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## Due Process of Human Transplants: A Proposal

Luis Kutner

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# DUE PROCESS OF HUMAN TRANSPLANTS: A PROPOSAL

LUIS KUTNER\*

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## I. INTRODUCTION

To paraphrase Clemenceau, human life is too important to leave to the physicians. The public has marveled at what the medical profession has wrought with organ transplants and the possibilities of biological reproduction. However, the physician cannot be permitted to play God, acting according to his whim in determining who may live and who may die. Institutional guidelines must be established through law. Modern medicine gives birth to new legal problems. The law and lawyers must play a significant role in developing techniques to protect human dignity and to assure that medical science is indeed utilized for the benefit of human well-being and not as an end in itself to satisfy the physician's simple curiosity or desire for notoriety.

This paper will focus on organ transplants, particularly the transfer of hearts, noting the state of technological development and the legal problems which have arisen, especially in determining when a person may be declared to be legally dead. In this regard, the author will propose a statute to establish standards of due process for determining the time of death.

## II. THE DEVELOPMENT OF ORGAN TRANSPLANTS

For centuries, surgeons had dreamed of the idea of replacing a diseased or injured limb or organ. Italian surgeons during the Renaissance occasionally succeeded in repairing a sword-slashed nose or arm with flesh from the patient's own arm, but attempts to graft from person to person always failed. The first widely attempted transplants were blood transfusions;—from lamb to man or man to man, with some succeeding, but most failing. The first consistently successful human monografts—between two individuals of the same species—occurred in 1905. These were transplants

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of the cornea, a transparent plastic covering of the eyeball which has no blood circulation.

The surgical techniques used in organ transplants were developed by Doctors Claude Guthrie and Alexis Carrell in 1905 in experimental animal transplants. In 1953, these techniques were complemented by the work of Sir Peter Brian Medawar, which revealed details of the immunity mechanism involving the white blood cells which manufacture anti-bodies against foreign invaders: The implantation of foreign tissue triggered the rejection mechanism. Accordingly, the first successful kidney transplants in 1954 involved identical twins, whose tissue had a common origin and was less foreign.<sup>1</sup>

The problem in transplants has been to devise a way of switching off the rejection mechanism long enough for the body to accept the transplant and then to restore the immunity so that the recipient will not be susceptible to infection. Some progress was originally made with X-rays, anti-cancer chemicals, and cortisone-type hormones. Complex methods have been devised to match white blood cells in order to reduce anti-body formation and, also, to make an antilymphotic serum in horses which reduces the white cells' activities. This partial success permitted kidney transplants with the recipient having a 65 percent chance of survival.<sup>2</sup> More than two thousand kidney transplants have been undertaken since 1954, with over 800 recipients surviving for more than one year. However, transplants of the liver and pancreas have resulted in little success.<sup>3</sup> Thirty-five liver transplants have transpired since 1963, with only one recipient surviving more than one year; seven spleen transplants since 1963, with two one-year survivors; seven pancreas transplants since 1966, with no recipient surviving one year; and eleven whole and partial lung transplants since 1963, with the longest survival being only 18 days.<sup>4</sup>

Heart transplants have received the most attention. Reports of such transplants in dogs first appeared in 1955; these were performed by Dr. Charles Bailey.<sup>5</sup> Ironically, 1955 was the same year in which Dr. Christian Barnard came to the University of Minnesota in Minneapolis for post-graduate study in surgery under Professor Owen Wangenstein, who was launching Minnesota's Department of Surgery upon a pioneering series of experiments in organ transplants.<sup>6</sup> Dr. Barnard's studies at the university were financed in part by a grant from the United States Health Service.

1. *The Ultimate Operation*, TIME, Dec. 15, 1967, at 64. See also Carroll, *The Ethics of Transplantation*, 56 A.B.A.J. 137 (1970).

2. *Kidneys Lead the Field*, 93 SCI. NEWS 214 (1968). In kidney transplantation, the time of death of the donor is less vital than in heart transplants, since the period of ischemia (lack of blood supply), if not too prolonged, may destroy some of the antigenic qualities of the transplant and thus make the kidney more acceptable to the recipient. Biorck, *When Is Death?*, 18 WIS. L. REV. 484, 491-92 (1968).

3. *Transplant Rounds*, MED. WORLD NEWS, Jan. 10, 1969, at 26.

4. *Transplant Score*, MED. WORLD NEWS, Sept. 27, 1968, at 27.

5. Lear, *A Realistic Look at Heart Transplants*, SAT. REV., Feb. 3, 1968, at 53.

6. *Id.*

The first heart transplant at the end of 1967 was the culmination for Dr. Barnard of over a decade of development and study of surgical techniques. The South African transplants were quickly followed by the transplants of Dr. Norman E. Shumway, Jr. of Stanford University, and Dr. Adrian Kantrowitz in Brooklyn. Transplants in the United States were later undertaken by Dr. Denton Cooley and Dr. Michael DeBakey in Houston. Within a year, 36 medical centers in 16 countries had performed heart transplants;<sup>7</sup> such countries included France,<sup>8</sup> Argentina,<sup>9</sup> Brazil,<sup>10</sup> Canada,<sup>11</sup> Great Britain,<sup>12</sup> India,<sup>13</sup> Israel,<sup>14</sup> and the Soviet Union.<sup>15</sup> Heart transplants have thus become a worldwide phenomenon.

The circus-like publicity given to the first heart transplants, as well as the experimental nature of the undertaking with its attendant risks, provoked skepticism among surgeons and physicians who urged a more conservative approach.<sup>16</sup> However, after a year of human organ transplants, these techniques have become routine to the art of heart surgery and have generally been accepted both in the United States and the Soviet Union.<sup>17</sup> Nevertheless, even the experts cannot agree as to whether organ transplantation or heart surgery in general is the best method for dealing with a defective heart.<sup>18</sup> If heart surgery, instead of transplantation, ultimately becomes the preferred technique, the future development of the artificial heart may eliminate the need for transplants.<sup>19</sup> However, in the absence of a perfected artificial heart, the debate over the propriety of transplants continues to rage due to the medical uncertainty surrounding the rejection phenomenon.<sup>20</sup> Moreover, some patients with heart transplants have expe-

7. *Id.*

8. Hess, *French Perform Europe's First Heart Transplant*, N.Y. Times, Apr. 30, 1968, at 51, col. 2.

9. *Transplants, An Anniversary Review*, TIME, Dec. 6, 1968, at 59.

10. *Troubled Hearts*, NEWSWEEK, June 24, 1968, at 60; *Beating Heart Implanted*, MED. WORLD NEWS, June 21, 1968, at 20.

11. *Id.*

12. *Id.*; *Perform 1st Heart Plant in Britain*, Chicago Tribune, May 4, 1968, at 15, col. 5. See also HOSPITAL TRIBUNE, July 14, 1969, at 1 (describing a second transplant which was performed in Britain in 1969).

13. See note 10 *supra*.

14. *Id.*; *Israel's First Heart Transplant*, ISRAEL DIGEST, Dec. 13, 1968, at 3.

15. Shabad, *Heart Transplants in Soviet Union Growing in Acceptance*, N.Y. Times, Jan. 2, 1969, at 27, col. 3.

16. See note 5, *supra*. Smothers, *Heart Transplant Doubts Rise*, Chicago Daily News, March 30, 1968, at 3, col. 3.

17. See notes 9 and 15 *supra*. *Shifting Stands on Heart Transplants*, MED. WORLD NEWS, June 7, 1968, at 24.

18. See note 5 *supra*. *What's Ahead*, MED. WORLD NEWS, March 21, 1969, at 51; *Even the Implanters Can't Agree on Surgical Strategy*, MED. WORLD NEWS, Jan. 10, 1969, at 18; *The Heart Transplant Debate*, Chicago Daily News, Jan. 22, 1969, at 1, col. 1.

19. Snider, *Artificial Hearts—One Up on Transplants*, Chicago Daily News, April 5, 1969, at 5, col. 1; *Practical Benefit of Heart Transplanting Remains Uncertain Despite Headlines*, Wall St. J., Nov. 25, 1968, at 21.

20. *Id.* See also *Problems Technical Not Ethical*, 93 SCI. NEWS 216 (1968).

rienced psychoses and personality changes<sup>21</sup> from the introduction of a new organ which conceivably effects the entire homeostatic make-up of the body.

