using daily treatments that combine cyclosporine, prednisone, and Mycophenolate Mofetil (MMF). See Stephen C. Rayhill & Hans W. Sollinger, *Mycophenolate Mofetil: Experimental and Clinical Experience*, in IMMUNOSUPPRESSION IN TRANSPLANTATION 47, 54 (Leo C. Ginns et al. eds., 1999). Treatments with immunosuppressive drugs occur with allotransplantation (human-human transplantation) as well. In fact, almost all transplant recipients remain on immunosuppressive drugs for the rest of their lives. See Kress, *supra* note 28, at 354.

228. Demand for organs is increasing as more medical centers are able to perform transplantation surgery and improvements are made in the techniques for managing rejection and infection. The laws simply are not adequate to meet the demand for organs. Even if policies are changed, better access to care, the AIDS epidemic, public ambivalence toward cadaveric organ donation and public health measures such as seat belt laws, higher ages for purchasing alcohol and tougher drunk driving laws all make it unlikely that the number of organs donated will increase. See ARTHUR L. CAPLAN, AM I MY BROTHER'S KEEPER? 104 (1997) [hereinafter CAPLAN, BROTHER'S KEEPER].

229. Xenotransplantation is being promoted as an alternative to current organ procurement methods because "it has the most realistic present-day potential for alleviating a certain shortage of organs, thus possibly saving tens of thousands of human lives each year in the United States alone." Kress, *supra* note 28, at 381.

230. See Donald V. Cramer & Leonard Makowka, *The Use of Xenografts in Experimental Transplantation*, in HANDBOOK OF ANIMAL MODELS IN TRANSPLANTATION RESEARCH 299 (Donald V. Cramer et al. eds., 1994).

231. The authors note that the greatest limit on the pool of organ recipients is the current shortage of organs. If availability of organs were to increase, then the number of transplants performed would also increase, as would the number of people who would benefit from the procedure. See *id.*

232. Chimpanzees are an endangered species, with approximately 100,000 left in the world. Their survival would be impossible if they were used as a source of organs. See LAMB, *supra* note 49, at 113.

233. Rebecca D. Williams, *Organ Transplants from Animals: Examining the Possibilities* (visited Sept. 8, 1999) <[http://www.fda.gov/fdac/features/596\\_xeno.html](http://www.fda.gov/fdac/features/596_xeno.html)>.

234. See *id.*

235. See Cramer & Makowka, *supra* note 230, at 299-300.



on the timing of the procedure. Indeed, timing is essential to a good outcome and an improved graft survival.<sup>236</sup> Advanced planning of surgery improves the chance of the patient's overall better health at the time of the operation because of the shorter wait for an organ and the decreased progression of the patient's disease.<sup>237</sup> The patient's better health at the time of surgery ultimately leaves him stronger during the recovery period.<sup>238</sup>

Xenotransplantation also allows a better size match between organs and recipients.<sup>239</sup> Currently, difficulty exists in obtaining organs for small adults and children.<sup>240</sup> Xenotransplantation offers a larger selection of organs from which to choose in matching donor organs with patients requiring them, and thus serves a broader spectrum of patients.

People object to xenotransplantation on a number of ethical grounds. Some argue that God divided humans and animals and that man should not cross that barrier.<sup>241</sup> A group of distinguished theologians disagreed with this religious argument when asked by the President's Commission for the Study of Ethical Problems in Medicine if Christian theology or Jewish law contains a prohibition against crossing species.<sup>242</sup> This objection also fails when one considers that a number of medical procedures currently use animal "parts" as replacements for comparable human body parts—surgical sutures come from sheep intestines, cow bones and tendons replace human bones and tendons damaged in accidents, and heart valves from pigs replace human heart valves.<sup>243</sup> Furthermore, the dramatically successful polio vaccine originates from monkey kidney cells.<sup>244</sup>

Proponents of animal rights provide another argument against xenotransplantation. They argue that it is unethical to kill animals for human purposes and to use animals that are on the endangered species list as sources for organs.<sup>245</sup> Those supporting xenotransplantation point out, however, that, while animals may have traits that entitle them to moral consideration and respect, treating them as equals in matters regarding human life and death

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236. *See id.* at 300.

237. *See Williams, supra* note 23.

238. *See id.*

239. *See Cramer & Makowka, supra* note 230, at 300.

240. *See id.* The shortage of organs is so severe that 30% to 50% of children under age two whose names appear on transplant waiting lists die prior to an organ becoming available. *See John A. Sten, Rethinking the National Organ Transplant Program: When Push Comes to Shove, 11 J. CONTEMP. HEALTH L. & POL'Y 197, 197-98 (1994).*

241. *See Albert R. Jonsen, Ethical Issues in Organ Transplantation, in MED. ETHICS 251, 253 (Robert M. Veatch ed. 1997).*

242. *See id.*

243. *See LAMB, supra* note 49, at 112. In 1988, Britain used approximately 1500 heart valves from pigs in humans with heart valve disease. *See id.* at 113.

244. *See Kress, supra* note 28, at 365.

245. *See Jonsen, supra* note 241, at 254.

overlooks what differentiates us from them.<sup>246</sup> One author suggests that animals raised as organ donors "will be among the healthiest and happiest creatures on the globe."<sup>247</sup> Because recipients want assurances of healthy animals, mistreatment or poor maintenance appears unlikely.<sup>248</sup> The International Transplantation Society, through its Ethics Committee, embraced xenotransplantation as ethical under controlled circumstances and made recommendations for the study of the procedure that were adopted in 1993.<sup>249</sup>

The transmission of infectious agents to humans through transplanted organs represents another significant concern of xenotransplantation.<sup>250</sup> Virus

246. See CAPLAN, *supra* note 228, at 114. Perhaps killing pigs for breakfast raises legitimate questions of ethical concern, but breeding pigs specifically for the purpose of saving a human life makes moral sense. *Id.* In an article in the *Journal of Medical Ethics*, John Martin wrote that:

Because of the clear distinction drawn between the nature of man and animals, if there is conflict between the well-being of one and the other then man's well-being must automatically come first. The application of such a philosophical approach to the problem of animal experimentation for medical need is helpful in a situation where emotions again give us opposing signals: a desire to cure . . . human disease and a desire not to harm animals. [This] approach clearly justifies that animal experimentation was done in the kindest way possible to help promote kindness towards man in the world.

Reprinted in Arthur L. Caplan, *Humans Should Be Allowed to Receive Animal Organ Transplants*, in *BIOMEDICAL ETHICS: OPPOSING VIEWPOINTS* 223, 227 (Terry O'Neill ed., 1994).

247. See CAPLAN, *BROTHER'S KEEPER*, *supra* note 228, at 113.

248. See *id.*

249. The Ethics Committee's recommendations include:

1. The feasibility of human xenotransplantation should have been demonstrated before clinical trials by demonstrable success in an appropriate non-rodent animal xenograft model.
2. The clinical trials should be carried out:
  - (a) by groups with a fully co-ordinated preclinical and clinical programme;
  - (b) with local institutional and/or State or National Ethics Review Board approval;
  - (c) with informed recipient consent.
3. The care and humane treatment of animals must always be of the highest standards.
4. All animal studies in transplantation must be approved by an institutional and/or State or National Ethics Review Board.
5. Endangered species must not be used.
6. Animals bred for the purpose of transplantation are the preferred source.
7. Research designed to diminish the need for use of animals in experimentation is to be encouraged.

Ethics Committee of the Transplantation Society, *Recommendations on Human Xenotransplantation from the Ethics Committee of the Transplantation Society* (1993), reprinted in Sir Roy Calne, *Ethics in Organ Donation and Transplantation: The Position of the Transplantation Society* (1996), in *ORGAN AND TISSUE DONATION FOR TRANSPLANTATION* 62, 64 (Jeremy R. Chapman et al. eds., 1997). The Council of the Transplantation Society adopted these recommendations on May 28, 1993. *Id.*

250. Michael Crichton wrote of medical activities that reached across species and unleashed new diseases of epidemic proportions in his book, *THE ANDROMEDA STRAIN*.

transmission becomes especially likely considering that patients receiving the xenograft must take drugs that purposely suppress their immune systems.<sup>251</sup> The fear of such viruses spreading throughout the population caused Britain to issue a moratorium on xenotransplantation until scientists know more about the risks involved.<sup>252</sup> There is hope that raising animals for xenotransplantation in pathogen-free environments, with limited exposure to infectious agents, will minimize the risks.<sup>253</sup>

The potential for a decrease in the number of human organs donated represents a final concern with xenotransplantation. Scientists foresee the publicity surrounding the success of xenotransplantation persuading the public that human organs are no longer needed.<sup>254</sup> This may lead to a new shortage of transplantable organs.<sup>255</sup>

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Scientists are apprehensive that a similar, though less catastrophic event, could occur. *See* Kress, *supra* note 28, at 365, 377. History provides several examples of diseases that have jumped the species barrier: the Ebola virus in Africa during the 1970s and the 1990s, the cercopithecine herpes virus 1 from macaques, Creutzfeldt-Jakob Disease ("mad cow disease") in Great Britain, and the disease in Hong Kong that caused the country to slaughter millions of chickens. *See id.* at 377-78. Additionally, evidence suggests that HIV-2 may have originated in chimpanzees, macaques, or red-capped mangabeys. *See id.* at 378.

251. *See* Kress, *supra* note 28, at 376.

252. Rachel Arrundale, the official in the U.K. Department of Health responsible for the nation's xenotransplantation policy, interprets the position of her government as one of caution. *See id.* at 382. She indicates that xenotransplantation will not occur now, but will proceed once "sufficient evidence of safety has been advanced." *See id.* Instituted in January 1997, Britain's stance has been referred to as a moratorium and has been strongly supported by prominent xenotransplantation researchers. *See id.* *See generally* *Britain Plays It Cautious on Animal-Human Transplants*, NATURE, Jan. 23, 1997, at 285 (indicating that a moratorium has been issued in the United Kingdom because of the fear of infectious disease); Peter J. Morris, *Pig Transplants Postponed: Until We Know More About Graft Rejection, Physiology, and Infectivity*, 314 BRIT. MED. J. 242 (Jan. 25, 1997) (stating that the Nuffield Bioethics Committee has concluded that xenotransplantation trials are not appropriate given the insufficient knowledge of cross-species infection); John Warden, *Xenotransplantation Moves Ahead in UK*, 317 BRIT. MED. J. 365 (Aug. 8, 1998) (discussing Health Secretary, Frank Dobson's, statement that xenotransplantation trials will only be allowed when he is satisfied that the risks are acceptable).

253. Cloning offers promise for the opportunity to minimize infection risks prior to any risk presentation. *See* Jodi K. Fredrickson, *He's All Heart . . . And a Little Pig Too: A Look at the FDA Draft Xenotransplant Guideline*, 52 FOOD & DRUG L. J. 429, 451 (1997). Recent successes in that area may allow scientists to breed and raise animals in environments that are almost entirely pathogen-free. *See id.* at 450.

254. *See* Kress, *supra* note 28, at 361.