The substance used in preventing organ rejection is anti-lymphocyte globulin—ALG—which interferes with the cells (lymphocytes) that seem to produce rejection. Unfortunately, ALG produces allergic reactions in some patients, and particular problems have arisen among patients whose transplant organs come from persons without matching tissue, particularly in kidney transplants where traces of cancer have appeared. An insidious rejection may occur within months or weeks after receiving therapy.<sup>22</sup>

Clearly, there are risks involved in heart transplants. Nevertheless, the surgeons who have undertaken them believe it is the only possible means of prolonging the life of a patient whose original heart has become diseased. In some cases, as in those of Dr. Blaiberg (who survived 563 days, dying August 17, 1969) and a former professional tennis player who was able, subsequent to a heart transplant, to resume his career, the results have been remarkable, making the patient feel as if he has been reborn.<sup>23</sup> However, such a patient must live with the fear that the new organ may suddenly be rejected. Furthermore, in at least two instances patients have had to undergo two heart transplants.<sup>24</sup> These problems, plus the fact that only about half of the patients have remained alive, make the practicality of undertaking transplants questionable.<sup>25</sup>

To add to the difficulty, the supply of available donors does not meet the demands of the recipients. For example, potential recipients requiring kidney transplants are expected to be 5,000 annually by 1977.<sup>26</sup> Among Americans aged 15 to 64, there are 200,000 deaths each year from acquired or congenital heart disease, with 160,000 of these deaths due to coronary heart disease. Over 80,000 of these people die before reaching the hospital. Among those who survive to be hospitalized, 80,000 with coronary heart disease and 40,000 with other forms of cardiac diseases may need some form of therapy not available. Though it is difficult to determine from the vital statistics precisely how many would have been saved by modern therapy, with intensive care it might have been as many as 40,000 of the total 120,000. The number of patients requiring cardiac replacement may be as few as 10,000 or as many as 50,000 of the total 120,000. National surveys indicate that 70 percent of the population are willing to donate their bodies for medical research and therapy. However, the total pool of donors

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21. Shenker, *Expert Says Some Heart Recipients Suffer Psychosis Afterward*, N.Y. Times, May 8, 1969, at 37, col. 1.

22. Weathersbee, *Double-Edged Knife: Rejection/Infection*, 93 SCI. NEWS 215 (1968); *ALG: Protection But Set*, 206 J.A.M.A. 494 (1968); *New Techniques Have Enabled Early Detection of Rejection*, HOSPITAL TRIBUNE, July 14, 1969, at 19.

23. Bradbury, *With Other People's Hearts*, LIFE, Jan. 10, 1969, at 82a; *Heart Transplant May Turn Net Pro*, Chicago American, Feb. 9, 1969, § 4, at 1, col. 4.

24. *Two Patients, Six Hearts*, MED. WORLD NEWS, Dec. 13, 1968, at 31.

25. Fishbein, *Before Barnard-and After*, MED. WORLD NEWS, Dec. 27, 1968, at 64.

26. 115 CONG. REC. S1500 (daily ed. Feb. 17, 1969).

—those dying from all causes other than heart disease or cancer age 15 to 64—comprises only 260,000 including many who would not be suitable donors. If donors continue to be derived largely from victims of trauma or spontaneous brain damage, only about 67,000 potential donors will be available annually. There is also the problem of organ transportation and preservation, as well as a need for the development of efficient matching systems.<sup>27</sup> Only one death out of ten will provide a heart potentially suitable for transplanting. A greater number of heart patients also suffer from lung diseases and may require lung transplants as well. Some physicians conceive of a complete heart and lung transplant.<sup>28</sup>

Heart and other organ transplanting involves a myriad of ethical, social, and legal problems. One ethical question was answered by Dr. Barnard and other surgeons simply by proceeding with transplants. They stated that, in their opinion, medical knowledge and technology had arrived at the point where such a task could be undertaken with a reasonable chance of success. This view is not universally shared by medical authorities. Apparently, much less agreement exists as to the state of the art with regard to the implanting of an artificial heart, as attempted by Dr. Denton Cooley to preserve life pending the availability of a human heart. He was criticized by Dr. DeBakey for use of such a device prior to full testing and approval.<sup>29</sup>

Assuming an adequate success ratio can be attained in transplants, a problem arises as to who is to be entitled to the scarce transplant resources and where are the donors to be found. Since transplants are radical undertakings, a patient should be determined to be in need of a transplant, particularly a heart transplant, only after careful and thorough diagnosis. In some instances, patients who have been diagnosed to have a hopelessly damaged heart have manifested remarkable recovery. Given a number of patients in need of transplants, a problem arises as to who is to receive priority, in other words, how, and by whom, is the decision to be made as to who should live. Not only is there the problem of a scarcity of donors, but there is also a scarcity of medical resources. The operative and post operative care is exceedingly expensive. Only a limited number of medical centers are equipped for undertaking transplants.

The most pressing problem is finding a qualified donor. Though a kidney donor may contribute a kidney without loss of life, it is obviously impossible for the donor of a primary organ, such as a heart or lung to survive. Since it is morally reprehensible to arbitrarily select living individuals and remove their hearts or lungs for transplantation, the donor must be in a condition such that his life has ceased but his heart can still be preserved for a transplant, *i.e.*, still functioning. This requires a definition of what constitutes death. The issue is too important merely to

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27. *Id.*

28. See note 25 *supra*.

29. Lerner, *Ethics of Transplants*, Chicago Sun Times, Apr. 17, 1969, at 92, col. 1.

leave, as Dr. Barnard suggests, to the determination of the physician.<sup>30</sup> Guidelines need to be developed as prospective recipients of transplants lie and wait.<sup>31</sup> Transplants are being undertaken with doubt, in many instances, as to whether the donor was indeed dead. Organs have been "cannibalized" in some cases with heart, kidneys, liver, and corneas removed from one donor for use by several recipients.<sup>32</sup>

Guidelines are necessary to protect both the surgeons and the donors. The individual patients (or his relatives) may fear entering a hospital lest his life be unnecessarily shortened. The current controversy regarding what constitutes death is demonstrated by the increased apprehension in recent years, of being buried alive.<sup>33</sup> The surgeon and the hospital may also fear being subject to a charge of murder or a civil action by relatives. The circumstances under which Dr. Barnard removed the heart of Olive Haupt for the transplant to Dr. Philip Blaiberg, without the consent of the widow, though with the mother's approval, might have exposed American surgeons to possible legal liability.<sup>34</sup> The problem was succinctly reported by Medical World News:

In Israel relatives of a heart donor accused surgeons of murdering the patient to obtain his heart. Japan's only cardiac transplant, Juro Wada, was charged with double murder—that of the donor and the recipient. In Houston, attorneys for two youths indicted for killing a man whose heart was later transplanted contended that Dr. Denton Cooley's team removed the organ while the man was still alive.

In a situation rife with possibilities for malpractice suits, a legislative committee in Texas—where most of America's heart transplants have been done—has asked the Texas Insurance Commission to poll all insurance companies doing business in that state. The question: What are their policies concerning professional liability coverage for members of transplant teams?

The committee decided to act after learning that the Medical Protective Insurance Co. had cancelled coverage for Dr. Cooley's co-workers last June after they had performed a cardiac graft. The physicians were able to get new protection from Hartford Insurance, Dr. Cooley's carrier, but at a much higher rate . . . .

Although no actual malpractice claims have arisen from heart transplants . . . the possibility of one came up in the very first operation done in Houston. The donor, a 15 year old girl had committed suicide by shooting herself in the head. After

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30. *A Day in the Life of Christian Barnard*, MED. WORLD NEWS, Oct. 25, 1968, at 38.

31. *Dozens Waiting for Heart Donors*, N.Y. Times, Oct. 29, 1968, at 1, col. 1.

32. *Planning for Transplants*, N.Y. Times, Feb. 21, 1969, at 42, col. 2; *Transplant Rounds*, MED. WORLD NEWS, Mar. 14, 1969, at 53.

33. Snider, *Fear of Being Buried Alive is Growing*, Chicago Daily News, Nov. 25, 1968, at 13, col. 3.

34. David, *When is A Transplant Legal Murder?*, Chicago Daily News, Nov. 17, 1968, (This Week Magazine) at 3.

the transplant was done, the girl's family went to the local TV station, claiming that the doctors had not tried hard enough to save her lost life. When the station refused to air the story, they turned to the publicized criminal lawyer, Percy Foreman, but he would not touch the case. Nothing further ever came of it.<sup>35</sup>

Traditionally, death has been commonly regarded as occurring when the heart stops functioning. However, the law is unclear as to what constitutes death.<sup>36</sup> Dr. Barnard defines death as when all bodily reflexes cease.<sup>37</sup> Many physicians, though, define the point of death as when the brain ceases to function as manifested by a continuously flat electroencephalogram.<sup>38</sup>

In addition to defining the point of death, a problem arises as to right of access to the body of the donor. Organs may not be taken without the consent of the next of kin. There is even doubt as to whether an individual, during his life has a property right in his body which he may will to medical science upon his death.

Problems which have arisen have prompted medical societies to formulate guidelines for the conduct of medical research. Lawyers have also become concerned with the problems and are seeking through legislative mechanisms to resolve them. Since the greater portion of medical research, including transplants, involves grants from agencies of the Federal Government, the problem has national implications. Accordingly, Senator Mondale has introduced a resolution calling for the establishment of a commission to investigate transplant problems and to suggest guidelines.<sup>39</sup>

The efforts of medical groups to formulate guidelines will be explored first, followed by a discussion of the state of the law and suggestions for legal reform.

### III. PROFESSIONAL MEDICAL GUIDELINES

Because of the investigative and experimental aspects of human tissue and organ transplantation, the clinical practice of transplantation is sub-

35. *Transplant Rounds*, MED. WORLD NEWS, March 14, 1969, at 53.