255. Xenotransplantation probably will result in a decrease in cadaveric organ donation because of negative media, revulsion, fear of technology, and a perception that a viable alternative exists which makes donation unnecessary. *See* A.S. Daar, M.D., Ph.D., *Ethics of Xenotransplantation: Animal Issues, Consent, and Likely Transformation of Transplant Ethics*, 21 WORLD J. SURGERY, Nov./Dec. 1997, 975, 978-79. Similarly, the current shortage of organs is exacerbated by public health and safety efforts that attempt to reduce the number of gunshot victims and individuals who die in automobile accidents from whom many hearts are obtained for transplant. *See* Kress, *supra* note 28, at 361. Economists refer sarcastically to this

Scientifically, rejection of animal organs by the human body presents the greatest obstacle to the success of xenotransplantation.<sup>256</sup> Rejection involved in xenotransplantation takes two forms—concordant and discordant.<sup>257</sup> Concordant rejection usually takes a number of days to occur and involves closely related species combinations such as baboons to man.<sup>258</sup> Discordant rejection, on the other hand, usually occurs within minutes following the procedure and involves distantly related species combinations such as pigs to man.<sup>259</sup>

The strategy for decreasing the rejection rates of discordant species involves genetically altering the species in order to make its organs more acceptable to the human body.<sup>260</sup> The British biotechnology company, Imutran, claims that it can inject human genetic material into pig embryos so that the pig organs carry genetic codes similar to those of humans.<sup>261</sup> By carrying the genetic code for human regulator proteins, the pig organs trick the human body into recognizing the xenotransplant as a human organ and avoid rejection of the organ.<sup>262</sup>

Xenotransplantation offers hope to many who may otherwise suffer the consequences of inadequate organ procurement legislation. While the technology for this procedure continues to develop at seemingly rapid rates, the legal aspects of xenotransplantation lag behind, due primarily to a quest for certainty of the unknown. The United States and the United Kingdom

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phenomenon as deriving from the "Law of Unintended Consequences." *See id.*

256. *See* David J.G. White, *Xenotransplantation—A Solution to the Donor Organ Shortage*, in *ORGAN AND TISSUE DONATION FOR TRANSPLANTATION* 446, 447 (Jeremy R. Chapman et al. eds., 1997).

257. *See id.* at 448.

258. Although concordant animal donors such as baboons are preferable from the standpoint that rejection does not occur as quickly, non-human primates are not favored because of the possibility that they are on the endangered species list and because their level of intelligence and social structure lead to questions regarding the ethics of their use. *See id.*

259. *See id.* Discordant rejection is sometimes referred to by people in the medical community as "hyper-acute" rejection. *See id.* Discordant xenotransplantation offers the greatest hope for the future of organ transplantation. *See id.* at 449. Pigs, a discordant species, are the animal of choice for xenotransplantation because their use as a food source makes them more acceptable as organ donors, they breed well, produce large litters, grow quickly and are easily cared for. *See id.*

260. Transgenic modification involves injecting a foreign gene (transgene) into the cells of an animal. *See generally* White, *supra* note 256 at 449-454 (discussing the scientific aspects of creating transgenic pigs for organ transplantation); INSTITUTE OF MEDICINE, *supra* note 3, at 30-32 (discussing the history and process of creating transgenic animals for organ donation).

261. *See* Fredrickson, *supra* note 253, at 435. The first transgenic pig was developed at Imutran by Dr. David White, research director, in 1992, when he injected human genetic material into pig embryos. *See* Klotzko, *supra* note 22, at 1. Imutran transplanted pig hearts "humanised" in this way into monkeys without the occurrence of hyper-acute rejection. *See* Kelly Morris, *No Early Rejection of Animal Organs in UK*, 349 LANCET 257 (Jan. 25, 1997).

262. *See id.*

both recognize the possibility of xenotransplantation, but each takes a different approach to the actual implementation of clinical human xenotransplantation trials.

#### A. *Xenotransplantation in the United States*

Xenotransplantation in the United States enjoys a reemergence of sorts. During the 1960s and 1970s, doctors in this nation performed approximately twenty xenotransplantation procedures.<sup>263</sup> The failure of these procedures,<sup>264</sup> as well as the advent of renal dialysis, caused the transplant community to invoke a voluntary moratorium on xenotransplantation.<sup>265</sup> However, the desperate need for organs, accompanied by the introduction of new immunosuppressants, led to the end of the moratorium in the 1980s.<sup>266</sup>

Some describe the United States' approach to xenotransplantation as aggressive.<sup>267</sup> Unlike other nations, such as the United Kingdom, the United States moves forward with caution, evaluating the risks along the way.<sup>268</sup> The Public Health Service Guideline, published in 1996, represents this permissive governmental attitude. This Guideline places the responsibility for the coordination of xenotransplantation, including clinical trials, in the hands of the already existing Food and Drug Administration (FDA) and the Center for Disease Control (CDC).<sup>269</sup> Coupled with the 1999 Amendments to the Public Health Service Act, this Guideline forms a framework for the study and use of xenotransplantation in the United States.

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263. In 1963 and 1964, doctors at Tulane University transplanted chimpanzee kidneys into six patients. *See* INSTITUTE OF MEDICINE, *supra* note 3, at 6. Twenty procedures, including experimental surgeries performed at the University of Pittsburgh, occurred in the United States by 1974. *See id.*

264. One of the patients receiving a chimpanzee kidney at Tulane University survived nine months after the procedure. *See id.* While the other grafts appeared to function normally, patients eventually died from graft rejection or infection resulting from large doses of immunosuppressive drugs. *See id.*

265. Other nations, including Sweden, China, and Hungary, proceeded to participate in xenotransplant trials during this time. *See id.* at 6-7. Even during the 1990s, when the United States and many European nations failed to engage in active clinical trials, several countries including Russia, China and other Eastern European nations, continued their efforts. *See id.* at 7. Poor patient documentation, follow-up, and publication leave the efficacy of these trials unknown. *See id.* at 7-8.

266. *See id.* at 7. One of these new immunosuppressants was cyclosporine, discussed *supra* note 16.

267. *See* Daar, *supra* note 255, at 980.

268. *See id.*

269. *See id.* This is very different from the United Kingdom, which established a new national committee to regulate xenotransplantation issues. *See infra* note 313 and accompanying text.

### 1. *Public Health Service Draft Guideline on Xenotransplantation*

In an effort to minimize the spread of infectious disease from animals to organ recipients and the general public, the United States Public Health Service (USPHS) published a guideline<sup>270</sup> in 1996<sup>271</sup> that addresses the issue of public health risks associated with xenotransplantation.<sup>272</sup> Inquiries from institutional review boards (IRBs) regarding the treatment of applications for the research and performance of xenotransplants prompted the development of the Guideline.<sup>273</sup> The Public Health Service Draft Guideline on Xenotransplantation (Guideline) attempts to achieve the goal of minimizing the spread of infectious disease by xenotransplantation through provisions that range from detailing the function of the transplant team to creating a centralized database for long term safety data.<sup>274</sup>

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270. The Guideline is non-binding, but is considered the minimum standard of care necessary in the performance of xenotransplantation. See Fredrickson, *supra* note 253, at 443. The decision to implement the Guideline rather than binding regulations exemplifies the FDA's policy of allowing greater flexibility to a developing industry while providing insight into the FDA's views. See *id.*

271. For a list of critical events leading to the publication of the Guideline see Food and Drug Administration, *Fact Sheet on Xenotransplantation* (visited Sept. 8, 1999) <<http://www.fda.gov/opacom/backgrounders/xeno.html>>. Just prior to the publication of these Guidelines, the Institute of Medicine published a report concluding that the benefits of xenotransplantation justified taking the risks of infection and calling for clinical trials to proceed. See Daar, *supra* note 255, at 980. The report also called for a national committee to coordinate xenotransplantation research and trials. See *id.*

272. See Daar, *supra* note 255, at 980.

273. See Fredrickson, *supra* note 253, at 433. The FDA was without the expertise to provide guidance on xenotransplantation so it sponsored a study on xenotransplantation, conducted by the Institute of Medicine (IOM), which ultimately resulted in the Guidelines. See *id.* The IOM, in its report to the FDA, made five recommendations to address the possibility of xenotransplantation clinical trials: 1) the establishment of guidelines that address the screening of donor animals, surveillance of recipients and those close to them, creation of tissue banks for animal sources and recipients, and the creation of national registries; 2) the requirement that all physicians and hospitals adhere to certain national guidelines; 3) that the ethical considerations involved in xenotransplantation be investigated; 4) that the bodies responsible for establishing the guidelines be coordinated; and 5) that xenotransplantation be permitted when scientific support exists. See *id.* at 433-434. These recommendations were substantially incorporated into the Guidelines. See *id.* at 434.

274. The Public Health Service document:

1. Outlines the composition and function of the xenotransplant team in order that appropriate technical expertise can be applied and that adequate data management, tissue storage, and surveillance procedures can be established.
2. Discusses aspects of the clinical protocol, clinical center and the informed consent relevant to public health concerns regarding infections associated with xenotransplantation.
3. Provides a framework for pretransplantation animal source screening to minimize the potential for cross-species transmission of known and unknown zoonotic agents.
4. Recommends approaches for postxenotransplantation surveillance to monitor for the potential transmission to the recipient and health care workers of infectious agents,

Under Section 2 of the Guideline, the transplant team involved in the xenotransplantation procedure must include, in addition to the transplant surgeons, individuals such as physicians specializing in infectious disease with experience in zoonoses,<sup>275</sup> transplantation, and microbiology; veterinarians; transplant immunologists; hospital infection control specialists; and directors of clinical microbiology laboratories.<sup>276</sup> All clinical centers involved in xenotransplantation must be associated with an accredited virology and microbiology laboratory whose Biosafety Committee, Institutional Animal Care and Use Committee, and Institutional Review Board review the protocol for xenotransplantation.<sup>277</sup> The protocol must detail the methods for screening for known infectious diseases and outline the steps taken in surveillance of the herd, as well as include a history of the source animals.<sup>278</sup> Finally, those persons obtaining consent from the recipient should adhere to good clinical practices and ethical principles.<sup>279</sup>

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including unlikely or previously unrecognized agents.

5. Recommends hospital infection control practices to reduce the risk of nosocomial transmission of xenogeneic infectious agents.

6. Recommends the archiving of biologic samples, (including sera, plasma, leukocytes, and tissues), from the source animal and the transplant recipient for the potential investigation of infectious diseases arising from xenotransplantation which could impact upon the public health.

7. Recommends the creation of a centralized database. This database will address the need for long term safety data required for public health investigations.

Draft Public Health Service (PHS) Guideline on Infectious Disease Issues in Xenotransplantation, §1.3, 61 Fed. Reg. 49,920, 49,922 (1996).

275. "Zoonoses" is defined as "diseases and infections that naturally transmitted from vertebrate animals to human beings." WEBSTER'S ENCYCLOPEDIA DICTIONARY 1148 (1990).

276. See Draft Public Health Service (PHS) Guideline on Infectious Disease Issues in Xenotransplantation, §2.1, 61 Fed. Reg. 49,920; 49,922 (1996).