36. See note 34 *supra*.

37. See note 30 *supra*.

38. Cooley, *Observations of A Heart Surgeon*, Chicago Daily News, June 22, 1969, (This Week Magazine) at 7.

39. 115 CONG. REC. S1558 (daily ed. Feb. 17, 1969). One physician, in commenting on Senator Mondale's Resolution, states:

Among 150 persons, mostly Deans, answering Mondale's questionnaire, 137 supported the idea, which makes me wonder how many were influenced by the thought that they would be opposing something influential legislators might want. I should not be so cynical but experience has taught me something! Apparently, the hope was that from such a study would come legislation to control transplantation, among other things. This assumes a degree of omniscience well beyond anything I know. There are already a plethora of committees, task forces, and the like discussing transplantation. It would be surprising if they discovered anything new. Their chief function seems to me to codify all that is known and bring it to our attention for discussion. This is a valuable function.

Page, *The Ethics of Heart Transplantation, A Personal View*, 207 J.A.M.A. 109, 113 (1969). See also Comment, *California's Response to the Problems of Procuring Human Remains for Transplantation*, 57 CALIF. L. REV. 671 (1969).



ject to the codes of ethics for conducting clinical research, particularly the Nuremberg Code, the Declaration of Helsinki, and the statement of the Medical Research Council of Great Britain.<sup>40</sup> These professional codes, judging from the extent to which they have been followed, appear to be good examples of effective self-government. The principles embodied in the Nuremberg Articles have been reformulated by International and national medical bodies<sup>41</sup> and have been reflected in a policy statement by the Surgeon General of the United States in which requirements for review to insure the rights of individuals involved in clinical research were set forth.<sup>42</sup> This statement stipulated that no grants supporting research were to be continued or awarded unless arrangements were made for consideration of proposals for research involving human subjects by the grantee's

40. World Medical Association, *Code of Ethics of the World Medical Association (Declaration of Helsinki)*, 2 BRIT. MED. J. 177 (1964) (accepted at Helsinki in June 1964); Medical Research Council, *Responsibility in Investigations on Human Subjects*, 2 BRIT. MED. J. 178 (1964) (statement in Annual Report for 1962-63). See also Ladimer, *Ethical and Legal Aspects of Medical Research on Human Beings*, 3 J. PUB. L. 467, 471, 497 (1954). *Trials of War Criminals Before the Nuremberg Military Tribunals Under Control Council Law No. 10*, 2 THE MED. CASE 181 (1949), in Beecher, *Experimentation in Man*, 169 J.A.M.A. 461, 472 (1959); The Nuremberg Articles, drafted by a committee of the American Medical Association, comprise ten points, set up in the form of accepted and established principles to deal with non-therapeutic research as a guide for the Nuremberg tribunals in trying Nazi criminals. Ten Articles provide, *inter alia*, for voluntary consent by each subject of experimentation; that human subjects be used only when fruitful results for the good of society unprocurable by other means may be promoted; that experiments must be based upon prior animal experimentation and upon knowledge of the natural history of the problem; that there be avoidance of unnecessary physical and mental suffering; that no experiments be made which involve the likelihood of death or disabling injury; that the risk must be set off against and not exceed the humanitarian importance of the project; that proper preparation and facilities be provided; that only scientifically qualified investigation be used; that the subject of investigation must be free to withdraw at any time; and that assurance must be given that the investigators will terminate the project at any time it seems to be getting out of hand.

41. The American Medical Association's Principles of Medical Ethics in 1946 reflected the principles of the Nuremberg Code, 132 J.A.M.A. 1090 (1946). In 1953, the National Institutes of Health, established Guiding Principles in Medical Research Involving Humans which required group review of the scientific and ethical propriety of projects deviating from accepted medical practice. See Stason, *Role of Law in Medical Progress*, 32 LAW & CONTEMP. PROBS. 563, 568 (1967). The Public Health Council of the Netherlands Report on Human Experimentation forbade all experiments on the dying under any circumstances. Ladimer & Newman, *Clinical Investigations in Medicine* 15608 (1963). A document, second only to the Nuremberg Articles in importance, is the Declaration of Helsinki, Code of Ethics of the World Medical Association, adopted in 1964 and approved by the American Medical Association, the American Federations for Clinical Research, the American College of Physicians, the American College of Surgeons, the Society for Pediatric Research, and the American Academy of Pediatrics. The Declaration distinguishes between purely scientific experimentation, presumably on normal persons, and experimentation for therapeutic purposes carried out on patients under the doctor's care, patients whose illness does not yield to conventional treatments, with more exacting standards imposed on the former than the latter. See Stason, *Role of Law in Medical Progress*, 32 LAW & CONTEMP. PROBS. 563, 589 (1967); 2 BRIT. MED. J. 178 (1964).

42. Memorandum on Group Consideration and Informed Consent in Clinical Research at Nat'l Inst. of Health, from the Dir. Surgeon General Public Health Service, Dep't of Health, Education & Welfare, INVESTIGATION INVOLVING HUMAN SUBJECTS, INCLUDING CLINICAL RESEARCH; REQUIREMENT OF REVIEW TO INSURE THE RIGHTS AND WELFARE OF INDIVIDUALS, U.S. Public Health Service, Policy and Procedure Order No. 129 (July 1, 1966).

institutional associates; that appropriate methods be used to obtain the informed consent of the prospective donee or his representatives, and that the risks of the procedure be proportionate to the potential medical benefits. The office of the Director of the National Institute of Health issued a memorandum<sup>43</sup> outlining the group consideration and informed consent practices which provides for an ascending hierarchy of committees to review all research projects involving the participation of normal volunteers, therapeutic or diagnostic studies of unusual hazards, and such non-diagnostic, non-therapeutic studies involving patients which might be referred. Guidelines for the voluntary and informed consent of patients were stipulated. The underlying principles included group consideration, informed consent of the patient and the volunteer, and the freedom of subjects to withdraw from a project at any time.

The Food and Drug Administration, pursuant to regulations issued under the authority of the Food, Drug, and Cosmetic Act,<sup>44</sup> requires the written consent of the patient before experimental drugs can be administered.<sup>45</sup> The regulation sets forth criteria for judging meaningful consent and provides examples of instances where exceptions to the written consent requirement may be made by the physician. Other guidelines are provided by statutes, codes of professional ethics, and in the professional practices of outstanding institutions.<sup>46</sup>

With regard to heart transplants, the American Medical Association's House of Delegates has issued guidelines which provide that the determination of death of a heart transplant donor must be made by at least two physicians not associated with the surgical team performing the transplant and that heart transplants should be restricted to patients for whom there is no other life-sustaining therapy.<sup>47</sup> The original statement defined the criteria of death as a flat electroencephalogram, indicating no activity of the brain, a cessation of breathing without mechanical assistance, failing blood pressure, lack of reflexes, and the dilation and fixation of the pupils. This was subsequently modified by adding the following criteria: "The cause of death must be evident and irreversible. The fact of death must be established and must be demonstrated by adequate, current and acceptable scientific evidence in the opinion of the physician making the determination."<sup>48</sup> The modification eliminated an assertion in

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43. U.S. Public Health Service, Policy and Procedure Order No. 129 (July 1, 1966).

44. 21 U.S.C. § 355(j)(1) (1964).

45. 21 C.F.R. § 130.37 (1967).

46. See Fletcher, *Human Experimentation: Ethics in the Consent Situation*, 32 LAW & CONTEMP. PROBS. 620 (1967).

47. *A.M.A. Sets Guide on Heart Implants*, N.Y. Times, Dec. 5, 1968, at 1, col. 2.

48. *A.M.A. Rules on Death and Issues Guidelines on Heart Transplants*, Wall St. J., Dec. 5, 1968, at 31; 205 J.A.M.A. 341 (1968). The Judicial Council of the AMA offers the following statement for guidance of physicians as they seek to maintain the highest level of ethical conduct in their practices.

1. In all professional relationships between a physician and his patient, the physician's primary concern must be the health of his patient. He owes the patient his primary allegiance. This concern and allegiance must be preserved in all medical

the original draft that one of the two physicians determining death should be a neurosurgeon or neurologist. The American Medical Association also recommended that a transplant registry be established and that uniform laws be enacted to facilitate the donation of organs. The American Medical Association resolution further provided that institutions engaging in heart transplantation must have adequate background in animal research, adequate sources of drugs to prevent the implanted heart from being rejected, and adequate follow-up and evaluation of the progress of the patient. The statement additionally asserted that heart implantation must be regarded as investigative since it is still too early to determine if an alternative method would yield better long term results. Continued research on methods of organ storage was urged and the development of artificial hearts and cardiac assist devices was stressed. It was also suggested that the feasibility of using xenografts—organs from animals—should be explored.

Delegates from 60 countries met in Sydney, Australia, at a conference of the World Medical Organization and issued a similarly vague statement

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procedures, including those which involve the transplantation of an organ from one person to another where both donor and recipient are patients. Care must, therefore, be taken to protect the rights of both the donor and the recipient, and no physician may assume a responsibility in organ transplantation unless the rights of both donor and recipient are equally protected.

2. A prospective organ transplant offers no justification for relaxation of the usual standards of medical care. The physician should provide his patient, who may be a prospective organ donor, with that care usually given others being treated for a similar injury or disease.

3. When a vital, single organ is to be transplanted, the death of the donor shall have been determined by at least one physician other than the recipient's physician. Death shall be determined by the clinical judgment of the physician. In making this determination, the ethical physician will use all available, currently accepted scientific tests.

4. Full discussion of the proposed procedure with the donor and the recipient or their responsible relatives or representatives is mandatory. The physician should be objective in discussing the procedure, in disclosing known risks and possible hazards, and in advising of the alternative procedures available. The physicians should not encourage expectations beyond those which the circumstances justify. The physician's interest in advancing scientific knowledge must always be secondary to his primary concern for the patient.

5. Transplant procedures of body organs should be undertaken (a) only by physicians who possess special medical knowledge and technical competence developed through special training, study and laboratory experience and practice, and (b) in medical institutions with facilities adequate to protect the health and well-being of the parties to the procedure.

6. Transplantation of body organs should be undertaken only after careful evaluation of the availability and effectiveness of other possible therapy.

7. Medicine recognizes that organ transplants are newsworthy and that the public is entitled to be correctly informed about them. Normally, a scientific report of the procedures should first be made to the medical profession for review and evaluation. When dramatic aspects of medical advances prevent adherence to accepted procedures, objective, factual, and discreet public reports to the communications media may be made by a properly authorized physician, but should be followed as soon as possible by full scientific reports to the profession.

In organ transplantation procedures, the right of privacy of the parties to the procedures must be respected. Without their authorization to disclose their identity, the physician is limited to an impersonal discussion of the procedure.

Reporting of medical and surgical procedures should always be objective and factual. Such reporting will also preserve and enhance the stature of the medical profession and its service to mankind.

as to what constituted death. They also stipulated that two physicians not connected with the organ transplant team must make the final determination of death. The World Medical Organization statement provided that the use of the electroencephalograph, a device to measure brain activity, would be a helpful indication and stressed that the donor must be undergoing an "irreversible process."<sup>49</sup>

The American College of Surgeons has undertaken the development of a transplant registry in Chicago for all organs, except kidneys (which are already accounted for by a registry in Boston). Besides "census information," the transplant registry will solicit data concerning the clinical indications for each transplant, the postoperative condition of the patient and donor, histo-compatibility typing and matching methods, surgical technique, and postoperative course, including rejection and countermeasures. Long term followups will be used to determine the degree of functional recovery, rehabilitation, and recurrence, if any, of the original disease.<sup>50</sup> A computer program has also been developed to classify the availability of organs for transplants according to a pattern utilizing 58 basic tissue types.<sup>51</sup> These developments involve a classification and coordination of data which will help physicians and surgeons in formulating and applying guidelines.

The heart transplant surgeons themselves convened in Capetown to pool their information.<sup>52</sup> The consensus was that cardiac transplantation should be reserved for end-stage heart disease and that advanced coronary artery disease is the primary indication of such disease. Most surgeons agreed that pulmonary hypertension and congestion resulting from long term pulmonary vascular obstruction were the greatest threats to a successful transplant. However, the severity of these lung disorders does not always determine prognosis. The conference indicated that tissue typing cannot be considered the sole determinant for selecting donors and recipients since so little is known about it. The surgeons agree that donors must have a normal heart with no evidence of functional or organic heart disease or other transferrable disease and that the condition of the donor's heart was more important than its chronological age. In determining the donor's death, all surgeons attending the conference agreed that neurological examination and electroencephalograph tracings should show no signs of cerebral activity, but the surgeons failed to set the length of time for this inactivity. In most heart trans-

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49. See Wecht & Aranson, *Medical Legal Ramifications of Human Tissue Transplantation*, 18 DEPAUL L. REV. 488, 493 (1969).

50. *Transplant Rounds*, MED. WORLD NEWS, Jan. 10, 1969, at 26.

51. *Computers to Decide Who'll Get Transplants*, Chicago American, June 6, 1968. The program is a joint effort of the University of Chicago, the University of Illinois, and the University of Wisconsin and involves the establishment of tissue typing laboratories in Chicago, Milwaukee, and Madison.

52. Cooley, *Minutes of the Cape Town Meeting*, MED. WORLD NEWS, Aug. 9, 1968, at 21.

plants, this period exceeds two hours.<sup>53</sup> The group concurred that respiratory and circulatory failure are equally as important as the absence of brain stem function. The surgeons also concurred that to avoid injuring the myocardium, no further heart stimulants should be administered once death has been established.

Traditionally, however, physicians are disinclined toward decision-making.<sup>54</sup> The physician's very professionalism generates doubts as to his qualifications for nonmedical decisionmaking, especially in light of the need for speed. This has generated a system of authoritarian *ex parte* behavior. The medical student is taught to respect authoritarian control. Advancement to decisionmaking roles goes only to the most technically skilled individuals and is achieved through unusual financial, physical, and emotional sacrifice. Furthermore, the most proficient physician may judge his fellow man by a perverse value system but, if in authority, his decisions will be accepted by his fellow doctors. It seems apparent, at least with respect to the earlier mentioned life or death matters, that one man's decision should not have the finality which the medical decision-making structure accords to the decision of the physician in charge. The decisionmaking function might be conferred on laymen, but even then guidelines would have to be developed. Such guidelines must be made by law.

#### IV. LEGAL GUIDELINES

As a preface to the following legal view of death, it is pertinent to note that, in the legal vernacular, there are several types of death. Where a defendant was sentenced to prison for life, he suffered *civil* death—"a deprivation of all rights whose exercise or enjoyment depends upon some provision of positive law."<sup>55</sup> A death would be labeled *violent* "if it resulted by reason of an external agency and was not in the ordinary course of nature."<sup>56</sup> In other words, *natural* death and *violent* death are mutually exclusive. Natural death is the relevant classification for legal analysis of the death concept.

The standard medical and legal definitions of death are fairly consistent and are equally resistant to change. As evidenced by the following legal dictionary excerpt, the law based its definition of death upon the traditional medical concept. Death is

the cessation of life; the ceasing to exist; defined by physicians as a total stoppage of the circulation of the blood, and a cessa-

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53. *Id.* Dr. Cooley observed that in two of his donors there was a flattened EEG for four days prior to transplantation.

54. Note, *Scarce Medical Resources*, 69 COLUM. L. REV. 620, 633 (1969).

55. *In re Donnelly's Estate*, 125 Cal. 417, 419, 58 P. 61, 62 (1899). See also *Avery v. Everett*, 110 N.Y. 317, 319, 18 N.E. 148, 150 (1888).

56. *Caffaro v. Metropolitan Life Ins. Co.*, 14 N.J. Misc. 167, 170, 183. A. 200, 201 (1936).

tion of the animal and vital functions consequent thereto, such as respiration, pulsation, etc.<sup>57</sup>

In *Smith v. Smith*,<sup>58</sup> the Supreme Court of Arkansas adopted verbatim the legal dictionary definition of death as controlling, thus institutionalizing the medical concept of heart death as law. The courts uniformly interpret death as "the complete cessation of all vital functions without possibility of resuscitation."<sup>59</sup> In actuality, all other definitions are routinely rejected. For example, in *In Re Estate of Schmidt*,<sup>60</sup> the medical experts could not agree on the time of death because they used different theories. The court categorically dismissed the "opinion of [some] medical experts [that] death might be the inability to resuscitate or an irreversible coma"<sup>61</sup> and considered Black's Dictionary as the ultimate authority.

A body is not dead, even though the brain may quit functioning, so long as there is a heart beat and that may be evidenced by the gushing of blood in spurts.<sup>62</sup>

Furthermore, even where medical testimony appears to the contrary, the court will not determine if one is dead if lay testimony shows that "blood pumped rhythm-like from the person's body."<sup>63</sup> The result of this absurdity is that laymen, rather than physicians, can pronounce legal death. The Ad Hoc Committee of the Harvard Medical School summarized the present state of law in America regarding death. In judicially noticing Black's definition of death, as the Arkansas Supreme Court did in *Smith v. Smith*,<sup>64</sup>

the court did not consider that definition open to serious controversy; it considered the question as settled in responsible scientific and medical circles. . . . [The court] considered the definition of death to be a settled, scientific, biological fact. It refused to consider the plaintiff's offer of evidence that 'modern medical science' might say otherwise.<sup>65</sup>

The inflexibility of the law to adapt to progressive medical and scientific theory is visible in the determination of the time of death. In the legal sphere, "death occurs precisely when life ceases and does not occur until the heart stops beating and respiration ends. Death is

57. BLACK'S LAW DICTIONARY 488 (4 ed. 1968).

58. 299 Ark. 579, 586, 317 S.W.2d 275, 279 (1958).