277. The FDA must still review and approve the proposed action before the procedure is performed. Draft Public Health Service (PHS) Guideline on Infectious Disease Issues in Xenotransplantation, §§2.2-2.3, 61 Fed. Reg. 49,920, 49,922-49,923 (1996). The FDA has given its approval to some of these xenotransplantation protocols. One clinical trial that received a great deal of publicity involved the 1995 transplantation of a baboon's bone marrow into a patient suffering with acquired immunodeficiency syndrome (AIDS). See Daar, *supra* note 255, at 980-981. The FDA has also approved studies including "perfusing fetal pig liver for acute liver failure, transplantation of pig neural tissue into patients with Parkinson's disease, and use of pig islets in patients with diabetes." *Id.*, at 981.

278. See Draft Public Health Service (PHS) Guideline on Infectious Disease Issues in Xenotransplantation, §2.4, 61 Fed. Reg. 49,920; 49,923 (1996).

279. The Guideline suggests that information provided to the organ recipient address the following points:

1. The potential for infection from zoonotic agents known to be associated with the donor species.
2. The potential for transmission of unknown xenogeneic infectious agents to the recipient. The patient should be informed of the uncertainty regarding these risks, the possibility that infections with these agents may not be recognized for some time, and that the nature of clinical diseases that these agents may cause are unknown.
3. The potential risk for transmission of xenogeneic infectious agents to the recipient's

Section 3 of the Guideline requires that animals used in xenotransplantation come from closed herds.<sup>280</sup> It expressly forbids the use of wild and imported animals, and allows the use of captive free-ranging animals only when suitable for a given procedure.<sup>281</sup> Section 3 also addresses issues regarding the record-keeping, the screening of animals for infectious disease, the qualifications for animals, and the archiving of animal medical records and specimens at the animal facility.<sup>282</sup>

In Section 4, the Guideline addresses the clinical issues related to xenotransplantation. These include procedures for surveillance of the recipient following the transplantation procedure as well as for informing those closest to the recipient of the possibility of xenogeneic infections.<sup>283</sup> The Guideline also explains the requirements of the hospital and the health-care team with regard to their ability to identify both known and unknown infectious diseases and to collect and store samples for investigation of possible infections.<sup>284</sup>

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family or close contacts, especially sexual contacts. Close contacts are defined as household members and others with whom the recipient participates in activities that could result in exchanges of body fluids. The recipient should be informed that transmission of these agents may be minimized by the use of barriers during sexual intercourse and that infants, pregnant women, elderly, and chronically ill or immunosuppressed persons may be at increased risk for infection from zoonotic or opportunistic agents.

4. Any need for isolation procedures during hospitalization (including the estimated duration of such confinement), and any specialized precautions (e.g., dietary, travel) following hospital discharge.

5. The need to comply with long-term or potentially life-long surveillance necessitating routine physical evaluations with archiving of tissue and/or serum specimens. The schedule for clinical and laboratory monitoring should be provided to the extent possible. The patient should be informed that any serious or unexplained illness in themselves or their contacts should be reported to their physicians immediately.

6. The need for the subject to inform the investigator or his/her designee of any change in address or telephone number in order to maintain accurate data for long-term health surveillance.

7. Discussion with the patient regarding performance of a complete autopsy. Joint discussion with the recipient and his/her family concerning the need to conduct an autopsy is also encouraged in order to communicate the recipient's intent.

8. Access by the appropriate public health agencies to all medical records. To the extent permitted by applicable laws and/or regulations, the confidentiality of medical records will be maintained.

9. Consent forms should state clearly that xenograft recipients should never, subsequent to receiving the transplant, donate whole Blood, blood components, Source Plasma, Source Leukocytes, tissues, breast milk, ova, sperm, or any other body parts for use in humans.

*Id.* §2.5.

280. *See id.* §3.1.

281. *See id.*

282. *See id.* §§3.2-3.7.

283. *See id.* §§4.1-4.2.

284. *See id.* §§4.3-4.4.



The final section of the Guideline suggests the establishment of a national registry that allows for the rapid identification of common features among xenograft recipients and provides a data base for monitoring safety.<sup>285</sup> Furthermore, the Guideline calls for the storage of sera, plasma, leukocytes, and tissue of both the source animal and the recipient to be stored for investigation purposes.<sup>286</sup>

The Guideline invites applause, especially for its treatment of the issue of informed consent in xenotransplantation. One author supports the Guideline's efforts in handling the "unique issues necessitated by the nature of xenotransplant research."<sup>287</sup> She believes that the Guideline, in requiring more information to be given to the patient, recognizes the significant risks involved in xenotransplantation and takes the appropriate steps to assure that the individuals involved are fully aware of their undertaking.<sup>288</sup> The shortcoming of the Guideline in this area, however, rests in the lack of informed consent owed to those closest to the recipient.<sup>289</sup> Some suggest that the present scheme ultimately puts the public at risk of infection because it leaves close contacts ignorant of the implications of xenotransplantation.<sup>290</sup> This area requires further reform so those closest to the xenotransplant recipient can protect themselves.<sup>291</sup>

A criticism of the Guideline addresses its efforts to control infectious disease. While the Guideline adequately speaks to the process of searching for and minimizing known infections, it lacks initiative when it comes to those diseases that are presently unknown.<sup>292</sup> Change in this area should involve the development of clear illustrations of the methods used in the identification of unknown agents and further research into how to minimize the risks of infection.<sup>293</sup>

The Guideline provides an excellent starting point for the regulation of xenotransplantation in the United States.<sup>294</sup> Efforts to learn more of xenotransplantation continue, however, and the law attempts to aid in these

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285. *See id.* §5.1.

286. *See id.* §5.2.

287. Fredrickson, *supra* note 253, at 446.

288. *See id.*

289. *See id.* at 447.