59. *United Trust v. Pyke*, 199 Kan. 1, 4, 427 P.2d 67, 71 (1967); *Vaegemast v. Hess*, 203 Minn. 207, 210, 280 N.W. 641, 643 (1938); *Telefilm, Inc. v. Superior Ct.*, 194 P.2d 542, 547 (Cal. 2d Dist. 1948).

60. 67 Cal. Repr. 847 (Ct. App. 1968).

61. *Id.* at 854.

62. *Gray v. Sawyer*, 247 S.W.2d 496, 497 (Ky. Ct. App. 1952).

63. *Schmitt v. Pierce*, 344 S.W.2d 120, 133 (Mo. 1961).

64. See note 56, *supra*.

65. *A Definition of Irreversible Coma*, 205 J.A.M.A. 337, 339 (1968).

not a continuing event and is an event that takes place at a precise time."<sup>68</sup> Whereas, in "the medical profession . . . death is a process and not a moment in time as the law believes."<sup>67</sup> The Declaration of Sydney, which was "adopted by the Twenty-Second World Medical Assembly in August 1968" stated that "death is a gradual process at the cellular level with tissues varying in their ability to withstand deprivation of oxygen."<sup>68</sup> The decisional lag is self-evident.

The divergence of traditional heart death and modern brain death poses significant legal ramifications to the transplant surgeon. A case on point portrays the medical-legal dilemma.

[I]n Houston . . . the heart of the victim of an assault, who had suffered irreversible brain damage, was kept beating by artificial means until a transplant could be performed. The coroner chose to certify the death on the basis of the cessation of heart function. The District Attorney was faced with the problem of whether a defendant can be tried for homicide when under present medical [and legal] standards the victim actually died under the transplant surgeon's knife.<sup>69</sup>

There are other reported cases involving a similar fact pattern of organ removal after brain death but before heart death.<sup>70</sup> The ability to artificially maintain circulation and respiration confuses the issue, and, consequently, the surgeon assumes the onerous burden of balancing medical success with possible legal repercussions.

When the brain-damaged patient is subjected to life-supporting techniques, there may be a choice of establishing death from cessation of brain activity or cardiac activity, and the time interval may extend to hours or occasionally days. This can have considerable juridical consequences and it goes to the roots of the death concept itself.<sup>71</sup>

In terms of legal consequences to the transplant team, one legal scholar views the physician's situation as perilous. "In the present state of the law I could only advise a client [surgeon] that he would incur the danger of a possible charge of homicide if by removal of an organ he causes

66. *Thomas v. Anderson*, 96 Cal. App. 2d 371, 376, 215 P.2d 478, 482 (1950). See also *Sanger v. Butler*, 45 Tex. Civ. App. 527, 532-33, 101 S.W. 459, 462 (1907); *Gugel's Adm'r v. Orth's Ex'r*, 236 S.W.2d 460, 462 (Ky. Ct. App. 1950).

67. Muller, *Legal Medicine and the Determination of Death*, 14 WORLD MED. J. 140 (1967).

68. Wecht & Aranson, *Medical-Legal Ramifications of Human Tissue Transplantation*, 18 DEPAUL L. REV. 488, 493 (1969).

69. Ford, *Human Organ Transplantation: Legal Aspects*, 15 CATH. LAWYER 136, 141 (1969).

70. See Wasmuth & Stewart, *Medical and Legal Aspects of Human Organ Transplantation*, 14 CLEV.-MAR. L. REV. 442, 467 (1965); Louisell, *Transplantation: Existing Legal Constraints* in ETHICS IN MEDICAL PROGRESS 92-93 (Ciba Foundation 1966) (both articles illustrate the removal of a kidney for transplantation before conventional death occurred).

71. Biorck, *When is Death?*, 18 WIS. L. R. 484, 494 (1968).

death, if life still continues in the conventional sense."<sup>72</sup> In other words, removal of a heart while it was still beating might subject the doctor performing the transplant to both civil and criminal liability.

The problem of the time of death has arisen in other contexts as well as in regard to transplants, since patients are now revived who formerly might have been pronounced dead. Situations have been created where patients are kept alive by artificial means; as a result, question has been raised in some cases as to whether the treatment was carried too far.<sup>73</sup> On the other hand, the doctor may do certain acts wilfully and voluntarily, knowing that as a direct result of these acts the patient will die. Unless he has some defense, he has committed murder.<sup>74</sup>

Generally, the criminal law requires an individual to act only in limited circumstances and he is free to omit all but the most basic and ordinary acts expected of one standing in his relationship to another. If, in the doctor-patient relationship, the doctor fails to give a certain treatment, he has merely made a value judgment in accordance with his training.<sup>75</sup> The *mens rea* required for a criminal conviction is lacking and, thus, there has been no known case where a doctor has been successfully prosecuted for omitting a treatment. If, however, the doctor disconnects the resuscitating machine, he commits an act of commission rather than omission, although he still may not be criminally culpable.

The law characterizes behavior as a commission when it alters the normal course of events and as an omission when it permits the normal course to be run.<sup>76</sup> If in the absence of treatment, death would ensue in the normal course of events, the law could deny culpability as long as the condition was irreversibly fatal, or if the treatment would not have reversed the patient's deteriorating condition.<sup>77</sup>

The physician's lack of culpability depends on the special circumstances of medical treatment and not on whether the act can be characterized as an omission. Doctors generally explain their freedom from culpability on the ground that the termination of treatment is always an omission. A simpler principle would be that a homicide resulting from the termination of treatment is justified whenever the withholding of treatment would have been justified. The suggestion has been made that the justification of "necessity" be made available where the doctor, lacking sufficient resources, switches one patient's resources to another, causing the death of the former.<sup>78</sup> Though such justification has been

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72. Louisell, *Transplantation: Existing Legal Constraints* in *ETHICS IN MEDICAL PROGRESS* 98 (Ciba Foundation 1966).

73. Stickel, *Organ Transplantation in Medical and Legal Perspectives*, 32 *LAW & CONTEMP. PROBS.* 597, 600 (1967).

74. Note, *Scarce Medical Resources*, 69 *COLUM. L. REV.* 620, 624 (1969).

75. Kamisar, *Some Non-Religious Views Against Proposed "Mercy Killing" Legislation*, 42 *MINN. L. REV.* 969, 982 (1958).

76. Hughes, *Criminal Omissions*, 67 *YALE L.J.* 590 (1958); see note 59 *supra*, at 626.

77. See note 54, *supra*.

78. See note 74, *supra*.



rejected by the courts,<sup>79</sup> the Model Penal Code provides an acceptable rationale for the physician-controlled death in those cases where the harm or evil sought to be avoided by such conduct is greater than that sought to be prevented by the law defining the offense charged.<sup>80</sup>

Applying these observations to heart and other organ transplants, a situation arises where patient A has incurred an injury to his brain; his reflexes and reactions cease; his bodily functions (*e.g.*, breathing, circulation and heart beat) are maintained by resuscitating machines and other supporting mechanisms; the brain indicates a continuing flat electroencephalogram; the prognosis for revival is nil and further deterioration of the patient's condition is to be anticipated. The heart, however, is in good condition. Assuming there is no inclination to perform an organ transplant, continued care of such a patient subjects his relatives to unnecessary emotional strain and devotes scarce hospital resources to a purpose bordering on the macabre. Under such circumstances, the doctor might be justified in disconnecting the supporting mechanism and permitting bodily functions to cease. Clearly, the doctor would not be criminally culpable. He would be regarded as having committed acts of omission.

Assume another element in this scenario: Patient B, who has a diseased heart, faces certain death within six months. The odds are 50-50 or 40-60 that he would enjoy a prolonged and productive life with a cardiac transplant. If, instead of merely disconnecting patient A's supporting mechanism the doctor chooses to remove A's heart for use by B, he should still not be regarded as having committed homicide. Patient A could be determined to be dead at the point where his brain had ceased functioning as indicated by his lack of reflexes and bodily responses, a flat electroencephalogram, and a prognosis that the probability of recovery was nil and there was irreversible bodily decay.

The disconnecting of the supporting mechanism for patient A, in the absence of further treatment would, in the normal course, result in total bodily deterioration and death. The removal of A's heart would be regarded as an anticipation of the normal course of events. From another perspective, the Model Penal Code analogy might be applied in that permitting the total deterioration of A with the resultant loss of the use of his heart (a scarce resource) would be a greater evil than removing the heart to save B. Clearly, the determination in these cases involves moral and legal values requiring procedures for decisionmaking.

Since criminal prosecutions are virtually nonexistent and unlikely to occur,<sup>81</sup> the physician or the hospital is most likely to be confronted with a tort action by the estate of patient A. Tort law has been most

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79. *Reginia v. Dudley*, 14 Q.B.D. 273 (1884); *United States v. Holmes*, 26 F. Cas. 360 (No. 15,383) (C.C.E.D. Pa. 1842).

80. MODEL PENAL CODE § 3.02 (P.O.D. 1962) and at 5-10 (Tent. Draft No. 8, 1968).

81. See note 75 *supra*, at 992.

active in doctor-patient relationships.<sup>82</sup> Malpractice doctrines require that the doctor provide a level of care not substantially less than that generally available.<sup>83</sup> Therefore, if the supporting mechanisms are not generally available, the doctor is not liable if such treatment is not provided to A. If, however, such treatment becomes generally available, liability would arise if the doctor failed to provide it.