290. *See id.*

291. *See id.*

292. *See id.* at 451. During the comment period for the Guidelines which ended in December 1996, Jonathon Allan of San Antonio, Texas, sent a letter signed by 44 scientists to the Center for Disease Control expressing their concerns that the Guidelines did not adequately address the possibility of infectious disease resulting from xenotransplantation. *See Daar, supra* note 255, at 980.

293. *See Fredrickson, supra* note 253, at 451.

294. *See id.*

labors. Congress's proposal for the 1999 Amendments to the Public Health Service Act indicates the government's commitment to increasing knowledge about xenotransplantation.

## 2. 1999 Amendments to the Public Health Service Act

Members of the House of Representatives introduced HR 2418 on July 1, 1999.<sup>295</sup> Known as the "Organ Procurement and Transplantation Network Amendments of 1999" (Amendments), this legislation amends the Public Health Service Act in an attempt "to revise and extend programs relating to organ procurement and transplantation."<sup>296</sup>

The primary feature of the proposed legislation is its creation of an Organ Procurement and Transplantation Network that establishes and operates a national matching system for donors and recipients, establishes and maintains lists of individuals in need of transplants, establishes medical criteria for allocating organs, establishes a twenty-four-hour phone and computer service to aid in organ matching, establishes standards for the acquisition and transportation of organs, prepares and distributes samples of blood sera from individuals having difficulty receiving organs because of their immune systems, and actively works to increase the supply of donated organs.<sup>297</sup> Its efforts to increase the supply of organs include projects to increase transplantation among groups with special needs or limited access to transplantation and to study the impact of xenotransplantation.<sup>298</sup>

The Amendments have been heralded on three main points.<sup>299</sup> First, they reinforce the original intent of NOTA by restating that the private sector

295. The bill was introduced by Rep. Bilirakis for himself, Rep. Green of Texas and Rep. Pallone. See H.R. 2418, 106th Cong. (1999). The history of the bill to date is as follows:

July 1, 1999 Referred to the House Committee on Commerce

July 21, 1999 Referred to the Subcommittee on Health and Environment

Sept. 30, 1999 Subcommittee Consideration and Mark-up Session Held

Forwarded by Subcommittee to Full Committee by Voice Vote

Oct. 13, 1999 Committee Consideration and Mark-up Session Held

Ordered to be Reported by Voice Vote

Nov. 1, 1999 Placed on Union Calendar, Calendar No. 250

See *Bill Summary & Status for the 106th Congress, H.R. 2418* (visited Nov. 22, 1999) <<http://thomas.loc.gov/cgi-bin/bdquery/D?d106:l:./temp/~bdbUYs:@@X/.../d106query.html>>.

296. H.R. 2418, 106th Cong. (1999).

297. See *id.*

298. See *id.*

299. These points were discussed by Dr. William W. Payne, President of UNOS, liver transplant surgeon, and Director of the Liver Transplant Program at the University of Minnesota during his testimony before the House Commerce Committee Subcommittee on Health and the Environment on September 22, 1999. See UNOS News Bureau, *UNOS President Testifies in Support of H.R. 2418* (visited 10/1/99) <[http://www.unos.org/newsroom/archive\\_newsrelease\\_19990922\\_nota.htm](http://www.unos.org/newsroom/archive_newsrelease_19990922_nota.htm)>.

and the medical community should have the responsibility for developing, establishing, and maintaining the medical criteria and standards for organ procurement and transplantation.<sup>300</sup> Second, they provide new direction in the areas of enforcement, accountability, and patient confidentiality.<sup>301</sup> Finally, the Amendments represent Congress' commitment to help the medical community increase the number of organs available for transplant.<sup>302</sup>

The Amendments' importance for xenotransplantation rests in the fact that they provide for the study of xenotransplantation at the local level,<sup>303</sup> freeing it from the confines of inhibiting federal regulations.<sup>304</sup> As one author points out, regulations provide less flexibility as technology progresses and cannot easily be changed.<sup>305</sup>

The Amendments represent continuing efforts in the United States to make xenotransplantation a real possibility. Given the increasing need for life saving organs, the significance of these efforts cannot be underestimated.

#### B. *Xenotransplantation In the United Kingdom*

British lawmakers take a more conservative approach to the regulation of xenotransplantation than do their American counterparts.<sup>306</sup> Rachel Arrundale, a U.K. Department of Health official, described the British stance on xenotransplantation as one of "no, but . . .," meaning that xenotransplantation may not proceed now, but will go forward once the government receives sufficient evidence of its safety.<sup>307</sup> Currently, a moratorium exists in Britain that forbids clinical xenotransplantation.<sup>308</sup>

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300. *See id.*

301. *See id.*

302. *See id.*

303. The study of xenotransplantation will be conducted by groups established under and regulated by the Organ Procurement and Transplantation Network, which is a private entity. *See* H.R. 2418, 106th Cong. § 2 (1999).

304. The Organisation for Economic Co-operation and Development (OECD) recognizes that, while extensive regulations generally insure the equitable distribution of acquired organs, laws and regulations may also make the procurement of organs more difficult. *See* OECD, *supra* note 17, at 18.

305. Regulations must comply with notice-and-comment procedures when first established and whenever substantive changes need to be made. *See* Fredrickson, *supra* note 253, at 443.

306. The British stance on xenotransplantation rests in the "precautionary principle." *See* Daar, *supra* note 255, at 980. This principle suggests that the government institute precautionary measures to avoid risks well ahead of any certainty about the natures of those risks, placing the burden of proof on those involved in developing the technology. *See id.*

307. *See* Kress, *supra* note 28, at 382. Dr. Amy P. Patterson, who chairs the FDA's Working Group on Xenotransplantation, alternately describes the United States position on xenotransplantation as one of "yes, if . . .," meaning that xenotransplantation may proceed in the United States if very strict rules are followed to insure safety. *See id.* at 381-82.

308. This moratorium began in January 1997, following the report of the British Department of Health's Advisory Group on the Ethics of Xenotransplantation. *See id.*

Frank Dobson, U.K. Health Secretary, indicates that this moratorium will continue until he believes that the risks are acceptable.<sup>309</sup>

Xenotransplantation regulation in Britain rests in the recommendations<sup>310</sup> of the Advisory Group on the Ethics of

309. See Warden, *supra* note 252, at 365.

310. These recommendations are made in ADVISORY GROUP ON THE ETHICS OF XENOTRANSPLANTATION: ANIMAL TISSUE INTO HUMANS (1996) and are referred to as the "Kennedy Report." See Daar, *supra* note 255, at 979. The conclusions and recommendations made in the report include:

1. Xenotransplantation is a valid supplement; if alternative found, will require reassessment.
2. Ethically acceptable to consider using pigs for xenotransplantation for currently envisaged procedures
3. Ethically acceptable to manipulate genes (limits exist)
4. Not ethically acceptable to use subhuman primates as source animals except for limited research (minimize)
5. Evidence overall is too limited to proceed to clinical trials; further research needed (i.e. effective embargo at present)
6. Risk of infection with fungi, parasites, bacteria, prions acceptable when control mechanisms in place
7. Not enough known about porcine viruses to proceed to clinical trials
8. Standard of animal care to be defined; mechanisms to be put in place; minimize harm
9. Sequential removal of organs unethical
10. When ready to proceed to therapy, national body needed to commission allocation of resources.
11. Current allotransplant donation may be affected by xenotransplantation; need public education; need efforts to increase donation and prevent organ failure in the first place.
12. No need to change to presumed consent (which remains unacceptable) at present for cadaveric organ retrieval
13. Xenotransplant clinical trials will become ethically acceptable when all conditions met; but conditions are necessary, not necessarily sufficient, and do not imply progression to therapy
14. National Standing Committee to be established to set standards, coordinate, assess, license, approve research, and decide when trials should start; when clinical trials allowed:
  - a. Children and incapacitated not to be subjects of research
  - b. Consent and legal and ethical issues extraordinarily complex, but current principles should apply; independent counsel provided for recipient
  - c. Psychosocial effects to be monitored
  - d. Conscientious objectors not to be penalized in the current organ allocation criteria and waiting lists
15. Train veterinary technicians, nurses now; allow them conscientious objection privilege
16. Hospitals for transplantation to be assessed now
17. Biosecure movement of tissue to be controlled, documented
18. Xenograft tissues to be brought under same regulatory controls as established for drugs and medical devices
19. If private sector to do xenotransplants: to come under same regulatory framework
20. International cooperation important
21. National standing committee to guide/work with local research ethics committees

Xenotransplantation (Advisory Group),<sup>311</sup> a body responsible for reviewing the acceptability of xenotransplantation and studying the ethical framework in which it may be undertaken.<sup>312</sup> The Advisory Group found it ethical to genetically alter pigs for use in xenotransplantation but warned against proceeding with clinical trials until the government established a National Standing Committee<sup>313</sup> to supervise research, develop mechanisms to protect the public and patients, oversee the welfare of the animals, and determine when clinical trials should begin.<sup>314</sup>

The British government responded to the Advisory Group's recommendations by establishing the United Kingdom Xenotransplantation Interim Regulatory Authority (UKXIRA)<sup>315</sup> to approve experiments and monitor progress in xenotransplantation until the recommended statutory regulation<sup>316</sup> emerges.<sup>317</sup> In addition, the government requested more information regarding the unacceptability of using subhuman primates and the conclusion that insufficient information existed about the immunological response, physiology and risk of zoonosis to proceed with clinical human trials.<sup>318</sup>

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311. The Department of Health commissioned this Advisory Group which was chaired by Ian Kennedy, professor of medical law and ethics. See Marie Fox & Jean McHale, *Regulating Xenotransplantation*, 147 NEW L.J., Jan. 31, 1997, at 139; Morris, *supra* note 252, at 242.

312. See *id.* The report of the Advisory Group mirrors the conservative attitude of the Nuffield Council on Bioethics, which published a similar report in 1996. See Daar, *supra* note 255, at 979. For more information regarding this report see NUFFIELD COUNCIL ON BIOETHICS, ANIMAL-TO-HUMAN TRANSPLANTS: THE ETHICS OF XENOTRANSPLANTATION (1996).

313. Interestingly, the Advisory Group called for a committee to regulate xenotransplantation in Britain, whereas the Institute of Medicine in the United States, in a similar report published in July 1996 called for a national committee to coordinate xenotransplantation. See Daar, *supra* note 255, at 980.

314. See Daar, *supra* note 255, at 980.

315. This group consisted of a chairman (Lord Habgood) and eight appointed members drawn from diverse disciplines who were also meant to represent the general public. See *id.*

316. The Advisory Group recommended that this legislation include a provision allowing for the conscientious objection of health professionals who viewed xenotransplantation as unethical. See *id.* Under such a statute, these health professionals could opt out of participation in a xenotransplantation procedure without resulting prejudice to their careers. See Fox & McHale, *supra* note 311, at 139. Only two other statutes in Britain provide for conscientious objection by health professionals: Section 4 of the Abortion Act of 1967 and Section 38 of the Human Fertilisation and Embryology Act of 1990. See *id.* It appears that physicians in Britain may favor xenotransplantation. John Dark, who runs one of the United Kingdom's four heart transplant units, states that he sees "no ethical problems in breeding pigs and using their hearts. We already use about 1,500 pigs' valves a year in humans with heart valve disease." See LAMB, *supra* note 49 at 112-113. Other surgeons at Columbia-Presbyterian have been conducting heart transplants from monkeys to baboons since 1984 and were ready to develop a program involving primate-to-human transplants by 1990. See *id.* at 113.