The doctor may also be subjected to a contractual liability, based upon the theory that the doctor owes his patient the duty to make a proper determination as to when to terminate the relationship.<sup>84</sup> A breach of this duty arises when the doctor discharges a patient prematurely or discontinues treatment without giving him the opportunity to secure other care.<sup>85</sup> An abandonment may occur even if the doctor does not formally remove himself from the case.<sup>86</sup> The decision of the doctor to disconnect the supporting mechanism could be considered such an abandonment. If, however, the prospective donor, A, could not get alternative care, no damage would be done. The court could imply a duty to continue unto death an extraordinary treatment only when A or his relatives employed the doctor in reliance upon that treatment being provided. Moreover, if the doctor acts to make patient A's heart available for heart transplantation, a breach of fiduciary duty may arise in that the doctor's primary duty is to protect and treat A; a conflict of interests arises where the physician treats both the donor and the donee.

As to hospital liability, private hospitals have no duty to furnish services to everyone,<sup>87</sup> but when a hospital opens an emergency room it undertakes to provide emergency care to the community.<sup>88</sup> Tort law requires the completion of an undertaking only when abandonment in midcourse would leave the patient in worse condition than he would have been in but for the undertaking.<sup>89</sup> The termination of care for A, the donor, would hardly leave him in any worse condition. In addition, the cause of A's death could be said to be the brain damage so that no wrongful death action could ensue for the dissection of the heart.

Hospitals may also be liable under the civil rights actions.<sup>90</sup> The

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82. Note, *Good Samaritans and Liability for Medical Malpractice*, 64 COLUM. L. REV. 1301, 1302 (1964); Schroeder, *Insurance Protection and Damage Awards in Medical Malpractice*, 25 OHIO ST. L.J. 323, 332 (1964). See also Halley & Harvey, *On an Interdisciplinary Solution to the Legal-Medical Definitional Dilemma in Death*, 2 IND. LEGAL F. 219 (1969); Ford, *Human Organ Transplantation: Legal Aspects*, 15 CATH. LAWYER 136 (1969).

83. McCoid, *The Care Required of Medical Practitioners*, 12 VAND. L. REV. 549 (1959); Shermon, *The Standard of Care in Malpractice Cases*, 4 OSGOOD HALL L.J. 222 (1966).

84. Levin, *The Abandoned Patient*, 1965 INS. L.J. 275; see note 74 *supra*, at 630.

85. *Alexandridis v. Jewett*, 388 F.2d 829 (1st Cir. 1968); *LeJeune Rd. Hosp. v. Watson*, 171 So.2d 202 (Fla. 3d Dist. 1962); *Carroll v. Griffin*, 96 Ga. App. 826, 101 S.E.2d 764 (1958); *Ricks v. Budge*, 91 Utah 307, 64 P.2d 208 (1937).

86. *Alexandridis v. Jewett*, 388 F.2d 829 (1st Cir. 1968).

87. *Lucy Webb Hayes Nat'l Training School v. Geoghegan*, 281 F. Supp. 116 (D.D.C. 1967).

88. *Cf. Wilmington Gen. Hosp. v. Manlove*, 174 A.2d 135 (Del. 1961).

89. See note 74 *supra*, at 629.

90. 42 U.S.C. 1983-95 (1964).

element of state action clearly exists as to hospitals administered by Federal, State or city Governments and, with the ever increasing degree of government involvement in funding, the operations of private hospitals may also involve state action.<sup>91</sup> Accordingly, the estate of A may claim a denial of his civil rights in that he was deprived of the right to life as a result of the discontinuing or denial of supporting mechanisms and the dissection of his heart. A denial of equal protection might also be claimed in that he was not accorded the same care as patient B. However, courts would be unlikely to uphold such claims if A's condition were so deteriorated as to constitute death.<sup>92</sup> If the hospital lacks procedural safeguards in making the determination, the court might determine this to be a denial of civil rights.

Another aspect of the legal problems of transplants involves the right to dissect the body of the donor. Common law principles, which originated in the English Ecclesiastical courts in the seventeenth century and carried into common law courts, hold there are no property rights in the dead human body.<sup>93</sup> However, certain private rights exist in the next of kin which may be regarded as "quasi property."<sup>94</sup> These rights involve the assurance of a dignified treatment of the body and a decent burial. These rights belong first to the surviving spouse, then to the children, and finally to the next of kin, unless a statute provides otherwise. The person who has the right to possession of the body is entitled to receive it in the same condition as when death occurred, unless the right is modified by law.

Damages may be recovered from anyone who mutilates or dissects a body, therefore, before a transplant may be undertaken, the surgeon must receive the consent of the next of kin. If a person, during his lifetime, makes an ante-mortem gift of his whole body or a portion of it, it will be a nullity under common law if the surviving next of kin object.<sup>95</sup> In most jurisdictions, the right of a person to dispose of his own body is determined by statute.<sup>96</sup> However, these statutes require compliance with certain formalities which vary in each jurisdiction.

The Uniform Anatomical Gift Act<sup>97</sup> was recently drafted to facilitate transplants. It provides for a simplified donation procedure. The Act lessens the witness requirements for ante-mortem gifts, makes donations

91. *Simkins v. Moses H. Cone Mem. Hosp. Center*, 323 F.2d 959 (4th Cir. 1963), *cert. denied*, 376 U.S. 938 (1964); *see note 55 supra*, at 631. Some courts have denied state action: *Shulman v. Washington Hosp. Center*, 222 F. Supp. 59 (D.D.C. 1963); *Mauer v. Highland Park Hosp. Found.*, 90 Ill. App. 2d 409, 232 N.E.2d 776 (1967).

92. *See note 74 supra*, at 631.

93. Stason, *The Role of Law in Medical Progress*, 32 LAW & CONTEMP. PROBS. 564, 569 (1967).

94. Finesilver, *Organ Transplants: A Multi-Discipline Challenge*, TRIAL MAG., April/May, 1969, at 41.

95. *See note 78 supra*.

96. Note, *Compulsory Removal of Cadaver Organs*, 69 COLUM L. REV. 693 (1969).

97. UNIFORM ANATOMICAL GIFT ACT (1968). *See R. PORZIO, THE TRANSPLANT AGE* 79-81 (1969).

by will effective immediately without probate, renders witnesses unnecessary when the donation is made by the next of kin, and allows the gift to be made by a telegram, recorded telephonic, or other recorded message. The Act also permits a donor to indicate his gift by carrying a wallet card, thus providing the means by which the existence of a donation may be quickly ascertained.<sup>98</sup> Any individual of sound mind and 18 years of age or older may, under the Act, give all or any part of his body to any hospital, surgeon or physician, accredited medical or dental school, college or university or any bank or storage facility for medical or dental education, research, advancement of medical or dental science, therapy or transplantation, or to any specified individual for therapy or transplantation needed by him. Next of kin, in order of priority of persons available at time of death, and in the absence of actual notice of contrary indications by the decedent or actual notice of opposition by a member of the same or prior class include: (1) the spouse; (2) an adult son or daughter; (3) either parent; (4) an adult brother or sister; (4) a guardian of the person of the decedent at the time of death; (6) any other person authorized or under obligation to dispose of the body. If the donee has actual notice of contrary indications by the decedent, or that a gift by a member of a class is opposed by a member of the same class or a prior class, the donee shall not accept the gift.

The Act does not provide a definition as to time of death. Instead, it provides in section 7, subsection (b), page 19:

The time of death shall be determined by a physician who tends the donor at his death, or, if none, the physician who certifies the death. The physician shall not participate in the procedures for removing or transplanting a part.

The commissioners who drafted the Act explain:

Subsection (b) [of section 7, page 19] leaves the determination of the time of death to the attending or certifying physician. No attempt is made to define the uncertain point in

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<b>UNIFORM DONOR CARD</b>	
<b>OF</b> _____	Print or type name of donor
In the hope that I may help others, I hereby make this anatomical gift, if medically acceptable, to take effect upon my death. The words and marks below indicate my desires.	
I give:	(a) _____ any needed organs or parts
	(b) _____ only the following organs or parts
	Specify the organ(s) or part(s)
for the purposes of transplantation, therapy, medical research or education;	
	(c) _____ my body for anatomical study if needed.
Limitations or special wishes, if any: _____	

time when life terminates. This point is not subject to clear cut definition and medical authorities are currently working toward a consensus on the matter. Modern methods of cardiac pacing, artificial respiration, artificial blood circulation and cardiac stimulation can continue certain bodily systems and metabolism far beyond spontaneous limits. The real question is when have irreversible changes taken place that preclude return to normal brain activity and self sustaining bodily functions. No reasonable statutory definition is possible. The answer depends upon many variables, differing from case to case. Reliance must be placed upon the judgment of the physician in attendance. The Uniform Act so provides.