317. See Fox & McHale, *supra* note 311, at 139.

318. See Daar, *supra* note 255, at 980.

The UKXIRA released its criteria for handling applications to proceed with xenotransplantation during the summer of 1998.<sup>319</sup> These guidelines require that the secretary of state grant approval prior to any treatments.<sup>320</sup> The UKXIRA must consider any application made for clinical trials and may submit the proposal to other state bodies for approval prior to granting authorization.<sup>321</sup> The attention of UKXIRA now focuses on establishing standards of tissue quality, as well as developing a system to monitor xenotransplant recipients.<sup>322</sup>

British biologists comprise one group that strongly supports xenotransplantation. In a response to the Advisory Group's recommendations, the Institute of Biology (IOB)<sup>323</sup> issued a statement indicating its belief that xenotransplantation will eventually be required in order to meet the transplant demand.<sup>324</sup> The IOB confirmed that the demand for organs in the United Kingdom continues to grow at a rate of five percent per year, and that a seemingly more effective system of organ procurement, such as presumed consent, would most likely fail to keep up with demand in the long run.<sup>325</sup> The IOB also states that, while initial media attention may cause some degree of public scrutiny, the overall success of xenotransplantation will insure public acceptance of the procedure.<sup>326</sup>

Significant achievements in xenotransplantation were announced during the summer of 1999 that suggest that Britain's moratorium on xenotransplantation may soon end.<sup>327</sup> Imutran released the results of its study of 160<sup>328</sup> patients from eight countries who had been exposed to pig tissue

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319. See Warden, *supra* note 252, at 365.

320. See *id.*

321. See *id.* Once submitted to UKXIRA, a team of approximately six referees will scrutinize each proposal then forward it to other state bodies as needed. See *id.*

322. See *id.*

323. The Institute of Biology acts as an independent and charitable body empowered by Royal Charter to represent biologists and biology in the United Kingdom. See Institute of Biology (1996) *Response to the Advisory Group on the Ethics of Xenotransplantation, Made to the Department of Health* (visited Oct. 1, 1999) <<http://www.primex.co.uk/iob/d13.html>>. Individual membership in the Institute of Biology numbers approximately 15,000, with roughly 70 affiliated specialist biological societies participating as well. See *id.*

324. See *id.*

325. See *id.* The IOB attributes this continued increase in demand to the aging of the U.K. population. See *id.* It states that the increasing number of elderly in the nation require more organs than potential young donors can provide. See *id.* The increasing health and safety of Britain's younger population, from whom the most viable transplant materials are likely, act to decrease further the number of organs available for transplant. See *id.*

326. See *id.*

327. The media asserts that the findings of this study will bring an end to the moratorium on animal-to-human transplants. See Peter Gerner, *Study: Transplants from Animals Hold Promise for People*, NEWS & OBSERVER, Aug. 21, 1999, at A1.

328. The study included 36 patients deemed high risk who were suffering from weakened immune systems. See *id.*

during the previous eight years.<sup>329</sup> These results showed an absence of the pig virus "Perv" in all of the patients.<sup>330</sup> Moreover, the studies indicated a potential survival of the pig cells inside the human body of at least eight years.<sup>331</sup> These results offer hope that transgenic pig organs could overcome rejection by the human body and function for years.<sup>332</sup>

Government officials in Britain state that their policy regarding clinical human trials will change when they gather sufficient information to help them make knowledgeable decisions about the risks inherent in xenotransplantation. Perhaps the results of the Imutran study will provide the impetus for this change and bring an end to Britain's moratorium on xenotransplantation.

## VI. CONCLUSION

Current legislation in both the United States and Britain proves inadequate to meet the demand of transplantable organs. Unfortunately, studies suggest that nothing can be done under the current systems of expressed consent and presumed consent that will ever provide enough organs.<sup>333</sup> Therefore, medical specialists must look elsewhere for viable alternatives to organ transplantation, and legislators must keep pace with new technology by providing efficient regulations for the procurement and transplantation of these alternatives.

The United States sets the pace for the regulation of xenografts in human clinical trials. Now that scientific studies dispel some of the fears that infectious disease will shift from pig tissue into the human recipients, Britain should end its moratorium on xenograft trials and focus Parliamentary efforts on relaxing the regulation of clinical human xenograft trials.

Britain has concerns over its organ shortage problem, but changing to a system of presumed consent will provide minimal relief at best. The goal

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329. *See id.*

330. *See* Roger Highfield, *Transplant Pig Cells 'Survive Eight Years,'* DAILY TELEGRAPH (London), Aug. 20, 1999, at 4.

331. *See id.*

332. *See id.*

333. It is estimated that the maximum number of potential cadaveric donors per million population in the United Kingdom could never exceed fifty, regardless of the circumstances. *See* Jeremy R. Chapman & Bill New, *Transplantation*, in ORGAN AND TISSUE DONATION FOR TRANSPLANTATION 1, 8 (Jeremy R. Chapman et al. eds., 1997). As of 1995, the number of transplants performed per million population in the United Kingdom totaled 59 (28.9 kidneys, 11.3 liver, 5.6 heart, 0.9 heart/lung, 1.8 lung, and 0.5 pancreas). *See id.* at 16. *See also* CAPLAN, BROTHER'S KEEPER, *supra* note 228, at 104 (stating that even if all human cadaver organs were available for transplant, supply would never meet the potential demand).

of providing every needy patient with an organ would be better served by making the organ donor laws more inclusive and by allowing organs to come from sources other than humans.

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