However, because time is short following death for a transplant to be successful, the transplant team needs to remove the critical organ as soon as possible. Hence, there is a possible conflict of interest between the attending physician and the transplant team, and accordingly subsection (b) excludes the attending physician from any part in the transplant procedures. Such a provision isolates the conflict of interest and is eminently desirable. However, the language of the provision does not prevent the donor's attending physician from communications with the transplant team or other relevant donees. This communication is essential to permit the transfer of important knowledge concerning the donor, for example, the nature of the disease processes affecting the donor or the results of studies carried out for tissue matching and other immunological data.<sup>99</sup>

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99. One writer, Bergen, makes the following observation:

Death, of course, is an emotionally charged subject. This may help to explain the excessive concern about this question. Some physicians tend to believe that they have a duty to take whatever heroic measures are necessary to continue a patient's circulation, respiration, or other more minimal vital signs as long as possible regardless of the circumstances and regardless of any ultimate benefit to the patient. The law, however, does not impose a duty of this kind. Most important, the patient himself has a right to reject such measures if he is capable of making his own decisions. If not, the physician may properly recommend to the family, in appropriate circumstances, that the patient be permitted to die in peace, if it is clear that he has no hope for a real meaningful restoration to health. In some instances at least, what is thought to be a prolongation of life is in reality nothing more than a prolongation of the process of dying, which would usually not be of any realistic benefit to either the patient or his family.

The death of a patient is the termination of his human life. Human life is the integrated functioning of a rational organism. Almost any part of this bundle of integrated functions can stop temporarily and then be restored so that the organism functions, as a whole. Some few functions can be lost permanently without really eliminating the total of integrated functions recognized as human life. In few, if any, instances do all functions terminate instantaneously at the same point of time. Typically, the functions deteriorate one by one until all are ended. Philosophically, death might be defined as the point at which the deterioration of functions becomes irreversible so that the organism can never again function as an integrated rational organism. The law would probably accept this kind of a philosophic concept if it had to, but it would prefer to rely upon the expert diagnosis and opinion of the attending physician. After all, this is the physician's field.

It is generally understood that some cellular activity continues in the human body for a substantial period of time after the body as a whole is indisputably dead. For example, when the head is severed from the rest of the body. The continuation of this cellular activity in these circumstances is certainly not human

The position taken by the National Conference of Commissioners on Uniform State Laws indicates that presently there is no consensus as to the time of death.<sup>100</sup>

The Act has been approved by both the American Bar Association and the American Medical Association.<sup>101</sup> It has been promoted by the American Medical Association Liaison Committee to the American Bar Association and the American Bar Association Committee. As of July 13, 1970, it had been enacted by the District of Columbia and 48 state legislatures with Nebraska and Massachusetts the two remaining states who have not adopted the Act.<sup>102</sup> However, the Act has been criticized as being primarily concerned with the protection of the surgeon and physician from liability rather than with the protection of the donor.<sup>103</sup>

The position taken by the Commissioners reflects the problem faced by medical men. On the one hand, there are the rights of the patient who is a potential donor, while on the other hand, are the rights of the patient who is a potential recipient and the needs of medical science for tissue transplants. Every dead body is a virtual treasure house of organs for medical use and a source of knowledge for the advancement of medicine. Even excluding the need for tissue transplants, a pressing need exists for cadavers to further medical knowledge.<sup>104</sup> For over 400 years, students desiring to become physicians and surgeons have needed

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life. Similarly, other minimal bodily activities, particularly those sustained by artificial means, do not constitute human life. The exact dividing line at which bodily activity becomes sufficiently significant and integrated to constitute human life, is a medical question, not a legal one. To the lawyer it appears to be a question of fact not subject to objective determination by a universally applicable scientific test.

If there is such a test and physicians generally agree on it, the law will undoubtedly accept it. If not, the law will be governed by the opinion of the physicians called upon as expert witnesses in the litigation in which the question is raised.

It appears, therefore, that the existing rules of law relating to medical practice provide a practical framework within which scientific medicine can continue to explore and test the heart transplant procedures without undue restrictions or undue legal risks. It is true that under the existing rules there are bound to be differences of interpretation from one case to another and differences of opinion among expert medical witnesses. These variances, however, are unavoidable no matter what legal rules are established. No law has ever been enacted that did not require interpretation and did not result in a variety of different applications in different cases.

It would seem wise, therefore, for both the public and the medical profession to rely on the existing laws governing medical practice to regulate the new phenomenon of heart transplants. The existing laws may not be perfect, but they are familiar and they do not provide practical and effective standards. If new laws are enacted for heart transplants, they might be better or worse than those we now have. Just because they are new, however, they will of necessity result in a period of uncertainty until they have been tested and interpreted by the courts.

Bergen, *Legal Regulation of Heart Transplants*, 54 DIS. CHEST 19 (Oct. 1968).

100. Sadler, Sadler & Staso, *The Uniform Anatomical Gift Act, A Model for Reform*, 206 J.A.M.A. 2501, 2504 (1968).

101. See note 97 *supra*.

102. TIME, July 13, 1970, at 67.

103. Lear, *A Realistic Look at Heart Transplants*, SAT. REV. (Feb. 3, 1968), at 53. Section 7(c) of the Act provides that a person who acts in good faith in accord with the terms of the Act or of the anatomical gift laws of another state or foreign country is not liable for any damages in any civil action or subject to prosecution in any criminal proceeding for his act.

104. American Medical Association Committee on Medicolegal Problems, *Leaving Your Body to Medical Science, A Report on the Disposition of Dead Bodies* (1963).

to study cadavers in minute detail to prepare themselves for treating living persons. At one time, the demand for cadavers so exceeded the supply that grave robbing was big business, and, as a result, the dissection of bodies met with public indignation.<sup>105</sup> Around the 1830's anatomy laws were enacted which provided that unclaimed bodies, under proper conditions, could go to medical schools. Today, however, this supply of cadavers has become inadequate.<sup>106</sup> The medical progress in tissue transplants only serves to aggravate the problem.

The hope of the drafters of the Act was that contributions would be encouraged. However, it is doubtful whether the effect of the Act will be to provide an adequate supply of transplant organs. The best donors would be the young, but they are also the ones who think the least about death.<sup>107</sup> In 1961, the British enacted the Human Tissue Act<sup>108</sup> which is similar to the Uniform Anatomical Gift Act. Seven years after the passage of the Act a conference arranged by the British Minister of Health concluded that the statute was not an adequate means for satisfying the need for transplant organs.<sup>109</sup> The conference proposed amending the Act to permit removal of organs without first seeking family permission.<sup>110</sup> Legislation may be enacted which assumes consent unless it is explicitly denied. It should be noted that any compulsory taking of organs will involve constitutional questions as to the taking of property, the free exercise of religious beliefs, and the right to privacy.<sup>111</sup> Such a statute would render even more pressing the problem of determining the time of death.

#### V. A PROPOSAL

Law reform beyond that provided in the Uniform Anatomical Gift Act (*i.e.*, liberalizing accessibility to cadavers) should await further experience under the Act. A continuing assessment should be made as to the need for transplants and the development of alternative approaches should be encouraged.

The problem of determining the time of death remains, and it involves a definition of death as well as procedures geared toward resolving any lingering doubts as to the donor's death among relatives and the general public. There is need for medical assurance that all life has indeed ceased in the body from which the organs are to be taken for transplant.

Generally, where transplants are not involved, death is determined by a routine observation by the attending physician. However, public concern has risen recently because of the ability to revive the heart beat

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105. Diamond, *Are We Ready to Leave our Bodies to the Next Generation?*, 114 CONG. REC. 10418 (1968) (remarks of Senator Mondale).

106. See note 88 *supra*.

107. See note 96 *supra*, at 695.

108. 9 & 10 Eliz. 2, c. 54 (1961).

109. Foulkes, *Organ Transplants*, 118 NEW L.J. 486, 487 (1968).

110. *Id.*

111. See note 96 *supra*.

and to maintain the functioning of bodily organs after the brain has apparently ceased to function. To permit a flat electroencephalogram to be the only indication of death is simplistic in that instances have been recorded where individuals, following a severe brain injury and comatose state, have been revived.<sup>112</sup> However, European specialists, particularly Dr. G.P.J. Alexandre, indicate that pronouncement of cerebral death is permissible provided the following six criteria are met: (1) complete bilateral mydriasis; (2) complete absence of reflexes, both natural and in response to profound pain; (3) complete absence of spontaneous respiration; (4) falling blood pressure, necessitating increasing amounts of vasopressive drugs; (5) a flat electroencephalogram;<sup>113</sup> and (6) measurement of oxygen consumed by the brain.<sup>114</sup>

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112. Beecher, *Ethical Problems Created by the Hopelessly Unconscious Patient*, 278 N. ENG. J. MED. 1425 (1968); 204 J.A.M.A. 337 (1968); Report by Rostoff and Schwab, presented at Meeting of American Electro-encephalographic Society, Atlantic City, N.J., *EEG in Establishing Brain Death: Ten Year Report with Criteria and Legal Safeguards in 50 States*, June 8, 1967.

With the increasing acceptance of brain death as a major criterion for pronouncing a person dead, researchers are turning their attention to quicker and surer ways of pinpointing the moment at which brain damage becomes irreversible. Now a test developed at the University of Vienna may provide the answer in 30 minutes. The technique simply measures the difference in oxygen pressure between a supplying artery and the bulbus venae jugularis. Blood samples are taken directly from both the artery and the bulbus and are then subjected to blood gas analysis. When irreparable brain damage has occurred, there should be either a small pressure differential or none at all. In one recent accident case tested, for example, the oxygen pressure differential (OPD) was 5 mm Hg—405 mm Hg in the artery and 400 mm Hg in the jugular vein.

So far the method has been tried on 100 accident victims and ten organ donors. In every case, the OPD technique has shown a 100% correlation with neurologic and EEG tests that are generally given in six-hour cycles to determine death conclusively, according to Dr. Christo Tschakaloff, who developed the OPD test. Dr. Tschakaloff, who is employed as an anesthesiologist in the intensive care unit of the University of Vienna General Hospital, says that instrument fault might make it possible to miss the exact moment of irreversible brain damage of a person already dead, but it is impossible to mistakenly declare a living person dead. Measuring the oxygen pressure gives a better indication of brain death than estimating the blood's oxygen content. He chose the bulbus venae jugularis because all the cranial blood vessels drain into it and because it can be punctured from either the left or right side of the neck.

Since the OPD Technique shortens the time for reliable prediction of brain damage, it should be most important in cases of potential organ donors. Another use, suggested by Dr. Tschakaloff, would be to help doctors decide which of several patients should have first call on equipment and services. But, at present, he emphasizes, the technique should only be used in conjunction with the classic methods that are currently accepted for determination of brain damage.

MEDICAL WORLD NEWS, Sept. 26, 1969, at 340. See also Wecht & Aranson, *Medical-Legal Ramifications of Human Tissue Transplantation*, 18 DEPAUL L. REV. 448, 491-92 (1969).

113. ETHICS IN MEDICAL PROGRESS 69 (Ciba Foundation 1966). See also Halley and Harvey, *Law-Medicine Comment; Anatomical Gifts*, J. KAN. MED. SOC'Y, 1968, at 343. The Report of the Ad Hoc Committee of the Harvard Medical School proposed similar criteria for determining brain death, but omitted falling blood pressure and clarified the flat EEG requirement to exclude the influence of sedation or anesthetic drugs. *A Definition of Irreversible Coma*, 205 J.A.M.A. 337, 338 (1968). Dr. J. P. Revillard would add two additional criteria: "interruption of blood flow in the brain as judged by angiography, . . . and the absence of reaction to atrophine." ETHICS IN MEDICAL PROGRESS 71 (Ciba Foundation 1966).

114. Wecht & Aranson, *Medical-Legal Ramifications of Human Tissue Transplantation*, 18 DEPAUL L. REV. 488, 491-92 (1969); Stickel, *Organ Transplantation in Medical and Legal Perspectives*, 32 LAW & CONTEMP. PROB. 597, 606-07 (1967).



These criteria could be woven into a statutory definition of the time of death. The definition could be formulated to permit flexibility to allow for the addition of other factors. The statute could be worded to provide that the presence of these above-mentioned criteria establishes a presumption of death for certain purposes, but would not be conclusive. Such an approach would compel the doctor to make a specific finding and to set forth definite criteria. In this way, reassurance would be provided that the donor had indeed expired.

Despite the ominous implications that might accrue to the transplant surgeon, there are certain protective measures that he can take to lessen the chances of liability. The Ad Hoc Committee of the Harvard Medical School set forth specific procedures that should be followed in transplant operations: 1) the decision to declare the person dead, and then to turn off the respirator, should be made by "the physician in charge of the patient [donor] in consultation with one or more other physicians directly involved in the case;" 2) the decision to declare the donor dead should "be made by physicians not involved in any later effort to transplant organs or tissue from the deceased individual;" and 3) "the patient [should] be declared dead before any effort is made to take him off a respirator, if he is then on a respirator. Otherwise, the physicians would be turning off the respirator on a person who is, under the present strict, technical application of law, still alive."<sup>115</sup> By adhering to these principles, the vulnerable surgeon will broaden the base of medical opinion and diminish the possibility of personal interest and influence, thus providing greater legal protection. Thus, when the patient's brain function indicates a flat electroencephalogram with his condition, as determined by the attending physician, to be in a state of irreversible deterioration and where bodily functions are maintained for a considerable period of time by supportive devices, such procedural safeguards should be established to protect the patient and his family from being exposed to the physical and emotional trauma of prolonged agony; to protect the patient from a premature determination as to his death; and to permit the availability of a possible transplant organ and, at the same time, to protect the doctor. Furthermore, in all such situations it is suggested that an ad hoc or permanent panel comprised of a neurologist or neurosurgeon and another physician be convened to independently examine the patient and make a determination. The panel should consult with the attending physician. Where a transplant is involved, the members of the panel should not include any physician or surgeon involved in the care or treatment of a potential transplant recipient, nor, where feasible, associated with any medical institution engaging in transplants. The panel could be appointed by a judge or magistrate, and it would report its findings to him. A summary hearing could be held at any time and could even be convened at the hospital.

The provision in the Uniform Anatomical Gift Act which allows a

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115. *A Definition of Irreversible Coma*, 205 J.A.M.A. 337, 339 (1968).

donor to make an ante-mortem gift by a card in his wallet represents an innovative advance. This provision could be combined with the proposal for a "living will," which would permit an individual to indicate by a card on his person that should he be confronted with a situation of irreversible bodily deterioration or a state of incurability, he competently authorizes and directs the attending physician to cease from providing treatment that merely serves to unnecessarily prolong his life or actually prolongs dying.<sup>116</sup> The "living will" could contain a provision that upon a final determination as to death and the cessation of treatment, the bodily organs or the body may be used for transplants or for the advancement of medical science. A panel, in determining the time of death, might consider any specific desires of the patient as expressed in the "living will." In the absence of specific desires, discretion would be the rule.

## VI. CONCLUSION

Since heart transplantation has become a worldwide phenomenon, the need exists for a treaty-statute to define death, to provide for the donation of organs, and to facilitate the transportation of body tissue.

Human transplants, especially the heart transplants, reflect the striving to participate in the eternal and the divine. Man is seeking to conquer his mortality and to achieve immortality.<sup>117</sup> Transplants are part of the technique for engineering the human divinity of physical immortality. However, this quest has received the blessings of religious leaders, such as Pope Paul, who indirectly indicated approval for heart transplants.<sup>118</sup> Transplants represent a revolution in medical concepts and, like the Copernican theories of astronomy and Einstein's Theory of Relativity, presage profound changes in moral outlook and social behavior. The law must accordingly adapt to these circumstances, providing guidance and sanctions.

The most pressing problem lies in defining death—the state in which a human being must exist before he may be buried or before his heart or other vital organs may be removed. Though the medical profession may formulate scientific criteria for the diagnosis of death, many doctors are unsure of the criteria and require help from other disciplines.<sup>119</sup> The law can provide the standards of due process to protect

116. Kutner, *Due Process of Euthanasia: The Living Will, A Proposal*, 44 U. IND. L. J. 539-44 (1969).

117. See generally HARRINGTON, *THE IMMORTALIST, AN APPROACH TO THE ENGINEERING OF MAN'S DESTINY*, (Random House 1969).

118. Ellenbogen, *Medical Miracles Need the Help of the Law*, CONG. REC. E. 3670 at E2671 (daily ed. April 3, 1968).

119. Corday, *Life-Death in Human Transplant*, 55 ABAJ 629 (1969); 205 J.A.M.A. 85 (1968); 1960 WIS. L. REV. 484, 497 (1968).

Death is an event where medicine, religion, and law meet around a human being in his last minutes. Medicine has done its share as physical life has come to an end. Religion claims the soul in the very moment it becomes separated from the body.

both the donor and the doctor, and, at the same time, facilitate organ transplants.

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When somebody is dead, he is no longer "somebody." The responsibility for his rights is taken over by law. At that moment, medicine has no more to offer and respectfully steps aside, while religion continues to support the departed soul and law perpetuates the abstract intentions of somebody, who is no more.

Dr. Lewis Weroke, head of the medical department of Sahlgrenska hospital and one of Sweden's foremost heart surgeons, has announced a plan which could make heart transplants out of date. His scheme is to remove a diseased heart from the patient, clean it of diseased material, and then return it to the patient. A major difficulty with heart transplants is getting the body to accept the "foreign" organ. Replacing the patient's own heart is technically simple, and rejection problems are unlikely to be encountered.

Dr. Weroke described at a press conference how a heart, removed from the body of a 35-year-old man who had died of a coronary thrombosis, was put into a physical cleansing bath and was made functional again. However, it was too late to put it back into the body because the patient was dead.

Based upon a disbelief in the practical value of heart transplants in the future, Dr. Weroke finds his process to be the only alternative and, according to him, it is within the limits of possibility to perform heart cleansing operations in the late 1970s "or at least in the 1980s." Weroke, *Chicago Tribune*, Aug. 7, 1969, at 6, col. 1.